IMPLEMENTING TRIPS IN INDIA: IMPLICATIONS FOR ACCESS TO MEDICINES

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Implementing TRIPS in India: Implications for Access to Medicines

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Declaration

I, Prabodh Malhotra, declare that the PhD thesis entitled *Implementing TRIPS in India: Implications for Access to Medicines* is no more than 100,000 words in length including quotes and exclusive of tables, figures, appendices, bibliography, references and footnotes. This thesis contains no material that has been submitted previously, in whole or in part, for the award of any other academic degree or diploma. Except where otherwise indicated, this thesis is my own work.

Signature

Date: 27 February 2009

Abstract

This thesis investigates the implications of implementing TRIPS in India for access to medicines drawing on three major factors; namely, (i) the TRIPS agreement, (ii), the global pharmaceutical industry, and (iii) the development of Indian pharmaceutical industry and the level of access to medicines in India. In doing so, the thesis examines the requirements of the TRIPS agreement and analyses the costs and benefits of its implementation, especially from a developing country view point. The fairness test shows that TRIPS prematurely forces developing countries to adopt protection standards, which a number of developed countries themselves did not adopt until they had achieved a certain level of economic development.

The examination of the global pharmaceutical industry explores the reasons for not developing new drugs for the diseases mainly affecting the poor. The primary reason for multinational companies (MNCs) showing no interest in investing into such ventures is the lack of potential for high returns. At present, there is an acceptance of the 10/90 gap meaning that 90 per cent of global research investments are directed to developing drugs for 10 per cent of the world's population. This thesis also considers different models for drug development.

Until 1970s, the Indian pharmaceutical industry was almost non-existent and the drug prices in India were among the highest in the world. India's pharmaceutical industry developed due to protectionist policies introduced in the 1970s primarily the abolition of patents on pharmaceutical products under the Patent Act 1970. Subsequently, the number of domestic firms proliferated and the number of MNCs declined losing bulk of the market share to local manufacturers. In the process, India turned from a net importer to a net exporter of pharmaceuticals and the drug prices in India declined to one of the lowest in the world.

However, the lowest prices did not translate into extending access to medicines to India's entire population because of high levels of poverty prevalent in the country. The price controls of the past and the new policies under consideration offer only a partial solution to India's healthcare problems. What India needs is an equitable model for extending healthcare including access to medicines to all sections of the population. The proposed model in Chapter 7 is based on the Australian healthcare model. The proposed model is equitable and implementable, and sensitivity tests show that it is also affordable.

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Finally, coming from a small village in India, I always dreamt but never expected to reach this level of education. I didn't think I had the ability to complete this journey. I firmly believe God's mercy helped me at every step in reaching this destination. So, a big thank you! God.

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Abbreviations

ABS	Australian Bureau of Statistics
AIDS	Acquired Immuno Deficiency Syndrome
ANVISA	Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency Brazil)
AYUSH	Ayurveda, Yoga & Naturopathy, Unani, Siddha, Homeopathy
BCG	Boston Consulting Group
BDMA	Bulk Drug Manufacturers Association
CBO	Congressional Budge Office
CDRI	Central Drug Research Institute
CDSCO	Central Drugs Standard Control Organization
CMH	Commission on Macroeconomics and Health
CRAM	Contract Research & Manufacturing
CSIR	Council for Scientific and Industrial Research
DCGI	Drugs Controller General of India
DPCO	Drug Price Control Order
EFPIA	European Federation of Pharmaceutical Industry and Associations
EGA	European Generic Medicines Association
EMEA	European Medicines Agency
EPL	Effective Patent Life
FDA	Food and Drug Administration
FICCI	Federation of Indian Chambers of Commerce and Industry
GATS	General Agreement on Trade in Services
GATT	General Agreement on Trade and Tariffs
GOI	Government of India
HIV	Human Immunodeficiency Virus
IBEF	India Brand Equity Foundation
ICRIER	Indian Council for Research and International Economic Relations
IDMA	Indian Drug Manufacturers Association
IFPMA	International Federation of Pharmaceutical Manufacturers Associations

IMF	International Monetary Fund
IP	Intellectual Property
IPO	Indian Patent Office
IPRs	Intellectual Property Rights
ISM	Indian System of Medicines
MHRA	Medicines and Healthcare products Regulatory Agency
MNCs	Multinational Companies
NIH	National Institutes of Health
NLEM	National List of Essential Medicines
NGO	Non government organisation
NPPA	National Pharmaceutical Pricing Authority
OECD	Organisation for Economic Co-operation and Development
OPPI	Organisation of Pharmaceutical Producers of India
PBS	Pharmaceutical Benefits Scheme
Pharma	Pharmaceutical(s)
PhRMA	Pharmaceutical Research and Manufacturers of America
PPP	Public Private Partnerships
TB	Tuberculosis
TGA	Therapeutic Goods Administration
TRIPS	Trade Related Aspects of Intellectual Property
UNCTAD	United Nations Conference on Trade and Development
UNCTC	United Nations Centre on Transnational Corporations
UNDP	United Nations Development Programme
US	United States of America
USPTO	United States Patent and Trademark Office
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Chapter 1

Introduction to the Research Project

1.1 Introduction

The purpose of this chapter is to introduce the research topic, its scope and its significance. The material below is set out as follows. Section 1.2 provides a brief statement of what this thesis is about, also proving an overview of the key issues and the key questions addressed. Section 1.3 describes the methodology used to analyse the issues addressed in the thesis. Section 1.4 outlines the scope and the significance of the study, while Section 1.5 outlines the organisation of the thesis. Section 1.6 specifies the distinctive contribution that the thesis aims to make.

1.2 What is this thesis about?

In a nutshell, the thesis deals with the implications of the introduction of the TRIPS-compliant patent protection regime, effective from January 2005, on India's pharmaceutical industry and on the access to medicines in India. In the process of doing so, the development of India's pharmaceutical industry is traced over the past three decades, when the industry passed through several crucial phases. Until the early 1970s, India's patent regime provided patents for products as well as processes in pharmaceuticals. Multinational companies (MNCs) held all the patents on drugs and pharmaceuticals and dominated the Indian healthcare market. India's domestic pharmaceutical industry was almost non-existent and the local manufacturing of medicines was negligible. India was a net importer of drugs and pharmaceuticals. The drug prices in India were among the highest in the world. The majority of the Indian population lived below the poverty line and access to medicines was limited to 15-20 per cent of the total population (Bhagat 1982).

In the 1970s, India introduced an array of protectionist measures including drug price controls and controls over foreign exchange. As a part of those measures, Patent Act 1970 was introduced abolishing pharmaceutical product patents but allowing process patents for 7 years from the filing date. The implications of this change were that every drug was virtually generic and hence could be legally copied for sale. The new

landscape provided Indian firms opportunities to enhance their reverse engineering skills and develop new manufacturing processes. In other words, India followed a model allowing the manufacture of copies of drugs patented elsewhere. Over the next three decades, the domestic firms proliferated making India almost self sufficient in drugs. The drug prices in India dropped to be one of the lowest in the world and access to medicines increased to around 35 per cent of the population. Even at this level of drug prices, the entire population was not able to gain access to medicines.

During the period of protectionist framework, India also became a net exporter of medicinal drugs. India's drugs were initially exported to the developing countries and the former Eastern Block countries. India supplied the poor countries with low-cost imitations of patented drugs as well as off-patent generics. India's exports increased drug availability as well as reduced drug prices in the developing countries. More recently, highly regulated markets such as the US and European countries have also become the destination of India's exports of off-patent generics. Thus, Indian firms have played a major role in significant price reductions after patent expiry in the overseas markets.

In 1991, India began introducing policies of economic liberalisation and industrial reforms. As a part of its shift towards liberalisation, India joined the World Trade Organization (WTO) in 1994. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) became a foundation block of the World Trade Organization (Maskus, K 2000). The other two major agreements were the General Agreement on Tariffs and Trade (GATT) and the General Agreement on Trade in Services (GATS). The developed countries implemented the TRIPS agreement virtually spontaneously, but the developing countries were given until 2000, and countries such as India, that previously did not provide product patents, were given until 2005 to implement a TRIPS compliant patent regime. Unless the WTO grants further extensions, the least developed countries (LDCs) have until 2016 to introduce the required changes.

The TRIPS agreement set out minimum standards for intellectual property protection across all member states. This standard is significantly higher than what the developing nations previously had. For example, TRIPS provides patents for 20 years.

Prior to TRIPS, the protection in the US was 17 years and in the EU was 15 years. The extension of the protection term is more significant in the developing member states. Because the developing countries, including India, previously did not provide product patents, the new regime has the effect of raising the term of patent protection from 0 years to 20 years for these countries.

1.2.1 Key issues and key questions

With the implementation of the TRIPS agreement, India has re-introduced from 2005 product patents in pharmaceuticals for 20 years. In simple terms, this change means that patented products can no longer be copied for sale in the domestic market or for exports. But on a holistic scale, the new regime has wider implications for the domestic pharmaceutical industry, its exports, drug prices and access to medicines within and outside India.

The new industrial landscape severely restricts the competitive environment that existed in India over the last 30 years. This change also creates monopolies for patent holders which almost entirely are MNCs. Many questions arise in the wake of these changes: How would the change affect availability and prices of patented drugs introduced in India? With the sizeable domestic industry that India now has, is the market likely to return to the pre-1970 MNCs domination?

Indian pharmaceutical industry is now faced with unprecedented challenges within its own territory and outside. The industry is undergoing a transformational process and trying new business models. Is the overall number of domestic firms likely to shrink? Are the small local firms likely to survive in the long run? What role would they play in the provision of India's healthcare?

There are general apprehensions that drug prices in India and also in other developing countries will rise significantly due to the regime change, further restricting access to medicines. Any rise in drug prices is going to further restrict access to medicines. Patented medicines are likely to be priced significantly high when launched in India. Thus, only a small share of the population would have access to those medicines. How can the entire Indian population gain access to and benefit from the latest drugs?

The TRIPS compliant regime does not affect India's exports of off-patent drugs. However, to what extent would the manufacture and exports of India's low-cost imitations of patented drugs be affected? These exports were confined to developing countries where drug prices and affordability are a major issue. This is primarily because the costs of medicines constitute 60-70 per cent of the total out-of-pocket healthcare costs in the poor countries.

Are the innovative activities likely to increase due to the regime change? What role are the MNCs and the Indian contract-research firms likely to play in the development of new drugs in India? Is the surge in local innovation likely to help India discover and develop drugs to meet its unmet needs?

Is India's pharmaceutical sector likely to attract more foreign direct investment (FDI) as a result of TRIPS compliant regime? How does the FDI in the pharmaceutical sector compare with other sectors within the Indian economy?

Specifically, this study addresses the following seven questions:

1. How does the regime change impact on India's pharmaceutical exports, particularly exports of the low-cost imitations of patented drugs to the poor countries?
2. What is the effect of TRIPS on foreign direct investment (FDI) into the Indian pharmaceutical industry?
3. How is the business model of domestic firms changing after TRIPS?
4. What impact does the regime change have on the innovative activities within the Indian pharmaceutical industry?
5. How effective have the price controls in India been in providing access to medicines until now and what form of price controls is India likely to have in future?
6. How can India extend access to medicines to its entire population? and
7. Is the TRIPS agreement fair to the developing countries?

An analysis of India's exports of low-cost imitations of patented drugs (or so-called generic drugs) to the poor countries is necessary, because these exports have been

critical in expanding access to medicines in these countries, in which, most of the health expenditure is generally met by the households via out-of-pocket spending and the share of pharmaceuticals accounts for more than two thirds of the total health expenditure (WHO 2004). Thus, any constraints on India's exports of low-cost imitation drugs would adversely affect access to medicines in the poor countries.

A significant increase in foreign direct investment (FDI) could substantially change the landscape of India's pharmaceutical industry. On the one hand, an increase in the number of players could intensify the market competition, lower the drug prices, and thereby improve the access to medicines. On the other hand, if the FDI is instead targeted at take-overs of domestic firms, it could shift the market dynamics in favour of multinational corporations (MNCs) and India could, in the long run, revert back to pre-1970 situation with rising drug prices, further restricting the access to medicines. The business models of domestic firms would determine what drugs are manufactured in India. Where these drugs are to be marketed and what price? All these factors play a vital role in providing access to medicines.

Business models of the domestic firms would determine which particular drugs are manufactured in India, where these drugs are to be marketed and at what price? All these factors would play a vital role in determining access to medicines.

Innovative activities of domestic pharmaceutical industry would determine which drugs are developed and for which diseases. For example, large MNCs have so far shown little interest in developing new drugs for tropical diseases, because profit margins are relatively small for these drugs. Thus, if domestic firms could develop new drugs to meet such unmet needs of the poor world, this should increase access to medicines.

1.3 Research methodology

This research was designed as an exploratory case study to gain greater insight into the likely implications of stronger patent protection for the pharmaceutical industry is in developing countries in general, and in India in particular. With a large population, a well-developed large pharmaceutical industry, and strong economic growth put

India in a unique position. But the prevalence of poverty and the large share of population paying out-of-pocket for medicines that constitute a significant proportion of total health expenditure place India in the same group as a large number of developing with similar conditions. Hence, the model developed in this thesis for the provision of healthcare in India may be useful as a guide for replication in other countries.

This study relies primarily on secondary data. On question 1, we use data on pharmaceutical exports for the years from 2000-01 to 2002-03. Data from Directorate General of Commercial Intelligence and Statistics (DGCIS) Kolkata and IndiaData.com provides the value and the composition details of the exports. South Africa was selected as the destination for India's exports for this particular examination, because that country is home to the largest number of HIV/AIDS patients and Indian firms such as Cipla are the major suppliers of imitations of patented antiretrovirals (ARVs). Because India did not provide product patents prior to 2005, each exported drug was checked for patent expiry in South Africa. The value of the drugs that were still under patent in South Africa in each of those years was summed up. This value was then compared to India's total pharmaceutical exports to determine the proportion of the exports that would be affected by the regime change.

On question 2, we use investment data from Shah (2003) for the period 1975-2000. This period is divided into five 5-year sub-periods. We convert the investment from Rupees into US dollar using exchange rate from the IMF database. Constant 2000 dollar value provides a fair comparison of FDI over the entire study period.

On question 3, we use an Ernst & Young model (cited in FICCI 2005) as the base to assess the change in the business model within the domestic pharmaceutical industry. We also add another model to the list that has been adopted by some leading Indian pharmaceutical companies.

On question 4, we use data from the National Institute of Science Technology and Development Studies (NISTADS) (2005) for the years 1990-2002. The innovative activities are measured in patent filings in the US as well as in India. The study period

is subdivided into three sub-periods; namely, 1990-94, 1995-98 and 1999-2002. The patent filing entities are also divided in three groups; 1) India-owned patents (IOP) refer to patent filings by Indian institutions, 2) foreign-owned patents (FOP) refer to filings by India-based foreign enterprises and 3) Indian individuals. This examination shows the change in patent filings specifically in the pharmaceutical industry.

On question 5, we use three different sets of data to address various aspects of the question. First, we determine the effectiveness of previous and present price controls on access to medicines. For this, we use the 1980-81 data by Bhagat (1982) and more recent data by Nanda (2006) on the share of population with access to medicines. We then translate this data into absolute numbers using corresponding populations. The difference is then assessed for its significance in relative terms as well as in absolute terms.

Second, we assess the impact the new regime on drug prices. In doing so, we examine the changes to the prices of 406 drugs over a three year period from 2005 to 2007/08. These drugs were randomly selected from the leading therapeutic categories. We use Drug Today (Jan-Mar 2005), CIMS (July-Oct 2007), Drug Today (Oct-Dec 2007) and IDR (Nov 2007-Jan 2008) to determine the change in prices. This examination is initially based on Sakthivel (2005), who examines 152 drugs for the period 1994-2004, but was expanded to add greater specificity about the form of drugs (e.g. tablets or capsules), their strength (e.g.10mg or 20mg) and the size of the package (e.g. 10 Tablets, 200ml). This added specificity ensures a comparison of apples with apples, a feature that was absent from the Sakthivel study.

Third, we consider the on-going negotiations between the government, the industry and other stakeholders on the future form of price controls. As a part of the agreement reached between the industry and the government, 11 leading firms agreed to reduce prices of 886 drugs from October 2006. The list of drugs along with their new and old prices is obtained from the website of the Department of Chemicals and Petrochemicals. We use the prices listed in CIMS (2007), Drug Today (2007 and IDR (2008) and compare against the agreed prices of each of the 886 drugs to check if the prices of these drugs have indeed been reduced.

On question 6, healthcare models in countries such as Australia, Canada, New Zealand and the United Kingdom are considered. Based on the Australian model, an IndiaHealth model is developed to provide equitable access to healthcare including access to medicines to its entire population. Prevalence of poverty and income levels in India form the basis of patient co-payments. This model is then tested to check if India can in fact afford to implement such a model. The affordability is based on the Singh Government's commitment to raise the level of public spending on health to 2-3 per cent of the GDP. Data on the GDP forecast is obtained from the IMF database.

On the final question, we consider the adoption of pharmaceutical product patents by different groups of countries and stages of their economic development. We also use cost and benefit analysis to weigh up the costs and benefits to member states with an emphasis on the developing countries. We also consider various models that experts suggest to improve upon the current situation.

1.4 Significance and limitations of the study

In recent years, a large number of studies have been undertaken to assess the impact of implementing the TRIPS agreement in India (see for example Galpalli (2004), Lanjouw (1998) and Scherer and Watal (2001)). While the global media has drawn attention of governments, public health activists and NGOs (non government organisations), a significant number of articles covering specific aspects of the impact have also been published in academic journals. The impact of TRIPS is comprehensively covered most notably by Chaudhuri (2005). Notwithstanding the great contributions made by the distinguished authors and experts in the field, none of the studies examines the issues in the post-TRIPS setting, as all the studies were undertaken pre-implementation and/or relied on pre-TRIPS data.

Considering the level of attention, the TRIPS agreement has drawn internationally, it is rather important to undertake a post-implementation analysis and support or dispel the apprehensions associated with the TRIPS agreement. While it would be too early to ascertain the full impact of the implementation, this study examines the impact using the most recent data and determines the changes in drug prices and market

behaviour. In other words, this thesis attempts to understand and explain scientifically the most likely impact of TRIPS on access to medicines.

The term *access to medicines* is indeed a multi-dimensional term. According to Gray and Matsebula (2003), improving access to essential medicines requires improvement in four components of healthcare provision; namely, 1) ensuring rational selection [of drugs], 2) providing sustainable financing, 3) ensuring efficient systems for distribution, and 4) maintaining affordable drug prices. It should be noted from the outset that while the model developed in Chapter 7 of this thesis considers all four areas noted in the Gray and Matsebula study, the absence of sustainable financing is regarded as the principal hindrance to access to medicines in this thesis. This approach is consistent with the literature on affordability of drugs. Thus, for example, the World Bank (2002) has pointed out that nearly 25 per cent of the poor people in India do not even seek healthcare because of the costs. Thus, the primary focus of this work remains on how to improve access to medicines by reducing costs of drugs to increase affordability. In Chapter 7, we also undertake sensitivity analysis of the proposed model to consider the long term sustainability of financing such a programme from the public purse.

Because of its reliance on secondary data, the main limitation of this study is that it is greatly influenced by the secondary sources. However, it must be noted in defence that reliable accurate data required for the study is not available, as some data is simply not collected whilst other data could be conflicting or misleading. For example, the number of pharmaceutical companies in India varies between less than 6,000 and over 23,000. As a result, some inaccuracies may be inevitable. It is safe to say, however, that the data provided here can be used as a reliable guide to determining the emerging trends in India's pharmaceutical industry and its healthcare market.

1.5 Organisation of the study

This thesis is divided into three parts. The first part comprises chapter 2 and chapter 3. These chapters examine the influence of global forces on the availability and affordability of new drugs. Chapters 4 to 7 in the second part pertain to India. These

chapters examine the development of India's pharmaceutical industry, the regulatory framework, and their contribution to increasing access to medicines. In the final part, chapter 8 questions the appropriateness of TRIPS for the developing countries. Chapter 9, the final chapter presents the conclusions of the study.

Chapter 2 considers the negotiations transforming the GATT into the WTO and the signing of the concluding agreements. This chapter discusses the implications of the TRIPS agreement for the pharmaceutical industry. The affirmation of the Doha Declaration on TRIPS and Public Health on the flexibilities is considered. TRIPS provides the flexibilities, such as compulsory licensing and parallel imports, under which member states are allowed discretionary powers to determine their own conditions to invoke these flexibilities. This chapter also discusses the impact of the attempts being made by the US and the EU to erode these flexibilities and to raise the protection standards through bilateral free trade agreements (FTAs) and other cross-border treaties with the poor countries.

Chapter 3 examines the global pharmaceutical industry with a particular focus on drug development. This chapter studies the structure of the global pharmaceutical industry and investigates its influence on the process and the costs of bringing new drugs to the market. This chapter finds that the direction of pharmaceutical innovation appears to be more focused on discovering the next blockbuster drugs[1] and/or developing the 'me too' drugs, rather than discovering new drugs for the diseases of the poor.

Chapter 4 examines the factors leading to the development of India's pharmaceutical industry. How did India become almost self-sufficient to meet its domestic demand and transformed itself from a net importer to a net exporter of pharmaceuticals? In recent years, India has emerged as the world's leading supplier of low cost generics. Over the last three decades, India's exports to developing countries with lax patent regimes included imitations of patented drugs. What impact would the new regime have on these exports and access to medicines in developing countries? This chapter also examines the emerging business models in the pharmaceutical industry. Also

[1] These are drugs with annual global sales of one billion dollar or more.

examined are the recent changes in the level of foreign direct investment (FDI) particularly in the pharmaceutical sector.

Chapter 5 examines the patents regime in India, with an emphasis on the Patent Act 1970 that played a crucial role in advancing the Indian pharmaceutical industry. Under its international obligations, India introduced three major amendments in 1999, in 2002 and in 2005. India now has a TRIPS compliant patent regime providing product patents for pharmaceuticals. Issues such as definitions of patentable subject matter and patentability of micro-organisms remain ambiguous. The issue of data protection v. data exclusivity and its implications for the domestic industry are also examined, together with an examination of the impact of TRIPS on industry's innovative and patenting activities.

Chapter 6 examines India's regulatory environment with an emphasis on drug price controls. The impact of the regulatory changes introduced in the 1970s contributed significantly to industry growth. Through the framework of Drug Price Control Order (DPCO), India controlled prices of drugs listed on its Schedule. The drug prices in India declined from one of the world's highest levels to one of the lowest level. But even this low level of prices failed to provide access to medicines to India's entire population. Thus it is clear that drug price regulation and controls are inadequate mechanisms for extending the access to medicines in a country like India, where widespread poverty is still a major issue. Accordingly, we also studied healthcare models in other countries, particularly in Australia, Canada and New Zealand in this chapter with a view to developing a healthcare model for India.

Chapter 7 follows on the consideration of healthcare models in other countries in the previous chapter and presents an equity driven model for providing healthcare, including access to medicines, to India's entire population. The model proposed for India is based on the Australian healthcare model and modified to incorporate India's particular demographic characteristics. The 3-tier patient co-payments are designed to cater for all income levels. Empirical data is used to compare the household expenditure on medicines under the current model and under the proposed model. The chapter also tests the proposed model for affordability and sustainability over the longer run.

Chapter 8 questions the appropriateness of the TRIPS agreement for the developing countries. Arguments for and against raising the protection standards are considered. This chapter examines the costs and benefits of implementing TRIPS. The costs of raising protection standards to the TRIPS level in Australia, Canada and the US are compared with those of the developing countries. A number of leading experts have suggested alternative models for financing R&D in the pharmaceutical industry and for developing new drugs. In addition to a discussion of these models, a new *minimum patenting* model is proposed as an additional policy option for the future.

Chapter 9 summarises the main findings of this study. Based on the concluding discussions, the study also makes some suggestions for future research.

1.6 Contributions of this study

Subject to the usual caveats of practicality and modesty, this study makes distinctive contributions in the following areas:

- It develops an equity based IndiaHealth model for the provision of healthcare including access to medicines to India's entire population. The significance of this model is that in the wake of TRIPS compliant regime introduced in India since 2005, drug prices have begun to rise further jeopardising accessibility to medicines. While India has drug price controls and other regulatory measures with the potential to bring or keep prices down, these measures fail to address the issue of poverty. Even the lowest prices that India claims to have provide access to medicines to only one in three Indians.

- It examines the change in prices of 406 drugs in a post-TRIPS setting. The previous studies have provided estimates of pre-TRIPS changes to drug prices. In the wake of apprehensions in the lead up to implementing TRIPS in India, the findings of this study are quite significant.

- It also examines the prices of 886 drugs that the Indian manufacturers are supposed to have voluntarily reduced under an agreement with the government in 2006. Our examination tests the market reality against the claims made by

both the government and the industry in relation to the significance of these price reductions.

- It examines India's pharmaceutical exports and determines the proportion that may be affected by the patent protection regime change. In particular, India's inability to export in the future imitations of patented products would affect the availability and the prices of drugs, further restricting access to medicines in the developing countries.

- It examines the correlation between FDI and the strengthening intellectual property rights (IPRs), and rejects the claim of the proponents of more stringent patent protection that stronger protection of IPRs is a pre-requisite to attracting FDI into the pharmaceutical industry.

- It adds a new model to the list of models designed to improve the provisions providing incentives to invest into drug development under the TRIPS agreement. It also suggests changes for the forthcoming review of the TRIPS Agreement.

- It examines innovative activities originating in India. It confirms a significant increase in patent filings in recent years by Indian institutions in the pharmaceutical industry.

In addition, a number of papers and articles were authored/co-authored during the course of this study (details of these are provided in Appendix A).

Chapter 2

The World Trade Organization and the TRIPS Agreement

2.1 Introduction

The aim of this chapter is to examine the impact of the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on the pharmaceutical industry. The TRIPS agreement is one of the three crucial international agreements signed in 1994 as a part of the establishment of the World Trade Organisation (WTO) – the other two agreements being the General Agreement on Tariffs and Trade (GATT) and the General Agreement on Trade in Services (GATS). The TRIPS agreement sets minimum standards for intellectual property protection in the member countries. In recent years, regional and bilateral agreements on investment, free trade and other issues have forced developing countries to raise protection standards for intellectual property beyond what is required under TRIPS. These higher protection standards, known in the literature as TRIPS-plus conditions, are also discussed in this chapter, together with their implications for access to medicines in the developing countries.

The WTO came into existence in 1995, when it replaced its predecessor organisation known as the General Agreement on Tariffs and Trade (GATT). With its mission to facilitate boundless global market environment for international trade, the WTO is one of the most important international economic institutions today. This multilateral body is charged with establishing and enforcing the legal framework for free flow of goods and services across nations. The WTO also provides a forum for negotiations for further liberalisation of trade, and for considering additional multilateral disciplines covering other trade related aspects.

The WTO varies significantly from its predecessor GATT. Firstly, the intellectual property was never a part of the GATT, whereas the TRIPS agreement brings the trade-related intellectual property very much under the ambit of WTO. Secondly, under the GATT, member states were free to pick and choose agreements to suit their specific needs. By comparison, the WTO is a fully integrated package based on all-in or all-out concept, with no provision for opting out of specific disciplines. Countries

wishing to join the WTO have little choice but to sign all agreements, including the TRIPS agreement. Other differences between the WTO and the GATT are discussed later in the chapter.

On becoming members of WTO, the developed countries were required to implement the TRIPS requirements from 1995, whereas the developing countries were allowed a period of 5 years to implement the same. Developing countries, such as India that had not previously allowed product patents in pharmaceuticals, were granted another 5 years to implement the TRIPS Agreement. That is why India became a TRIPS compliant nation from 1 January 2005. The least developed countries (LDCs) have until 2016 to introduce TRIPS compliant regimes.

The TRIPS agreement has significantly raised the protection for intellectual property in developing countries. For example, the new regime in India has increased the patent protection period from 7 years to 20 years for manufacturing processes, including the manufacturing of pharmaceutical drugs. For product patents, the protection has increased from 0 to 20 years. However, TRIPS allows member countries certain flexibilities, such as compulsory licensing and parallel imports, to deal with country-specific public health situations. These flexibilities were reaffirmed under the Doha Declaration on the TRIPS Agreement and public health, and are discussed below.

The remainder of the chapter is organised as follows. Section 2.2 considers the major differences between the GATT to the WTO. Section 2.3 examines the relevant Articles in the TRIPS agreement and considers the implications for pharmaceutical innovation. Section 2.4 examines the TRIPS-plus conditions in international agreements and their implications for developing countries. Section 2.5 provides a summary of the main conclusions.

2.2 From GATT to WTO

From the perspective of the pharmaceutical industry, the WTO differs from the GATT on a number of accounts. One major difference is that while the GATT dealt with

trade only, the WTO relates to services, trade as well as intellectual property. But, as the discussion below outlines, there are other differences also.

2.2.1 Major differences between the GATT and the WTO

The role of the WTO is much more extensive than that of its predecessor. The GATT permitted the member countries to select disciplines based on national interests and opt out of unsuitable agreements. In contrast, the WTO is a wholly integrated package binding member countries to all WTO agreements. It's a 'one size fits all' concept, because there is no option of selecting agreements on the basis of suitability or national interests. Many experts are apprehensive that national governments would, to a certain extent, have little control over specific disciplines. For example, Hoekman (2002) suggests that 'the adoption of specific multilateral rules may affect detrimentally the ability of governments to regulate domestic activities and deal with market failures' (p. 4).

A significant difference between the GATT and the WTO is that intellectual property was never a part of the former. But:

> ... the TRIPS agreement was unnecessary as most of its functions have, for up to a century, been fulfilled by ... conventions such as the Paris Convention ... Rome Convention ... and the UN-based World Intellectual Property Organization (WIPO). (Dunkley 2001, p. 69)

The WIPO is responsible for promoting intellectual property (IP) and administers 23 international treaties on IP matters. The WIPO has a membership of 180 countries. Yet it is perceived as a 'toothless tiger'. In particular, developed countries were 'dissatisfied with the implementation of the IPRs through the WIPO as it did not have an effective enforcement system' (Zutshi 1998, p. 41). In contrast, the WTO is significantly more powerful than its predecessor. Unlike the GATT, the WTO has an enforcement mechanism, a Dispute Settlement Body (DSB) and an Appellate Body.

Another difference between the two organisations is the actual functioning of the organisation. Under the WTO Rules and Procedures Governing the Settlement of Disputes, a defendant member no longer has the ability to block the adoption of a WTO panel report (Hertz 1997). This is a considerable departure from the old policy. Under GATT:

> ... when a ruling went against a country, the country could block the adoption of the panel decision by denying the needed consensus. Smaller nations were often left fuming when the United States used this tactic to delay unfavourable decisions indefinitely. (Drohan 1996, p. A12)

Dispute settlement under the GATT was a time consuming process that often did not resolve the problems. By comparison, the WTO dispute resolution process is significantly more efficient. It follows a strict timetable for consultations, panel investigations as well as for appeals. Moreover, the WTO decisions are enforceable. Under the GATT, investigations went on endlessly and decisions-delivered often gathered dust while parties continued to argue (Drohan 1996).

The large countries may not be able to technically block a WTO decision, but they certainly influence it. According to Reichmann (1998), large MNCs, certain trade associations, and some governments use bullying tactics to pressurise international organisations to achieve a favourable outcome. The WTO acknowledges that while 'the private sector, non-governmental organizations (NGOs) and other lobbying groups do not participate in WTO activities except in special events such as seminars and symposiums', but they can [and they do] 'exert their influence on WTO decisions through their governments' (WTO 2006a, p. 9). In its attempt to dislodge myths about the running of the WTO, its website emphasizes that 'the WTO does not dictate to governments to adopt or drop certain policies. In fact, it's the governments who dictate to the WTO' (WTO 2006a, p. 2). The question, which begs to be asked here, is which governments dictate to this powerful institution. It certainly would not be the developing country governments.

2.3 The TRIPS agreement

The TRIPS agreement requires all members of the WTO to provide a set of minimum standards for protection of intellectual property, including patent protection for pharmaceutical drugs. This obligation has resulted in substantial amendments to IP regimes of more than 140 countries, including the US (Jorge 2004). Prior to TRIPS, the level of protection varied significantly across developing as well as developed countries. Developing countries generally allowed so-called 'weak' protection comprising process patents but not product patents. Developed nations had relatively stronger IP regimes including pharmaceutical product patents. The patent term also

varied from 5-7 years in India to 17 years in the US. The TRIPS agreement harmonised the term to 20 years from the filing date. TRIPS is a comprehensive agreement that has revolutionised the international intellectual property law (Reichman 2000), raising the standards of protection in areas such as copyrights, trademarks and patents.

A number of experts have stressed the significance of TRIPS, especially for the developing countries. For example, Shiva (2004) describes the TRIPS agreement as 'the most far-reaching determinant of human rights to food, health, livelihood and creativity in the context of globalisation' (p. 665). According to Correa (2006), the most crucial impact of TRIPS, as far as the developing countries are concerned, is the mandating of the implementation of IPRs, notably patents for pharmaceutical products. Professor Frederick Abbott (1998) writes in the editorial of the special issue of the Journal of International Economic Law devoted to TRIPS, that:

> ... the most critical policy issue to be addressed at the international level with respect to the international intellectual property system of laws and institutions is how it can best be constructed and implemented to facilitate economic growth and social welfare in the developing and newly industrialising countries. (Abbott 1998, p. 498)

2.3.1 .The role of TRIPS in the pharmaceutical industry

This thesis is concerned only with patent protection under TRIPS as it is applicable to the pharmaceutical industry. Article 1 of TRIPS provides that 'members may, but shall not be obliged to, implement in their law more extensive protection that is required by this agreement, provided that such protection does not contravene the provisions of this agreement' (*Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)* 1994). A consequence of this provision has been that a large number of regional and bilateral agreements have introduced even stronger IPRs than the TRIPS agreement stipulates (these 'TRIPS-Plus' provisions are discussed later in the chapter).

In all, the TRIPS agreement has 73 Articles that can be divided into three major components. The first component (Articles 1 to 40) sets out the aims and objectives, and the standards of IPRs. The second component (Article 41 to 61) deals with enforcement mechanisms. The final component (Articles 62 to 73) deals with specific

mechanisms, such as the transitional arrangements, technical cooperation, technology transfers, and the institutional arrangements for monitoring and review, which are devoted to addressing the special needs of developing countries (UNDP 2003, p. 203). The major points relevant to pharmaceutical patents are as follows:

'Patents shall be available for any inventions, whether *products* or *processes*, in *all* fields of technology, provided that they are new, involve an inventive step and are capable of industrial application ... and whether the products are imported or locally produced' (Article 27). *Products* and *all* are relevant here, because patents on pharmaceutical and food products had previously been excluded in many countries. Developing countries, such as India, had provided process patents, but not product patents. Thus, the previous regime allowed reverse engineering to re-manufacture a patented product by a different process. The first part of Article 27 effectively prevents the use of reverse-engineering.

The second part of the Article refers to equal treatment of local and imported products for patenting purposes. The implications of this part would be that companies would simply import patented products from their home countries (presumed developed). This would constitute working of the patent in the host country (presumed developing). Forcing importers of patented products to manufacture locally would be deemed a contravention of the provisions of Article 27. Patent regimes in countries like Brazil and India with fairly developed pharmaceutical industries provide for compulsory licensing in case of non-working patents. But when the patented products are being imported, such provisions can not be invoked to grant compulsory licences. The absence of competition results in consumers paying monopoly prices. The domestic players also lose out on participating in the manufacture of new products.

As noted in the introduction, the term of protection must be a minimum of 20 years from the filing date (Article 33). This applies to patents for products as well as processes. Previously, the patent term in many countries was shorter. In developing countries, the term was significantly shorter. India for example, provided protection for processes for seven years from the filing date or five years from the date of grant whichever was shorter. While the term for process patents increases significantly to 20 years, for product patents, the increase from 0 to 20 years is even more significant.

The change to the patent term in the developed countries was relatively small. For example, the pre-TRIPS term of 17 years in the US was increased to 20 years.

A patent confers on the patentee the exclusive rights, to prevent third parties not having owner's consent from the acts of: making, using, offering for sale, selling, or importing the patented product; and in case of subject matter of a patent being a process, to prevent third parties not having owner's consent from engaging in any of the activities noted above for the purpose of obtaining the patented product by that process (Article 28).

The intent of this article, which is to exclude others from engaging in the manufacture of the patented product, has been criticised by some for not considering the potential benefits of participation of others in technology advancements. For example, Somaya (2000), examines the ideology behind the patent systems in four leading countries; namely, the US, the UK, Germany and Japan. He concludes that while authorities in the US and the UK support the exclusivity of property rights of patentees, the Japanese and the Germans authorities view inventions more as a public good and less as a private good. The emphasis of the official approach in Japan and Germany is more on the dissemination of technology and less on its exclusivity, as patents are viewed more as a means to reward inventions and less as a right to exclude others from using it (cited in Drahos & Braithwaite 2002, p. 476). The fact remains that in spite of these important differences among the developed countries, the TRIPS agreement is positioned closer to or identical with the ideology of the US and the UK. Accordingly, in assessing the implications of TRIPS, the original concept of granting exclusive patent rights needs to be revisited.

2.3.2 Patents and innovation

A patent is a property right granted by a sovereign state to the inventor of a novel, non-obvious and useful invention (Lehman 2003). Patents grant monopoly rights to inventors for disclosing their invention to the public domain. While rewarding inventors with monopoly rights encourages innovation, patents may also hinder further technical progress by preventing others from making a similar invention due to the risk of infringement. Economists and inventors have been divided over the issue

of rewarding inventors with patent protection and the issue of patent protection has been controversial for a very long time. The controversy gained new heights between 1850 and 1875, with the critics of patent protection laws demanding not merely reforms to the patent regimes, but a complete abolition of the patent system. Indeed, for a while, it looked as if the abolitionist movement was going to win (Machlup & Penrose 1950).

A brief review of the intellectual property rights in the historical context provides a recap of the issues involved in the controversy. According to Government of Australia (2008), intellectual property refers to property of mind or intellect, which in business term means ownership of proprietary knowledge. Claims of ownership of intellectual property, as such, appear to have begun with the identifiable markings of goods around 6,000 years ago (Ruston 1955). But there is no evidence to suggest that others were prohibited from copying the originals. According to Dongre (1982), sale of knowledge was considered a bad thing and as such prohibited in ancient India. Similarly, the notion of human ownership of ideas or their expressions was also absent from the Chinese, Islamic, Jewish, and Christian civilisations of the pre-modern world (Hesse 2002). Claiming ownership of knowledge is a concept of the modern times.

Before IPRs were formalised in Europe, the rulers utilized [letters of] grants for the exclusive exploitation of innovative and previously unknown practices (David 1993). The intellectual property rights (IPRs) in a formal sense first emerged with the enactment of what later became known as the Venetian Statute of 1474. It became the first legal institution to establish the ownership of knowledge with the intention of explicitly promoting innovation (Nard & Morriss 2006). The intention, in this case, was limited to promoting innovation by recognising inventor's contribution. Britain issued its first patent in 1559 to Jacobus on the basis that 'the innovator should receive certain benefits and rights relative to his invention' (May & Sell 2006, p. 80). The Venetian Statute was not concerned with the inventor receiving specific benefits. As the laws of intellectual property began to evolve in different countries, the British Statute of Monopolies of 1624 became a landmark piece of legislation. Under Section 6 of this Statute of Monopolies the following parameters served as guiding principles:

1. the term of patent must not exceed fourteen years;
2. the patent 'must be granted to the first and true inventor';
3. 'it must be of such manufactures, which any other at the making of such Letters Patents did not use';
4. it must not be contrary to the law;
5. it must not be 'mischievous to the state by raising of prices of commodities at home;
6. it must not hurt trade; and
7. it must not be generally inconvenient (May & Sell 2006, p. 83)

It is worth considering what the implications would be if this Statute were to be applied to the pharmaceuticals industry today. The outcome would clearly be that drug prices could not be raised in the domestic market (Clause 5), as monopoly rights could not be exploited at home. Under Clause 6, the Indian pharmaceutical industry would be able to continue to manufacture generic medicines as imitations of patented products for exports to the poor countries, because doing otherwise would hurt trade. Under Clause 7, no Exclusive Marketing Rights would be granted. The large price differences between the originator and imitator products could not exist, because today's pricing levels set by the originator companies would be seen as a breach of Clause 7.

In the USA, each state operated under its own patent rules until the late 1700s. The Philadelphia convention in 1787 was the first attempt to have a federal patent law. The proposed national patent and copyright provisions at the convention became the basis for the Patent Act in 1790 (Nard & Morriss 2006). The Venetian Statute of 1474, the British Statute of Monopolies of 1624, and the US Patent Act of 1790 are considered to be the three main pillars of the intellectual property development around the world. Patent laws were introduced in Austria in 1810, Russia in 1812, Prussia in 1815, Belgium and the Netherlands in 1817, Spain in 1820, Bavaria in 1825, Portugal in 1837 and Saxonia in 1843 (Machlup & Penrose 1950). In Germany, the 1877 Statute created a federal patent system. The patent fees in Germany were deliberately set high to eliminate claims for frivolous inventions (Khan 2002). The current Indian Patent Act denies patents for frivolous inventions, but faces challenges from pharmaceutical multinationals (MNCs) for doing so.

The inventors have also been divided over the issue of protection of such rights. On the one side were inventors, who preferred to protect their inventions. For example, the Wright brothers had secured patents in aviation. Similarly, James Watt had patented his invention of steam engine. Ashton (1964) notes that the problem with this concept was that it blocked progress in steam technology by preventing others from constructing new types of steam engines it. The industrial revolution did not really take off until Watt's patent expired in 1785.

On the other side of the debate were distinguished people like Benjamin Franklin, who refused to patent the invention of his famous stove. He argued that 'as we enjoy great advantages from the invention of others, we should be glad of an opportunity to serve others by any invention of ours, and this we should do freely and generously' (cited in Cole 2001, p. 84). Henry Ford, the father of the auto assembly line, was another critic of patents who withdrew all patents to allow unrestricted access to all Ford inventions (Flink 1990).

The first group of inventors (Wright brothers, James Watt) could be considered what Hofstede (2001) calls *individualist* for being protective of their knowledge and preventing others from using it. Under their approach, the inventor deserves to be rewarded for his genius. But the follow-up progress is blocked or slowed down. The second group of inventors (Benjamin Franklin, Henry Ford) could be considered what Hofstede calls *collectivist* for sharing their knowledge with all. Their approach is more considerate of the society as a whole at the expense of an individual reward. The inventor does not get formal rights bestowed on him by the authorities, but gets wider acceptance and recognition by the society.

The debate on the protection of intellectual property has gained fresh momentum in the wake of the TRIPS agreement. The experts remain as divided on this issue today as they were more than a hundred years ago (Hope 2003). As the following two sub-sections reveal, the proponents of legal protection argue that patents provide incentives for investment into R&D secured through monopoly pricing that spurs innovation. The opponents of such protection argue on the other hand, that IPRs

create unnecessary monopolies that are barriers to free markets and to further innovation.

2.3.3 The case for protection of intellectual property rights

A large body of literature advocates strong protection of intellectual property rights to encourage innovation. For example, Solow (1957) and Dennison (1979) argue that the technical progress leading to economic growth would not have taken place without the protection of IPRs (cited in Cole 2001). North (1968) also supports this argument and suggests that the lack of systematic protection of property rights until recent times was the main reason for the slow technological progress and innovation. North holds that the development of systematic incentives through protection of IPRs increased private returns and encouraged technological innovation.

Reflecting the controversial nature of the case for legal protection of IPRs, a study was conducted not long ago to find out how the absence of patent protection would affect innovations (i.e. delayed or not introduced at all). Mansfield (1986) randomly selected 100 firms, excluding small firms, across 12 industries in the US (chemical, pharmaceutical, office equipment, petroleum, machinery, fabricated metal products, electrical equipment, motor vehicle, instruments, primary metals, rubber, and textiles) and sent them sent a questionnaire. In addition, 25 senior executives from these firms were interviewed. Responses from individual firms were then combined to estimate industry-wide results (see Table 2.1).

Table 2.1 shows that around two thirds of the new pharmaceutical products would not have been introduced without patent protection. This share in the chemical industry was 30 per cent. Inventions affected by absence of patents in the petroleum, machinery and fabricated metal products industries would have been significantly lower than in the chemical industry. 'In the office equipment, motor vehicle, rubber, and textile industries, the firms were unanimous in reporting that patent protection was not essential for the development or introduction of any of their inventions' (Mansfield 1986, p. 174). This is because 'not all patentable inventions are patented ...firms rely instead on trade secrets, because technology is progressing so rapidly that it may be obsolete before a patent is issued' (p. 176).

Table 2.1: Percentage of innovations that would not have been developed or introduced

	Industry	Percent that would not have been introduced	Percent that would not have been developed
1	Pharmaceuticals	65	60
2	Chemicals	30	38
3	Petroleum	18	25
4	Machinery	15	17
5	Fabricated metal products	12	12
6	Primary metals	8	1
7	Electrical equipment	4	11
8	Instruments	1	1
9	Office equipment	0	0
10	Motor vehicles	0	0
11	Rubber	0	0
12	Textiles	0	0

Source: Mansfield (1986, p. 175).

The mission of the PhRMA noted in its (2007) Annual Report suggests that strong intellectual property incentives and abolition of price controls are the necessary keys to encourage the discovery of new drugs. The PhRMA (2002) argues that the developing countries should have the same level of protection as the developed countries, because stronger patents will stimulate more research efforts to discover new drugs needed in developing countries. This argument lacks the support of empirical evidence, however. India had a stringent regime for 60 years before the introduction of Patent Act 1970 with little investment or innovation in its pharmaceutical industry.

According to Schmookler (1966), 'an invention is largely an economic activity which, like other economic activities, is pursued for gain' (p. 206). He suggests that the amount of invention is governed by the extent of the market size. In other words, the larger the market in dollar terms, the higher the number of inventions would be. Acemoglu and Linn (2004) also suggest that profit incentives and market size are significant considerations in innovation decisions. Lehman (2003) suggests that developing countries would benefit from new medicines for tropical diseases by introducing stringent patents regime, because it would lead to the development of pharmaceutical markets. But this argument appears suspect, as it ignores the fact that stronger patents would also mean a market with higher drug prices, making the drugs inaccessible to the people in the developing countries. As Mayne (2002) has pointed

out, stronger patents in poor countries will not change the basic market reality and that reality is the lack of purchasing power. Developing countries already have large markets in terms of patients. What these countries do not have are neither the medicines to treat the tropical diseases nor the capacity to pay for the available medicines. When Lehman speaks of the 'development of a market', he also speaks of a monopoly market in which the patent holder would be free to charge monopoly prices.

To his credit, Lehman also suggests that consumers in all countries should share the burden of drug development '*equitably by paying for medicine at a price level consistent with their means*' (p. 14). It is not clear, however, what this equity would mean in a country like India? As will be discussed in later chapters, two-thirds of Indians do not currently have access to medicines even at the world's lowest drug prices that exist in India today. Under the stronger (post 2005) protection and *sharing the burden of drug development* as Lehman suggests, drug prices would rise significantly and access to medicines would be restricted even further. If the pricing level was consistent with the means of the poor as Lehman also suggests, the prices would have to fall instead of rising. Accordingly, the argument for introducing stringent patent regimes in the developing world remains less than convincing.

Khan (2002) suggests that the industrial supremacy of the US is a testimony to its treatment of inventors and inducements held out for innovative activity. The US has one of the most successful patents systems in the world with more than six million patents granted since the system was established in 1790, notes Khan. PhRMA (2007) suggests that the US introduces 70 per cent of the new drugs worldwide, and this is because, the US has the world's strongest intellectual property regime. A comparison of the level of patent protection between the US and Europe suggests that on a number of accounts, Europe provides stronger protection for pharmaceutical patents (see Table 2.2). Yet, the share of new drugs discovered in Europe has declined over the last decade. In 1992, six out of 10 the top-selling drugs originated in Europe compared with just two of the top ten products in 2002 (Verheugen 2005).

Table 2.2 shows that the basic protection under TRIPS is the same in both in the US and the European countries. The US provides five years of data exclusivity compared

with up to 10 years in Europe. This means that the generic manufacturers can not rely on the data submitted by the originator company during that period. The US provides for the so-called 'Bolar provision' to enable the generic manufacturers to test and prepare the bio-equivalency of patented drugs. Thus, the generic version would be ready for launch upon patent expiry. By comparison, a number of European countries do not provide Bolar provisions, which delays the entry of generics. In fact, according to Nigel Stoate, a London based solicitor specialising in intellectual property, the EU negotiators were seeking to have the Bolar provisions abolished as a pre-condition for Hungary, Poland, Slovakia and Slovenia to join the EU (Stoate 2001/2002). The originators enjoy the extended monopoly in the EU countries. Finally, under the US law, pharmacists are permitted to provide generic substitutions for patented drugs. This is not the case in many European countries. Consequently, the sale of originator products by prescriptions would be higher in Europe than in the US as the 2006 sales shows. According to the European Generic Medicines Association (2007), the generics constituted 10 per cent or less of the sales by volume in a number of countries, including Italy, Ireland, Greece, Finland, Portugal and Switzerland. By comparison, the generics share in the US accounted for almost 60 per cent in 2005 (PhRMA 2007). Despite the overwhelming evidence suggesting that the EU has stronger patent regime than the US, the level of innovative activity measured by new drugs developed in Europe has declined over the last decade.

Table 2.2: Level of patent protection (US v EU)

Level of protection	US	EU
Basic product patents	20 years	20 years
Data exclusivity blocks market entry of generics	Five years	10 years
Patent extensions supplementary protection certificates (SPC)	14 years maximum	15 years maximum
Bolar provision allowing generic R&D before patent expiry	Yes	No (in most states)
Market access to generics immediately after patent expiry	Yes	No
Generic substitution by pharmacists	Yes, in all 50 states	No, in many member states

Source: Based on European Generic Medicines Association (2003).

The comparison of patent protection between the US and EU suggests that stronger patent regime may not necessarily attract investors to invest into the pharmaceutical R&D. Other factors, such as the size of the US market, lack of price controls, and availability of public funding for research through National Institute of Health (NIH)

also appear to influence the investor decisions (see Chapter 3 for more details). There could be no disagreement that the development of new drugs requires large funds and patents provide incentives for investors to invest into pharmaceutical R&D. However, patents are not the only way to spur innovation as the opponents of protection claim.

2.3.4 The case against protection of intellectual property rights for medicines

A significant number of experts remain unconvinced about the need for stronger IPRs to increase innovation. They question the role patents have played in technological progress or economic growth. Ashton (1964) for example argues, that discovery and development would have occurred even without the framework of patenting, because competitiveness and pursuit of new knowledge are also major drivers of innovation. Mokyr (1990) also argues that a patent system may have been a stimulus to invention, but it certainly was not a necessary factor. He believes that contribution of patents to innovation is grossly overstated. Davis (1994) also argues that there is no real evidence to suggest that a patent monopoly promotes R&D, casting doubts on the fundamental premise of the concept of patents. On the contrary, it can be argued that there is evidence to suggest that protection hinders [further] innovation. For example, James Watt blocked progress in steam technology by preventing others from constructing new types of steam engines. The result was that technological progress was slowed down or blocked by patenting and the industrial revolution did not really take off until Watt's patent expired in 1785 (Ashton 1964).

Professor Davis (1994) of Cleveland State University argues that from an economist's point of view, patents are an embarrassment to the idea of a free-market. He opines that patents are essentially a form of subsidy insofar as the government grants the patentee the opportunity to charge a monopoly price for its product. The difference between the monopoly price and free-market price is, effectively, a subsidy to the patent holders. The government, instead of paying the patent holder directly, authorises the patentee to collect the premium from consumers, but the end effect remains the same, suggests Davis.

Other experts also argue against the concept of patent granted monopolies. Hayek for example, (1988) suggests that a slavish application of the concept of intellectual

property has done a great deal to foster the growth of monopoly. He questions the award of monopoly as the most appropriate and effective form of rewarding investors for investments in scientific research. In a world of scarce resources, free marketing optimises resource allocation increasing efficiency. Granting patent rights to create monopolies seems contradictory to the concept of free marketing. Referring to intellectual property rights, Cole (2001), suggests that:

> ... since these rights do not arise from the scarcity of the appropriated subject matter; ... rather, their sole purpose is to create scarcity, thereby generating the monopoly rents for holders of such rights. In such case the law does not protect property over the scarce good, since the law itself created the scarcity ... and in case of patents and copyrights, the scarcity arises only after the property right is defined. (pp. 80-81)

Scientists do not seem to be concerned about patent protection. They generally hold that patents at best could be considered a bonus, because basic research is not dependent on patents. Basic research goes on regardless. It goes on because science is looking for new knowledge. Thomas Alva Addison, the holder of 1,000 patents, believed that '[A patent] is simply an invitation to a lawsuit.... [I have] lost all faith in patents, judges and everything else relating to patents' (cited in Melethil 2005, p. E723). Melethil (2005) sums up the concept of patenting as 'scientists invent, lawyers patent' (p. E723).

Former Vice President of the World Bank and Nobel laureate Stiglitz (2002b) believes pharmaceutical patents cause unnecessarily hardship to the poor in the developing countries. Market competition would force businesses to innovate in any case, he argues. In order to secure an edge over competitors, entrepreneurial firms would invest into innovative products and develop efficient processes to manufacture them regardless of the level of protection provided.

Thomas Jefferson, the third President of the US, was explicitly against protection of patents when he had said: 'Knowledge is like a candle – as it lights another candle, light of the original candle is not diminished' (cited in Stiglitz 2006, p. 108). Similarly, Posner (2002), a distinguished judge on the U.S. Court of Appeals for the Seventh Circuit, also holds that the use of intellectual property by one person does not reduce the value of its use by another. Knowledge grows when shared and it stops growing when locked away. Monopolising knowledge is considered impediment to free marketing and economic growth. Perhaps that is why the strongest claim against

the concept of patenting came from *The Economist* (1851). 'No possible good can ever come out of patent law, however admirably it may be framed' (cited in Singleton 2006).

The controversy over patenting presents a real dilemma. Arguments of the proponents as well as the opponents of patents have some degree of merit and claims of neither side can be dismissed entirely. On the one hand, patents seem to provide incentives for investments into R&D. On the other hand, patents create monopolies, which is contrary to the concept of free and competitive markets. Machlup, one of the leading economists of the 20th century, acknowledges the validity of arguments on both sides. In his famous review of the patent system, he states:

> If we did not have a patent system, it would be irresponsible, on the basis of the present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of present knowledge, to recommend abolishing it. The last statement refers to a country such as the United States of America -- that's not a small country and not a predominantly non-industrial country, where different ways of argument might well suggest another conclusion. (Machlup 1958, p. 80)

While the controversy over patents in general continues, patents in pharmaceuticals in particular have more significance than in the other industries. For example, the patents in the music industry may raise the cost of entertainment. People can choose to forego the expensive form of entertainment. The effect of foregoing the choice would be minimal. The same cannot be said, however, about the pharmaceutical industry. If a patented medicine becomes so expensive that most patients cannot afford to buy it, this could mean the difference between life and death for the patient. If a large number of people have to go without medicines because of high prices, health outcomes would suffer and patents would become a national problem. Thus, the impact of patents in pharmaceuticals is more far reaching than any other industry and most of the developing countries have recognised this fact, which became the primary driver for the affirmation on flexibilities under the Doha Declaration on the TRIPS Agreement and Public Health in 2001.

2.3.5 Flexibilities under TRIPS

The TRIPS agreement provides flexibilities viewed as 'limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do no

unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the interests of third parties' (Article 30). The rationale of these provisions is to provide low-cost alternatives to originator medicines. The flexibilities such as compulsory licences and parallel imports enable member states the use of a patent without the consent of the right holder. These flexibilities can be used in national emergencies and under other circumstances that render the use necessary.

The conditions, under which the provisions of flexibilities could be used, remained controversial, however, until resolved at the Doha Ministerial Conference in 2001. The Declaration on the TRIPS Agreement and Public Health (generally known as the Doha Declaration) states that:

> ... the TRIPS Agreement does not and should not prevent members from taking measures to protect public health (and) ... We affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all (Paragraph 4)

and

> ... each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles. (Paragraph 5 a)

The Doha Declaration also affirms each member's right to determine its own grounds to make use of the flexibilities. The Declaration also allows members freedom to define what constitutes a national emergency. Useful as they are for countries with a reasonably developed pharmaceutical industry, these flexibilities are no great help for a large number of the least developed countries (LDCs) that have no pharmaceutical industry or insufficient manufacturing capacity to meet their health needs. That this latter group of countries could not make use of these flexibilities is recognised by the Declaration in stating that:

> ... members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002. (Paragraph 6)

The Decision of the WTO made on 30 August 2003 is now known as Article 31*bis*. Under this Article, *any least-developed country* is eligible to import low cost generics from a source other than the originator. The process of such import is significantly complex and highly time-consuming. Klein's (2003) description is perhaps most befitting the plight of the poor countries to overcome the complexity of these

provisions when she writes that 'countries wanting to import cheap generics must jump through multiple hoops to prove they are truly in need, unable to afford patented drugs and incapable of producing the medicines domestically' (p. 12). The fear of retaliation as well as the complexity of the process has kept the poor nations away from making use of these provisions. After almost four years of sustained effort, Rwanda became the first country in May 2008 to import generic versions of an on-patent medicine under Article 31*bis*.

Compulsory licensing

A compulsory licence refers to 'an authorisation given by the government for the use by a third party, without the consent of the right-owner of a patent or other intellectual property right' (Correa 2002a, p. 48). While TRIPS does not use the term compulsory licensing, Article 31 refers to 'other use without authorization of the right holder' instead. Compulsory licences can be granted under the circumstances determined by members themselves. However, certain conditions for such use of a patent are stipulated.

The proposed user must have 'made efforts to obtain a voluntary licence from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful *within a reasonable period of time'* (Clause b). This omission of spelling out what a reasonable period of time could cause unnecessary delays as well disputes. The Indian experience shows that some MNCs did not respond at all to requests by domestic manufacturers for a voluntary licence or they deliberately dragged on for years (see for example Chaudhuri 2005). Specificity of maximum period time would have eliminated any eventuality of such problems.

'The right shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization' (Clause h). The term adequate is not defined in the TRIPS agreement. This omission is also likely to cause contradictions and disputes. This is because different regimes place different values on what constitutes adequate. Under the previous patent regime, India had a ceiling of 4 per cent on royalties paid to the patentee under compulsory licensing. By

comparison, these royalties were capped at 40 per cent in the UK, while there was no maximum limit on royalties in the US (Koshy 1995).

Parallel imports

Parallel imports or parallel trade refer to arbitrage of movement of genuine originator products from a low-priced country to a high-priced country without the consent the right holder. The principle of parallel imports was extensively developed in the framework for European integration (Correa 2002a). To avoid market fragmentation, the European Court of Justice later extended this principle to the entire common market. According to Scherer and Watal (2001), certain conditions have to exist for parallel trade to occur. There must be underlying monopoly power and/or market imperfections. The originator company exploits the patent through a strategy of price discrimination, suggest Scherer and Watal. In other words, both countries have the same product sold at different prices. The term parallel imports must not be mistaken for importing low cost generics. It explicitly refers to moving commercial quantities of originator products to take advantage of a price difference.

The question is whether moving a patented product to another country constitutes an infringement of the rights of the holder. The TRIPS agreement is silent on it and states 'nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights' (Article 6). Correa (2002a) however suggests that this silence in the Article is a recognition of the 'possibility of legally admitting parallel imports, based on the principle of exhaustion of rights' (p. 43). Parallel imports are justified applying the doctrine of exhaustion to intellectual property. Experts argue that unless explicitly notified, the sale of a patented product gives the purchaser 'all the normal rights of an owner, including the right to resell' (Cornish 1989, p. 200). Under the US law, the doctrine of exhaustion is known as the 'first sale doctrine' (Yusuf & Moncayo von Hase 1992).

The Doha Declaration addresses the issue of parallel imports to a certain extent, but does not explicitly define the exhaustion of rights. Again the Doha Declaration grants members the freedom to customise their regime to suit their national circumstances. The Declaration states that:

> ... the effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4. (Paragraph 5(d))

Parallel imports do not affect the manufacturer's overall global sale by volume. However, they do reduce the global revenue of the company. This is because the company sells more products in the low-priced country and arbitrageur capitalises on the price difference by moving them for sale in a high-priced country. Parallel imports of pharmaceuticals are common within the EU countries. Brand medicines sold in Portugal and Spain are often moved for resale in France, Germany or the UK. In 2006, parallel imports constituted 15.2 per cent of sales in Denmark, 14.7 per cent in UK, 13.3 per cent in Sweden, and 10.4 in Netherlands. In other EU-countries, the share of parallel trade was less than 10 per cent of sales. In all, parallel trade was estimated at €4.3 billion in 2006 (EFPIA 2008).

Other flexibilities

Other flexibilities available include use for the purpose of experimental research, and for the so-called Bolar exemption. The use for the former allows inventing around and improvement on the patented product. The latter allows testing of generics to establish the bio-equivalency to a patented product in order to obtain marketing approval. This facilitates timely launch of generics on patent expiry. While the US, Canada and Australia have incorporated these exemptions into their framework, other countries had doubts whether such exemption would be consistent with the TRIPS obligations. The consistency of the 'Bolar exemption' with TRIPS was examined by the Dispute Settlement Body (DSB) in a case between Canada and the European countries. In 1998, the European communities and their members requested the WTO to examine the application of Bolar provisions in the Canadian Patent Act with regards to Canada's obligations under TRIPS. In 2000, the DSB panel concluded that Canada's law was consistent with TRIPS in allowing the development and submission of information on bio-equivalency in order to obtain marketing approval for patented products without the consent of right holder. However, Canada's practice of allowing the manufacture and stockpiling of generics during the last 6 months immediately prior to the patent term was not consistent with the TRIPS obligations (WTO 2000).

While this ruling makes it clear that the Bolar exemption is in fact, consistent with TRIPS, only a handful of developing countries, such as Argentina, Israel, Thailand have included them in their regimes (Correa 2002a). The Doha Declaration also makes it clear that compulsory licensing and parallel imports are TRIPS compliant. Yet, a large number of developing countries have either not considered these options or various bilateral or regional agreements have forced these countries to forfeit their right to exercise these options (discussed later in the chapter).

2.3.6 Protection of submitted data

This issue involves protection of test data for establishing efficacy and safety of a product submitted to relevant authorities for obtaining marketing approval. The generation of such data requires extensive testing of medicines on thousands of subjects over several years at substantial costs. Manufacturers of originator products submit this data seeking marketing approvals. A large number of countries, developing and developed alike, allow generics manufacturers to submit data proving bioequivalence to the originator product for granting marketing approval for follow up products. In the US for example, the Patent Term Restoration Act (1984) or more popularly known as the Hatch-Waxman Act permits testing of medicines to determine the bio-equivalency of a generic drug to a patented product. A submission of an *Abbreviated* New Drug Application (ANDA) calls upon authorities to rely on the originator data submitted for safety and efficacy.

Two different terminologies are used for the protection of the submitted data; namely data protection and data exclusivity. *Data protection* relates to unrestricted reliance by authorities on the submitted data for subsequent product approvals. This data however must not be disclosed to third party users. *Data exclusivity* refers to confidentiality of the regulatory file submitted to regulatory authorities for a specific period (Morag-Sela et al. 2004). Data exclusivity prohibits authorities for a specified period from relying on the originator data for the approval of subsequent products. This form of exclusivity effectively delays the development and market approval of generics. In the absence of provisions for reliance on the originator data, generic manufacturers would have to conduct their own clinical trials to establish the safety and efficacy. The repeat of such trials is not only unnecessary and expensive; it takes a few years to

complete. Drahos et al. (2004) doubt if ethical standards committees would approve a repeat of such studies putting patients at risk to provide data that are already known. For doing so would contravene the basic international standards of human research ethics (see Chapter 5 for detailed discussion).

The US provides data exclusivity for a period of 5 years. The EU's pharmaceutical legislation introduced comprehensive reforms in 2004. Since then, the EU provides data exclusivity for 8+2+1 years meaning the following. Generic manufacturers may apply for market approvals 8 years after an originator product first enters the market. But the actual market entry of generics will only be allowed after 10 years of the launch of the originator product. If new therapeutic indications (new uses) on the originator products are authorised, data exclusivity may be extended by another year (EurActiv 2005). Less developed countries prefer data protection as compared to data exclusivity. New economies within the EU, such as Poland and Hungary have requested a 15-year transition period for introducing data exclusivity. On this account alone, the standard of protection in the EU is significantly higher than that in the US.

While the TRIPS agreement does not explicitly mention the word *data exclusivity*, the Agreement is also vague in defining its position on the protection of the submitted data. Article 39.3 of TRIPS states that:

> ... Members, when requiring ... the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use. (Article 39.3)

The Article is not clear in its intentions on at least two accounts. First, the Article does not spell out how the data is to be protected. It leaves open to questioning that if the authorities can rely on the data to approve subsequent products without disclosing the data to third parties. Second, a definition of 'unfair commercial use' is not provided in the TRIPS agreement. These ambiguities in the Article have resulted in controversial interpretations by different parties with vested interests. Originator companies and their representative associations, such as the PhRMA argue that the provisions of the Article refer to data exclusivity. They contend that under Article 39.3, the authorities can not rely on the submitted data for subsequent approval during the patent term. Developing countries supported by public health advocates, NGOs and civic society

groups argue that TRIPS obligations amount to data protection and not to data exclusivity. After an intense public debate however, India is preparing to modify its Patent Act to provide data exclusivity for five years counted from the first market approval granted anywhere in the world. A significant number of poor countries also provide data exclusivity under obligations of their bilateral and/or regional agreements.

2.3.7 Other Articles of importance

A number of Articles are of particular interest with regards to our later discussions. Article 7 states the objectives of the TRIPS agreement as:

> ... The protection and enforcement of intellectual property right should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and uses of technological knowledge and in a manner conducive to social and economic welfare, and to balance of rights and obligations. (p .323)

Article 8 states the principles of the Agreement. It states that:

> ... Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. (p. 323)

These two Articles are fundamental to the development of the TRIPS agreement and provide the developing countries what Correa (2002b) calls sufficient manoeuvrability, as these countries may amend their regimes to incorporate their unique requirements for economic and technology development and to meet their public health needs. The objectives of the TRIPS agreement are clearly stated to contribute to the mutual advantage of *producers and users...conducive to social and economic welfare, and to balance of rights and obligations.* In accordance with Article 8, members may *adopt measures necessary to protect public health and nutrition.*

The TRIPS agreement obliges member countries to:

> ... provide for criminal procedure and penalties to applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of corresponding gravity ... Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale. (Article 61)

Although the TRIPS agreement mentions the need for balancing the rights and obligations of producers and users, the Agreement clearly favours the producers. It mandates member countries to introduce criminal procedures to protect the interests of the patent holders. But the Agreement has no provisions to deter the patent holders from abusing their intellectual property rights. It does not balance the rights and obligations of producers and users of knowledge. As Zutshi (1998) notes 'consistency is not a virtue practiced by nations, particularly in trade negotiations' (p. 44).

Under the provisions of Article 71, the TRIPS agreement is supposed to be reviewed every two years starting from 1 January 2005. The first opportunity for such a review was in 2007, but was not availed of by any country. The next opportunity will come in 2009 and we suggest that the leading developing countries like India, China and Brazil need to push for a review this year. The European Commission (2008)[2] has already identified the problem of excessive patenting by the drug companies as one issue for the agenda for such a review. We suggest additionally that similar to the provisions of Article 61 of TRIPS, the next review should include provisions for criminal procedures and penalties to be applied for excessive patenting. In any case, developing countries should consider amendments to introduce similar provisions to hold the top officials of companies accountable for excessive patenting. This type of deterrent would be a *measure necessary to protect public health.* The suggested measure is by no means anti-innovation. The suggestion needs to be seen in the right context to appreciate its intentions.

2.4 TRIPS-plus provisions

It was noted above that in recent years several countries have introduced patent protection provisions (known in the literature as TRIPS-Plus provisions) that are even more stringent than the one discussed above as part of the TRIPS Agreement. This section considers TRIPS-plus provisions and their implications for access to medicines. The US and some of the European countries have increasingly employed strategies, as part of bilateral and free trade agreements, to raise to TRIPS-plus standards the level of protection in developing countries. The US alone has bilateral

[2] Pharmaceutical sector inquiry: Preliminary report submitted on 28 November 2008 found up to 1,300 patents filed EU-wide on a single medicine. We have termed this act as *excessive patenting*.

agreements on intellectual property with more than 100 countries (Mayne 2005). A comprehensive report on the TRIPS-plus conditions is beyond the scope of this study. However, a brief summary based on Fink and Reichenmiller (2005) and Mayne (2005) is outlined in Table 2.3 and discussed below.

Table 2.3: TRIPS-plus conditions in select US Free Trade Agreements (FTAs)

Condition	Detail	Country/region with the US FTA
Protection period beyond TRIPS	Offset delays in marketing approvals and/or granting patents	US-Australia, US-Chile, US-Morocco, US-Singapore, US-DR-CAFTA
Ever-greening	New uses of known products	US-Australia, US-Bahrain, US-Morocco
Data exclusivity	Not less than 5 years	All US FTAs
Compulsory licensing	Restricted to emergencies only	US-Australia, US-Jordan, US-Singapore, US-Vietnam
Parallel imports		US-Australia, US-Morocco, US-Singapore

Source: Based on Mayne (2005) and Fink and Reichenmiller (2005).

Under the bilateral free trade agreements between the US and Australia, US-Chile, US-Morocco, US-Singapore, and US-DR-CAFTA (Dominican Republic and the Central American States of Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua), patent period can be extended beyond 20-years for delays in granting marketing approvals and/or patents. Extending the protection period adds to the monopoly period of the patent holder. Whether the protection period is extended due to a delay in marketing approval, granting patents or for new found uses of an existing product (ever-greening), the end effect is the same. This delays the entry of low cost generics affecting access to medicines. Data exclusivity indirectly bars generics for the stated period. The US-Jordan FTA calls for the same period of data exclusivity as the originator's country. This period varies from 5 years in the US to 10 years in most EU countries. The US-Oman FTA provides 5-years exclusivity on pharmaceuticals and 10-years on agricultural chemicals. The US-Morocco and US-Bahrain FTAs, provide a period of three years of data exclusivity for new clinical information (new use of known products). This is another tool for ever-greening built into these agreements.

Provisions contained in the selected bilateral agreements limit the ability of governments to issue compulsory licensing. The US agreements with Australia, Jordan, Singapore, and Vietnam restrict compulsory licensing to emergency situations, the trust remedies and public non-commercial use. All agreements, except the US-Vietnam and US-Jordan FTAs, prevent marketing approval of generics during

the protection period without the consent of the patent holder. This effectively renders compulsory licensing futile in those countries, including Australia and Oman. The US-Morocco FTA does not explicitly prohibit compulsory licensing. However, the FTA bars the generics manufacturers from relying on the originator data during the period of data exclusivity (Weissman 2004). It is ironic that 'the United States frequently takes advantage of compulsory licensing, but the US is negotiating trade agreements that significantly limit developing countries' ability to employ this vital policy tool' (Scherer, I 2004). Some countries have refused to sign agreements limiting the use of compulsory licensing, but according to Correa (2002a), they face the threat of bilateral retaliations or suspension of aid by the developed countries.

Under the US FTAs with Bahrain, Chile, DR-CAFTA, Jordan and Vietnam, TRIPS standards would apply for parallel imports. Nevertheless, the FTAs with Australia, Morocco and Singapore stipulate that patentees may limit parallel imports through licensing contracts. This means that consent of the patentee may be required before importing. Moreover, placing a limit on what quantities can be imported favours the patent holders at the expense of consumers. Because the lower the import quantity, the less feasibility of arbitrage, and the higher the cost for the consumers.

2.4.1 Implications of TRIPS-plus for developing countries

TRIPS-plus conditions exist in developing countries as a consequence of them signing agreements to forfeit or restrict their right to use the flexibilities TRIPS provides. A recent study highlights the implications of such forfeiture for developing countries. Malhotra and Grewal (2008) examine 15 bilateral and regional agreements involving the US or the EU and developing countries. These agreements leave little or no room for developing countries to make use of the flexibilities provided under TRIPS. For example, their analysis of the US-Sri Lanka agreement on intellectual property (IP) shows the veracity of the US intent to ensure these countries are deprived of the opportunity to intervene if and when the need arises. The Sri Lankan agreement limits the issue of compulsory licensing to the three situations specified below:

8. if *adjudicated* violation of competition law occurred;
9. *during existence* of a *declared* emergency; and
10. to enable compliance with national air pollution standards.

A full discussion on the above conditions in legal terms is beyond the scope of this work; however, the first two points are briefly discussed below:

Under the first condition, the insertion of the word *adjudicated* means that a judgement would have to be pronounced by a court of law declaring that there has been a violation of the competition law. Compulsory licences are issued because there is an immediate need for the medicine. The court cases and appeals processes take years to come to a final judgement. Thus, proving occurrence of *adjudicated violation of competition law* effectively defeats the whole purpose of compulsory licensing.

The second condition is even more rigid than the first one. The second condition has three words, *during*, *existence* and *declared* inserted. This literally means that the Sri Lankan government must have *declared* a state of emergency and only *during* the *existence* of this catastrophic event could compulsory licensing be issued. Once that condition no longer exists, compulsory licensing would be revoked, because it not *during* the *existence*. The following example explains why this condition has graver consequences than the first one.

In fear of the bird-flu pandemic, a large number of countries, including Australia were stockpiling Tamiflu in the early 2000s. This was the most trusted drug at the time believed to fight the H5N1 bird-flu virus. Tamiflu was developed by Gilead, a US based research firm, which licensed the drug out to Roche for marketing. Because of the huge demand from around the globe against a limited production, the drug was priced significantly high. Under conditions of the agreement, Sri Lanka could not issue a compulsory licence to a third party in anticipation of the pandemic, because it was not *during* the pandemic , and it was not a *declared emergency.*

From the discussions above, it is clear that the US and other developed countries have deliberate strategies to curtail the use of TRIPS flexibilities by developing countries. Regional and bilateral agreements on investment, free trade and other issues trap the poor countries to commit to conditions that jeopardise public health. Developed countries threaten to retaliate if the TRIPS-plus conditions were broken.

Consequently, access to medicines in poor countries has been reduced further than it would have been just under TRIPS obligations.

2.5Conclusions

The WTO is one of the most powerful multilateral institutions today. Unlike GATT, the jurisdiction of the WTO includes trade related aspects of intellectual property rights (TRIPS). The WTO has enforcement mechanism to ensure implementation of its decisions, a power the GATT did not have. The functioning of the WTO also varies from its predecessor insofar that powerful countries like the US no longer have the ability to block an unfavourable decision indefinitely.

The TRIPS agreement stipulates minimum standards for protection of intellectual property. The Agreement has considerably raised the level of protection in developing countries. A large number of developing countries previously did not provide product patents for pharmaceuticals. All member states, except the least developed countries (LDCs), are obliged under the Agreement to provide product as well as process patents for 20 years. This has raised the protection for product patents from 0 to 20 years in a large number of developing countries. The least developed countries have until 2016 to implement the provisions of the Agreement.

The Doha Declaration on TRIPS and Public Health reaffirms member states' rights to protect public health. It emphasises the flexibilities built into the TRIPS agreement available to members should the need arise. Members are free to determine their own grounds to make use of the flexibilities, such as compulsory licensing and parallel imports. Least developed countries with no or insufficient capacity to manufacture pharmaceuticals to meet their own public health needs can import low-cost generics during the protection period. However, the fear of retaliation and the complexity of the process to import keep poor countries away from using these provisions.

The stated objectives of IPRs under the TRIPS agreement include *mutual advantage of producers and users* and *to a balance of rights and obligations*. Yet, the Agreement clearly favours the drug producers. The Agreement obliges members to provide for criminal proceedings with penalties of imprisonment and/or fines for commercial

infringers of copyrights and other intellectual property rights. The Agreement calls for punishing [small] firms/individuals inflicting a monetary damage to the right holder. The Agreement would indeed be balancing the *rights and obligations of producers and users* if it also called for the same kind of treatment for companies for excessive patenting (such as filing up to 1,300 patents on a single medicine). This level of patenting of 'anything and everything' denies access to medicines and has a realistic potential for loss of life. This issue needs to be addressed in the next review of TRIPS. Independent of TRIPS, developing countries need to consider amending their regimes to introduce provisions similar to those of Article 61 of TRIPS and fill this gap.

In recent years, the US and the EU countries have negotiated with developing countries bilateral and regional agreements on free trade, investment and other issues. These agreements have forced developing countries to forfeit their right to use flexibilities provided under TRIPS raising the protection standards to TRIPS-plus level. Poor countries, but also countries like Singapore and Australia, are unable to make full use of the flexibilities provided under TRIPS. Consequently, public health in those countries may be jeopardised.

Chapter 3

The Global Pharmaceutical Industry and Developing New Drugs

3.1 Introduction

The previous chapter considered the protection of intellectual property rights under the TRIPS agreement, particularly the patents on products and processes in pharmaceuticals. These patents have implications for access to medicines in the developing countries. This chapter aims to examine the role of the global pharmaceutical industry in developing new drugs. With its extensive research and development of new drugs, the pharmaceutical industry has contributed significantly to improving the length and quality of life (Schweitzer 1997). Patents on new drugs secure market exclusivity with a potential for high returns and profits on best selling drugs can be substantial. The pharmaceutical research environment is a high risk/high reward environment, in which, large multinational companies (MNCs) dominate the industry (OECD 2001). Thus, priority-setting by large MNCs determines the direction of pharmaceutical research.

The pharmaceutical industry is highly capital-intensive and research-intensive. Firms in this industry depend significantly on the pipeline of new drugs. The process of discovering and developing new drugs is costly, lengthy and uncertain. In their latest study, DiMasi and Grabowski (2007) estimate the cost of developing a new drug at more than $1.3 billion dollars. However, other studies question this $ figure (see for example Collier (2009), Dukes (2006) and Goozner (2004), see p. 64 for more details). The development process involves testing thousands of compounds for suitability. From the 10,000 compounds tested, around 100 would reach the clinical testing stage, and only 1 would be marketed. According to Gassmann, Reepmeyer and Zedtwitz (2008), only 3 out of 10 products in the market generate revenues to meet or exceed the R&D expenditure. The whole process of drug development from initiation of research to marketing takes 10-12 years.

Despite the significant risk of failures in the R&D, the pharmaceutical industry is very profitable. In fact, the pharmaceutical industry has been the most profitable of all

industries since at least 1960. According to a recent study by the OECD for the 1960-1991 period, the return on equity in the pharmaceutical industry was the highest at 18.4 per cent for the largest 500 industrial companies. This return was more than 50 per cent higher than the corresponding returns in the second ranked telecom sector at 11.9 per cent (OECD 2001). Another study finds that the 'profits on assets of the nine largest pharmaceutical companies were 4 ½ times greater in 2003, than the average profits for the Fortune 500 companies' (Mayne 2005, p. 26). Yet, the industry seems least interested in developing drugs for diseases prevalent in poor countries.

The pharmaceuticals industry sits firmly at the interface of globalisation and health care. Firms in this industry are increasingly either becoming global or are competing with global firms for markets, for capital investment and for skilled workforce. As a part of their globalising strategies, large MNCs are shifting some of the functions to low cost countries saving in costs and tapping into local labour markets. Lacetera (2001) suggests that it is not uncommon for large firms to 'granting stock options and [even] seats on the board of directors, as means to "hold" scientists within the organization for long periods' (p. 45). Small firms struggle to secure venture finance for R&D projects, and also lose out on the skilled workers in high demand. Because small firms simply can not match the remuneration and the perks offered by the MNCs let alone beating them. The globalisation process has opened up traditionally protected markets, in which, MNCs are benefiting at the expense of small domestic firms with virtually no or little gains for the consumers.

The rest of the chapter is set out as follows. Section 3.2 considers the industry structure, its impact on access to medicines and the role of generics in healthcare. Section 3.3 examines the process and the costs of research and development (R&D) in the pharmaceutical industry. Section 3.4 summarises the conclusions of the chapter.

3.2 The industry structure

This section examines the industry structure and its impact on healthcare. The global pharmaceutical industry predominantly has a two-tier structure. First, a small number of large multinational corporations (MNCs) primarily based in the US, Europe and Japan dominates the industry. Within this group, the US dominance is noticeable from

the fact that of the top 15 companies by pharmaceutical sales, around half have their headquarters in the US alone (OECD 2008). The largest 100 MNCs known as the 'big pharma' manufacture and supply nearly 80 per cent of the world's drugs (OECD 2001). These companies are also known as the originator companies for their lead role in developing new drugs. These companies hold most of the pharmaceuticals patents. According to Franz Humer, the Chairman and CEO of F. Hoffman-La Roche, the level of market concentration has significantly increased in the last two decades. The collective market share of the world's top ten companies in the pharmaceutical industry has doubled from 25 per cent in 1985 to 50 per cent 2005 (Humer 2005). In 2006 also, the top ten companies accounted for around half of the global sales (OECD 2008). According to Dukes (2006), this group of companies plays:

> ... only a minor role in most developing countries, especially those at the middle and lower levels of development, where it has confined itself very largely to the sale of its products through local agents to relatively affluent urban populations. (p. 11)

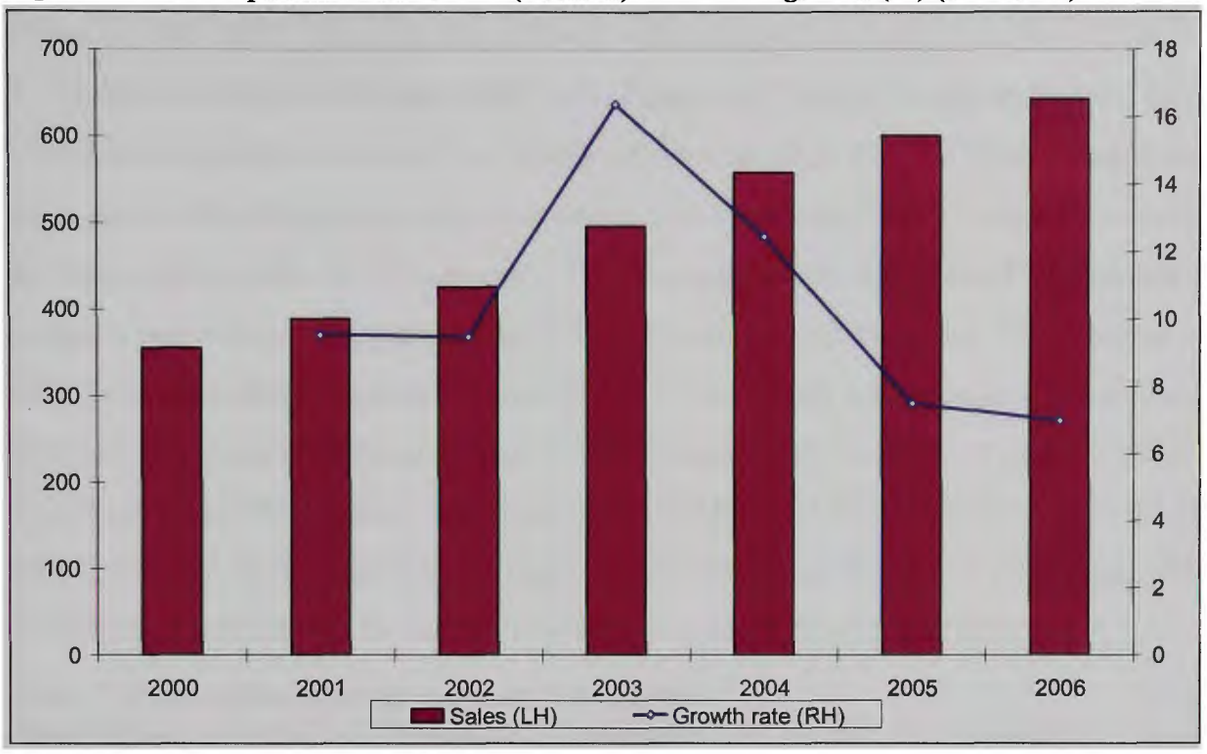
The second group consists of a large number of small to medium enterprises (SMEs) located in developed countries but also in developing countries like China, Brazil, India, Israel and South Africa. This group of companies is classified as generics manufacturers, because generally they do not engage in innovative activities, particularly in basic research. These companies supply off-patent products competing against the MNCs after patent expiry on their innovator product. Some of the SMEs engage in a subservient role to the 'big pharma' in contract research and manufacturing known in the literature as the CRAM activities. The contract research firms form a valuable link in the development of new drugs but undertake only a part of the research process. These firms lack the resources to fully develop new drugs and market them on their own. Other firms in this second tier are the manufacturers of intermediates such as bulk drugs also known as active pharmaceutical ingredients (APIs). Bulk drugs or APIs are the basic ingredient to produce formulations i.e. ready to consume medicines such as capsules, tablets, injectibles, and syrups.

3.2.1 Pharmaceutical sales, companies and profits

The global pharmaceutical sales increased from US$356 billion in 2000 to US$643 billion in 2006 (Medicines Australia 2008). In 2004, the global pharmaceutical sales crossed the half a trillion dollar mark for the first time. The world market growth recorded annually around 9.5 per cent in 2001 and 2002, peaked at 16.4 per cent in

2003, and declined to 12.5 per cent in 2004 (see Figure 3.1). The growth has slowed down to less than 8 per cent since then.

Figure: 3.1: World pharmaceutical sales ($ billion) and annual growth (%) (2000-2006)



Source: Based on Medicines Australia (2008).

According to EFPIA (2008), the US industry accounted for almost 40 per cent of the global sales in 2006. This share suggests that the US industry now clearly leads the global pharmaceutical landscape, a role traditionally played by the European pharmaceutical industry (see Table 3.1). The corresponding share of whole of Europe combined constituted 35.2 per cent, followed by Japan at 9.5 per cent and the rest of the world (ROW) at 16 per cent (EFPIA 2008). India's contribution remains around 1.3 per cent by value and around 8 per cent by volume (Nanda & Khan 2005).

Table 3.1: Global pharmaceutical product (2006)

Country/Region	Share (%)	Share ($ billion)
US	39.3	252.7
Europe	35.2	226.3
Japan	9.5	61
Rest of the World	16	103
Total	100	643

Source: Share based on EFPIA (2008, pp. 15-6) and sales based on Medicines Australia (2008).

Ever-since the discovery of Tagamet, the first blockbuster[3] in 1976, there has been a significant shift in the industry's marketing and growth strategy. These 'blockbusters' are the backbone of large originator company strategies aimed at recouping R&D investments' (European Commission 2008, p. 33). 'Delivering a blockbuster drug is

[3] Product with annual sales of more than a billion dollars.

the Holy Grail for any pharmaceutical company' (Gassmann, Reepmeyer & Zedtwitz 2008, p. ix). This is because blockbusters are the most profitable products yielding six times their average R&D investments and 55 per cent of all new drugs' quasi rents (Scherer, FM 2007). The number of blockbuster drugs increased from 46 in 2000 to 87 in 2004 to 105 in 2006 (see Table 3.2). Figures in Table 3.2 suggest that the total pharmaceutical sales increased by around 80 per cent from 2000 to 2006. During the same period, the share of blockbuster drugs also increased from 23 per cent of total pharmaceutical sales to 36 per cent. The increase in the number of blockbusters suggests more drugs exceeding sales of $1 billion in 2006 than earlier. The increase in the blockbuster share suggests that sales have progressively become more blockbuster oriented and more concentrated than at the beginning of the study. Table 3.2 shows that the average blockbuster sales have increased from $1.79 billion in 2000 to $2.20 billion in 2006. In 4 of the 7 years studied, the average has been over $2 billion. This once again confirms that the industry is becoming more blockbuster oriented.

Table 3.2: Blockbuster drugs and sales (2000-2006)

Year/Category	Total pharmaceutical sales ($ billion)	Blockbuster share (%)	Blockbuster sales ($ billion)	No. of blockbusters	Average blockbuster sales ($ billion)
1	2	3	4=(2*3%)	5	6 =(4/5)
2000	358	23	82.3	46	1.79
2001	386	24	92.6	51	1.82
2002	421	30	126.3	58	2.18
2003	490	29	142.1	70	2.03
2004	545	31	169	87	1.94
2005	601	36	216.4	94	2.30
2006	643	36	231.5	105	2.20

Source: Based on Scrip News (2005e, p. 13), OECD (2008, p. 11), Scott (2006) and Cutler (2007).

According to Gassmann, Reepmeyer and Zedtwitz (2008), 24 companies accounted for marketing the 58 blockbuster drugs in 2002. In 2003, Lipitor became the first 'super blockbuster' or mega blockbuster by annual sales exceeding $10 billion and its sales further increased to more than $13 billion in 2006. In its annual review (2007), Pfizer notes 8 blockbusters (Lipitor, Norvasc, Celebrex, Lyrica, Viagra, Xalatan /Xalacom, Zyrtec/Zyrtec D, and Detrol/Detrol LA) totalling sales of $25.9 billion. The Pfizer review also shows another 5 drugs (Camptosar, Zyvox, Chantix/Champix, Geodon/Zeldox and Genotropin) with sales of between $843 million and $969 million, which could possibly become blockbusters in 2008/2009. Table 3.3 shows the top ten blockbuster drugs with sales in 2006 and the owner companies.

While blockbuster drugs boost company's global sales, these drugs also increase company dependency on such products. For example, Lipitor sales constituted 30 per cent of Pfizer's and Risperdal accounted for 35 per cent of Johnson & Johnson's global sales in 2007 (European Commission 2008). These sales often continue to occur or even rise during the patent period. However, the patent expiry on such a product is likely to have implications for the company. If the company is not ready with a replacement drug, before the patent expires, its revenues as well as its market capitalisation could suffer significantly. In Lipitor's case, Pfizer has been trying to keep competitors out of the market for as long as possible. Ranbaxy, an Indian generics manufacturer and Pfizer have been in litigation with regards to the Lipitor patent in a number of countries. The Lipitor patent is due to expire in 2011/2012 in the US and most of the other developed countries. Torcetrapib, a cholesterol drug was being developed to replace Lipitor upon patent expiry (Bloomberg 2006). In 2006, Pfizer abandoned further testing of torcetrapib for safety reasons. The scale of the significance of this drug can be appreciated from the fact that after Pfizer announced the halt of clinical testing of Torcetrapib, the company's market value fell by $21 billion overnight and 10,000 job cuts followed (Cutler 2007).

Table 3.3: Top ten blockbuster drugs in 2006

	Brand	Indication	Company	Sales ($ million)
1	Lipitor	Hyper-cholestrolemia	Pfizer	13,633
2	Seretide, Advair	Asthma, COPD	GSK	6,618
3	Plavix, Iscover	Thrombosis	Sanofi-Aventis, BMS	6,290
4	Epogen, Procrit	Renal and cancer anemia	Amgen Johnson & Johnson	5,691
5	Nexium	GERD	AstraZeneca	5,182
6	Norvasc	Hypertension	Pfizer	4,866
7	Enbrel	Rheumatoid arthritis	Amgen, Wyeth, Takeda	4,475
8	Risperdal, Consta	Schzophrenia	Johnson & Johnson	4,184
9	Aranesp	Renal and cancer anemia	Amgen	4,121
10	Rituxan, MabThera	B-cell lymphoma	Roche (Biogen)	3,912
	Total of top ten			58,972

Source: Based on Gassmann, Reepmeyer and Zedtwitz (2008, p. 7).

Over the last two decades, mergers and acquisitions (M&A) have significantly reduced the number of companies at the top of the pharmaceutical industry. Danzon Epstein and Nicholson (2007) study the M&A activity of 383 pharmaceutical /biotechnology firms for the 1988-2001 period. They find that large firms merged because of expected excess capacity due to expiry on patents and gaps in a firm's product pipeline. The SMEs primarily used mergers as an exit strategy in response to

financial problems. Danzon Epstein and Nicholson estimate the effects of mergers using a propensity score to control for selection based on observed characteristics. Controlling for merger propensity, they conclude that merged large firms experience a positive change in enterprise value, sales and R&D output. But these firms record slower growth in operating profit compared with firms that did not merge. The foregoing authors also conclude that mergers may be a response to a problem, but they are certainly not a solution.

Pfizer for example ranked 6 with sales of less than $2 billion in 1983 and ten years later its sales increased to over $5 billion (see Table 3.4). In 2003, the sales reached nearly $40 billion making Pfizer the world leader. In the process of growth in the second decade, Pfizer acquired Warner & Lambert for $90 billion in 2000 (Deloitte Recap 2009) and also took over Pharmacia for $60 billion in 2003 (Frank & Hensley 2002). The significance of the latter acquisition is that Lipitor actually belonged to Pharmacia, which has now become the flagship drug for the acquirer. Pfizer's gigantic size can be appreciated from its market capitalisation that now competes directly with economic size of some of the nations. Pfizer ranks 17 ahead of Sweden (19) and well ahead of Singapore (39) (Blech 2006, p. 12).

Table 3.4: Top 10 Pharmaceutical Companies by sales (US$ billion) (1983, 1993, 2003 & 2006)

Rank	1983		1993		2003		2006	
	Company	Sales	Company	Sales	Company	Sales	Company	Sales
1	Hoechst	2.6	Merck & Co	8.8	Pfizer	39.6	Pfizer	46.1
2	Bayer	2.4	Glaxo	8.5	GlaxoSmithKline	30.9	GSK	37
3	Merck & Co	2.4	Bristol-Myers Squibb	6.5	Sanofi-Synthelabo and Aventis combined	26.7	Novartis	31.6
4	American Home Products	2.3	Hoechst	6	Merck & Co	22.5	Sanofi-Aventis	31.1
5	Ciba-Geigy	2.1	Roche	5.3	Johnson & Johnson	19.5	Johnson & Johnson	27.3
6	Pfizer	1.9	SmithKline Beecham	5.2	AstraZeneca	18.4	AstraZeneca	26.7
7	Eli Lilly	1.6	Pfizer	5.1	Novartis	16	Merck & Co	25
8	Abbott	1.6	Ciba- Geigy	5.1	Roche	15.9	Roche	23.5
9	Bristol-Myers	1.5	Sandoz	5	Bristol-Myers Squibb	14.9	Abbott	17.6
10	Roche	1.5	Bayer	4.8	Wyeth	12.6	Amgen	16.1

Source: Scrip Pharma (2004a, 2004b) and Medicines Australia (2008).

According to the media reports in January 2009, Pfizer is negotiating to take over Wyeth for $68 billion. This acquisition, if completed, would place Pfizer at almost an

unchallengeable position. Table 3.4 shows that Wyeth was one of the top ten companies in 2003. Similarly, Novartis reached the top ten companies in 2003 by taking over Ciba-Geigy as well as Sandoz ranked in top ten in 1983 and 1993. Glaxo merged with SmithKline Beecham to form GlaxoSmithKline (GSK). Likewise, the emergence of Bristol-Myers Squib (BMS) can also be attributed to mergers and acquisitions. On the one hand, mergers and acquisitions reduce the number of competitors in the market. On the other hand, they boost sales as well as the market share of the new entity increasing company's market power and profits.

The pharmaceutical industry is the most profitable industry as noted in the introduction. The profitability in the pharmaceutical sector is highlighted by operating margin of most of the top 20 companies (see Table 3.5). In 2004, Pfizer ranked first with more than $21 billion operating profit and a net income of over $11 billion. Had Pfizer not merged, collective profits of the individual companies (Pfizer, Warner Lambert and Pharmacia) would have been even higher (Danzon, PM, Epstein & Nicholson 2007). The Table shows that Merck & Co has close to 60 per cent operating profit margin followed by Pfizer at 40.96 per cent, Takeda at 35.38 per cent and Amgen at 31.73 per cent.

The global pharmaceutical market has registered a significant growth over the last few decades. From 1970 to 2002, the global market grew at an average of 11.1 per cent annually but has slowed down to a rate between 5 per cent and 8 per cent since (Gassmann, Reepmeyer & Zedtwitz 2008). The US is not only the world's largest producer of pharmaceuticals but it is also the largest consumer of pharmaceuticals (see Figure 3.2). According to Mathew and Torreblanca (2005), the US accounted for 43.6 per cent of the global pharmaceutical sales in 2004 and its share further increased to 43.8 per cent in 2007. The EFPIA (2008) estimates the combined share of the European markets at 31.1 per cent and the Japanese at 9.4 per cent share of the global sales in 2007. When these shares are measured against the shares of global production of pharmaceuticals (noted earlier), the US remains a net importer of pharmaceuticals, while the EU is a net exporter.

Table 3.5: Profits of the top 20 companies (2004)

Rank	Company	Net income (US$ million)	Pharma operating profit (US$ million)	Pharma operating profit margin (%)
1	Pfizer	11,361.0	21,510.0	40.96
2	GlaxoSmithKline	8,243.0	10,400.0	26.66
3	Sanofi-Aventis	2,309.0	n/a	n/a
4	Johnson & Johnson	8,509.0	7,608.0	16.07
5	Merck & Co	5,813.4	13,451.5	58.64
6	AstraZeneca	3,813.0	4,770.0	22.26
7	F Hoffman-La Roche	5,851.0	4,910.0	17.43
8	Novartis	5,767.0	5,253.0	18.60
9	Bristol-Myers Squibb	2,388.0	4,257.0	21.97
10	Wyeth	1,234.0	4,040.1	23.28
11	Eli Lilly	1,810.1	2,941.9	21.23
12	Boehringer Ingelheim	1,229.0	n/a	n/a
13	Amgen	2,383.0	3,348.0	31.73
14	Takeda	2,701.2	3,868.7	35.38
15	Abbott	3,235.9	2,459.0	12.49
16	Schering-Plough	-947.0	13.0	0.16
17	Bayer	816.0	408.8	1.01
18	Novo Nordisk	912.1	1,270.0	24.04
19	Eisai	540.4	860.4	16.58
20	Merck KGaA	891.5	528.9	6.67

Source: Charlish (2006, p. 13).

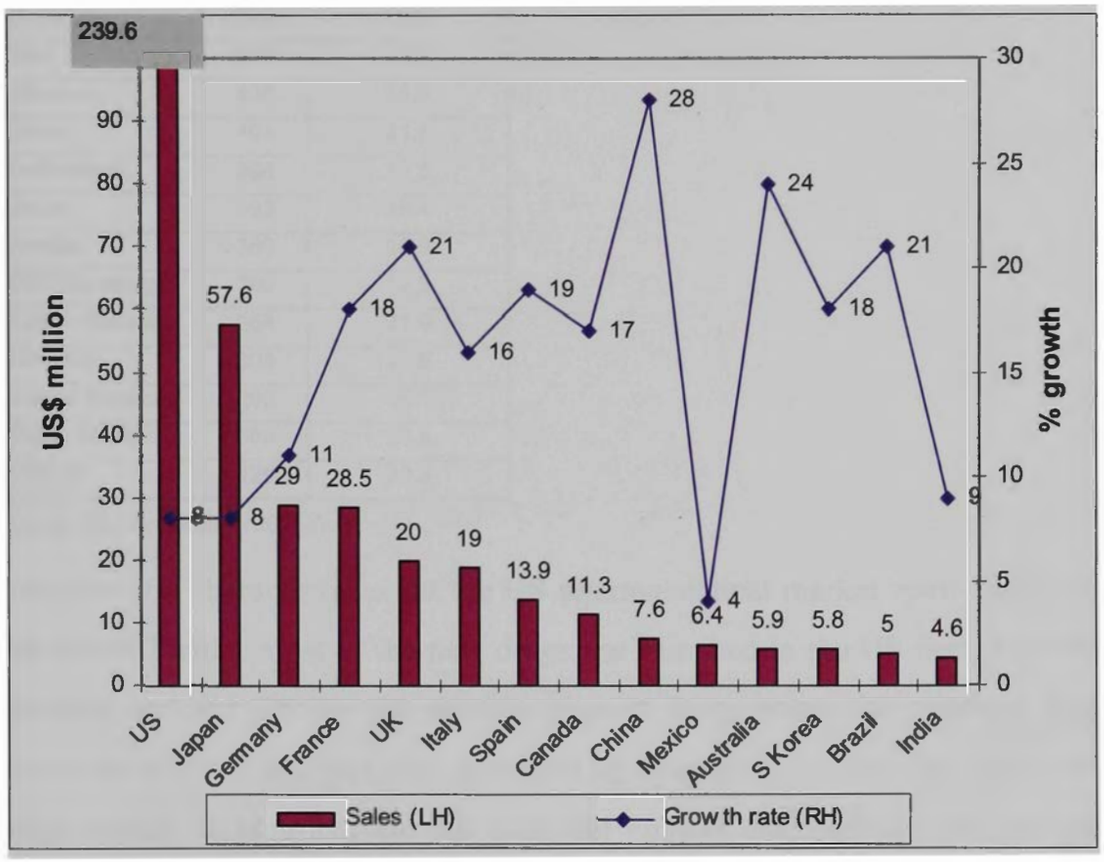
3.2.2 Major pharmaceutical markets, pharmaceutical spending and generics

In the last 20 years, the market dynamics have shifted the global pharmaceutical sales. The top six markets now are the US followed by Japan, Germany, France, UK and Italy. In 2007, nine OECD countries accounted for around 80 per cent of the global sales of pharmaceuticals (OECD 2008). The US share as a percentage of the global sales increased from 28 per cent in 1987 to almost 44 per cent in 2004. The corresponding share of the Japanese dropped from more than 21 per cent to 11 per cent in the same period, while the share of the European market also declined from over 40 per cent to around 30 per cent (EFPIA 2006; Lewis, Class & Edery 2005).

The higher growth rate in smaller markets is likely to again shift the global sales over the next decade. For example, China recorded the highest annual growth (28 per cent) in sales for 2004, while Australia (24 per cent), Brazil and the UK (21 per cent) also grew significantly (see Figure 3.2). The US and Japan had a relatively moderate growth. But in absolute terms, the total of even this moderate growth in both markets added more than the collective sales of Australia, South Korea, Brazil and India. In

2007, the pharmaceutical market in Asia grew at 13.1 per cent, in Europe at 6.7 per cent and in the US at 4.2 per cent (EFPIA 2008). This growth rate if continued in Asia is likely to enlarge the Asian markets significantly. However, in the wake of the financial meltdown in 2008, the Asian growth rate is likely to slow down, while the true nature of growth remains unpredictable.

Figure 3.2: Leading pharmaceutical markets by sales (US$ million) and growth rate (2004)



Source: Based on Mathew & Torreblanca (2005, p. 47).

One of the major reasons for such a huge size of the US pharmaceutical market is its pharmaceutical expenditure per capita. According to The Economist (2005b), the US spent $728 per capita on pharmaceuticals accounting for 12.9 per cent of the total health expenditure in 2003. Sager and Socolar (2006) estimate the US health expenditure per capita in 2006 to be at $7,256. If the pharmaceutical expenditure as a share of the health expenditure remained constant at 12.9 per cent in 2006, it would translate into $936 being spent on drugs for each person living in the US. Table 3.6 shows that except France and Canada, all other countries spending less than $500 on pharmaceuticals per capita. The per capita spending on pharmaceuticals in France and Canada is estimated at $606 and $507 respectively. Pharmaceutical expenditure as a share of total health expenditure in the US is lower than the OECD average, but this share is particularly high in the former Eastern Block countries.

Table 3.6: Pharmaceutical expenditure per capita in selected OECD countries (2003)

Country	US$	Pharmaceuticals as a percentage of total health expenditure
US	728	12.9
France	606	20.9
Canada	507	16.9
Italy	498	22.1
Germany	436	14.6
Spain	401	21.8
Switzerland	398	10.5
Japan	393	18.4
Austria	389	16.9
OCED average	380	17.5
Czech Republic	284	21.9
Hungary	308	27.6
Slovak Republic	299	38.5
South Korea	309	28.8
Poland	225	30.3

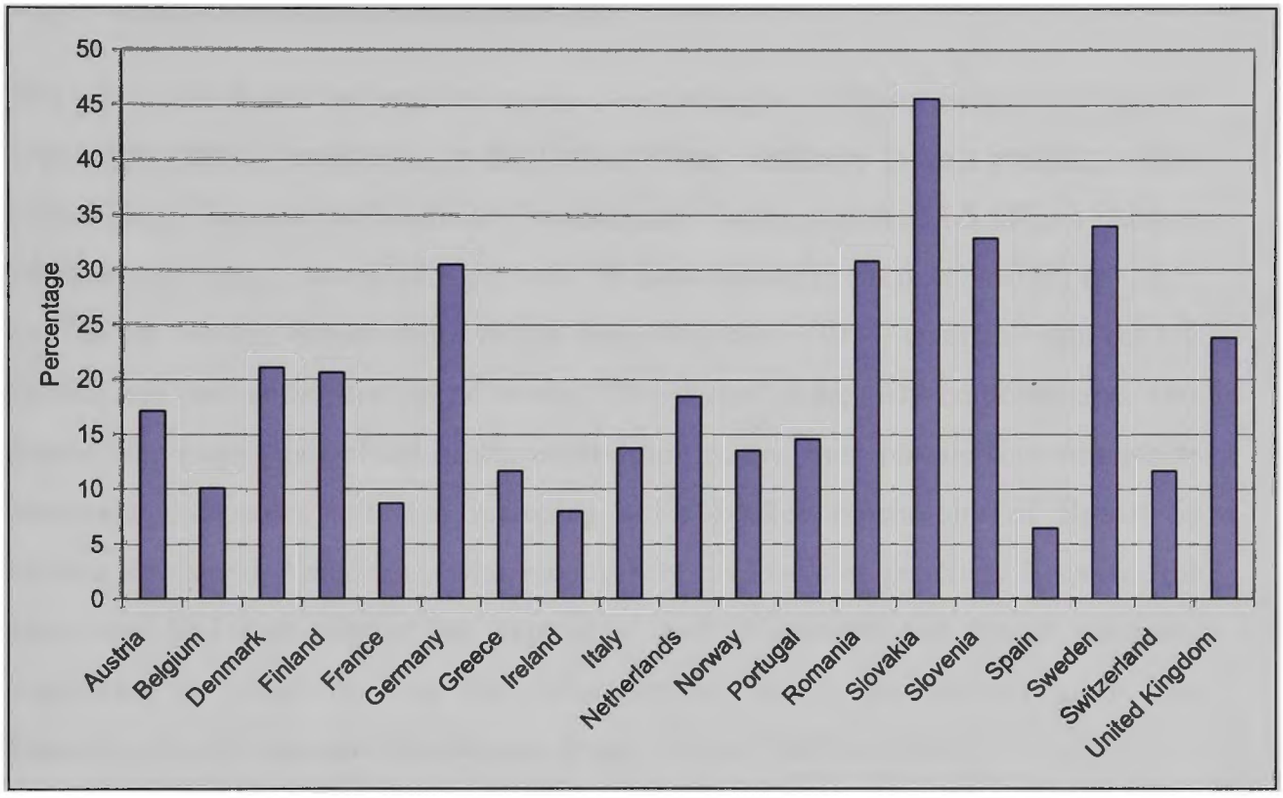
Source: *The Economist* (2005b).

Two specific characteristics set the US pharmaceutical market apart from the rest of the world. Firstly, most of the new drugs are launched in the US first. New drugs are patented and the US has the world's highest drugs prices for patented drugs. The European markets are generally governed by drug price controls and universal health programmes. In contrast, the US does not control drugs prices and provides only limited healthcare programmes such as Medicaid and Medicare covering specific segments of the population. This factor pushes the pharmaceutical spending per capita upwards in the US. According to IMS data, 65 per cent of sales of new drugs marketed since 2002 are generated in the US compared with 24 per cent in the EU (cited in EFPIA 2008, p. 5).

Secondly, generics in the US are low priced relative to other countries and generics constitute a significant share of the US market. The share of generics by volume increased from 51 per cent in 2000 to 67 per cent in 2007 in the US (PhRMA 2008b). The PhRMA deliberately uses the word *sales* (instead of volume) to exaggerate the share of generics. The word *sales* is usually associated with the dollar value, which in the case of PhRMA's description of share of generics is misleading. To put into the right perspective, in the 12 months to June 2005, generics accounted for 60 per cent of

total prescriptions in the US but constituted just 12 per cent of the total *sales*. In dollar value, this share represented $21.5 billion of the $179 billion pharmacy sales for the period (Genepharm 2005). Globally, generics accounted for 14 per cent of the sales value in 2007 (OECD 2008). In Australia, the generics share was estimated at 17.9 per cent of the Pharmaceutical Benefits Scheme (PBS) expenditure (Sweeny 2008). Across European countries, the share of generics varies from a low of just 6.4 per cent in Spain to as high as 45.6 peer cent in Slovakia (see Figure 3.3).

Figure 3.3: Share of generics by sales value in EU countries (2006)



Source: EFPIA (2008, p. 18).

While most of the developed countries have some form of universal health insurance programmes, the generics as a share of pharmaceutical sales varies significantly across countries shown in Figure 3.3. Generally, countries with a well developed pharmaceutical industry tend to have lower share of generics (see for example Switzerland and France). These countries have policies in place to support the innovative industry and discourage the use of generics. Countries with relatively less developed industry tend to have high share of generics (e.g. Slovakia). However, some exceptions to this rule can be observed. Figure 3.3 shows that share of generics in the UK and Germany is 23.8 per cent and 30.5 respectively and we know that both countries have one of the most advanced pharmaceutical industries.

Governments are increasingly faced with rising healthcare costs and containing which have become an essential part of future public policy debates. The problem of rising healthcare costs is acknowledged by industry leaders. For example, Richard Clark, President and CEO of Merck is also the Chairman of the Pharmaceutical Research and Manufacturers of America (PhRMA). In the *Annual Report* (2008) of the PhRMA his message as the chairman reads:

> ... Rapidly growing health costs globally are creating even greater pressures on utilization and payment and reimbursement systems. The pressure to control overall health care costs is real even though pharmaceutical costs are being targeted by critics well beyond their actual contribution to rising healthcare costs. (p. 2)

The US is also facing the healthcare issue. According to Professor Scherer of Harvard University (2007), 'healthcare in the United States continues to be a pressing public policy issue' because the healthcare expenditures 'surpassed the $1.5 trillion mark in 2002, comprising a record 14.9 per cent of gross domestic product' (GDP) (p. 267). Dr. Phillip Brown, former editor of the Scrip Magazine (2004) estimates that the US federal and state authorities spend around 7.5 per cent of the GDP on healthcare. This means that almost half of the health expenditure comes from private sources such as insurance companies but also including out-of-pocket expenditure of almost 50 million uninsured Americans, who mostly rely on low cost generics. Because 'the uninsured find many drugs too expensive' and 'if current cost trends continue, Americans are likely to lose their tolerance for paying substantially more than Canadians do for the same brand-name drugs' (Cutler 2007, p. 1292).

It is well known in the literature that the generics entry in the US market coincides with prices on average 50-60 per cent below the price charged for the originator product. The drop in price is gradual and dependent on the number of generics entering the market. First generic entrant in the US generally gets six months market exclusivity. Thus, there is little incentive for a significant drop in price. However, when more generics enter the market, the price declines rapidly. According to the Generic Handbook (2007), 'the average retail price for a generic prescription in 2005 was $29.82, or 29.3 per cent of the $101.71 branded drug average' (p. 21). When the patent of Ciprofloxacin expired for example, generics entry forced a price drop of over 90 per cent in the US (Kamath 2004). If the price of generics did not drop significantly as it currently does, the total health expenditure in the US would rise

substantially. In that case, the pharmaceutical spending per capita would be much higher than the current level.

The European Commission (2008) suggests that in the EU, generics first enter the market at a price on average 25 per cent lower than the originator price. Two years later, the generics price falls on average to 40 per cent below the originator price. Generics typically capture around 30 per cent of the volume sold at the end of the first year and 45 per cent after two years.

By comparison, generics in Australia are technically priced at the same level as the originator price even after patent expiry. If a generic product enters at a lower price than the originator, the government simply reduces the base price of the originator. Consumers wishing to purchase the originator product pay a brand premium. Thus, there are no real incentives to offer low prices on generics in countries with healthcare programmes such as Australia's Pharmaceutical Benefits Scheme (PBS). However, Government of Australia (2007b) and Lofgren (2007) suggest that recent policy initiatives have been aimed at reducing the price paid for generics. In 2005, Australia introduced a mandatory discount pricing of 12.5 per cent on the launch of the first alternative brand of an already PBS-listed drug; however, with substantial incentives offered to pharmacists, around 40 per cent of prescriptions are dispensed with a brand premium, even when a generic alternative is available (Lofgren 2007).

Under the changes initiated in 2007, PBS-listed items would be divided into Formulary 1 (F1) and Formulary 2 (F2). Medicines, for which only a single brand is listed on the PBS (mainly patented drugs) or have just one supplier, would be placed under F1. Medicines with multi-brands would come under F2 category, which is further divided into two sub-groups. Category F2A would list medicines with low price competition. Commencing on 1 August 2008, prices for medicines under F2A will be annually reduced by 2 per cent for 3 years. This is in addition to the 12.5 per cent discount for the first alternative brand noted above. From August 2007, suppliers listing of a new brand must also agree to disclose the actual market price as a pre-condition to listing. Category F2T would list medicines where price competition is high. Medicines listed under F2T will be subject to a one off mandatory price reduction of 25 per cent. The 12.5 per cent discounted price will also apply where

relevant. Price reductions for medicines listed under F2T flow on to all brands, strengths and forms of all medicines to which that medicine is interchangeable (Government of Australia 2007b).

Sweeny (2008) studies the impact of price changes in Australia after patent expiry of 103 medicines from August 1991 to July 2005. Different formulations of medicines have different patent expiries. During Sweeny's study, a total of 112 patents expired on medicines. He uses 'the Commonwealth price to pharmacist divided by the manufacturer's pack size because it provides the clearest picture of trends in prices' (Sweeny 2008, p. 112). Of all the medicines studied, only 46 (or 41 per cent) attracted competing brands for at least one of the forms of the medicines. Sweeny also finds that 17 of the medicines registered either price increases, or no changes or insignificant decreases in price despite the competing brands being present in the market. For example, patent on Aciclovir expired in September in 1995. Under an arrangement with GSK, the originator, Arrow Pharmaceuticals and Alphapharm had their products listed prior to the patent expiry but they did not drop the price. The first and second decrease in price of mere 3 per cent each time occurred in August 1999 and February 2003, possibly following the market entry of Douglas Pharmaceuticals, Genepharm and Hexal Australia.

Generics play a vital role in the provision of healthcare, the level of their contribution depends upon a country's framework regulating the healthcare industry. Generics constitute around two thirds of the US market, but account for less than 15 per cent of the global sales. The generics share varies significantly across the EU countries. Generics are priced significantly low relative to the originator price in the US. But the same difference is not observed in markets such as Australia.

3.3 Developing new drugs

This section examines the development of new drugs. According to the European Commission (2008), the life cycle of a new medicine consists of three distinct stages. Stage 1 involves from research and development to market launch. Stage 2 is the period between market launch and patent expiry. Stage 3 is the period following the loss of market exclusivity, when generics can enter the market. Stage 3 has in part

been considered above. Stage 2 is the core topic of this thesis and discussed throughout the thesis. Stage 1 is discussed hereunder.

It is well established that the drug development process involves significant investments, technical know-how and takes several years to complete the process. In recent years, investments into pharmaceutical R&D have grown much faster in the US than in the EU suggesting a shift in the R&D base. The EFPIA (2008) notes that between 1990 and 2007, the R&D investments increased by 330 per cent in the EU compared with an 520 per cent increase in the US. The EU has been a traditional leader in pharmaceutical innovative activities. This shift has implications for the EU as well as for the Japanese industry as the following study shows.

A recent study examines new chemical or biological entities developed over a 20-year period in the leading regions. The EFPIA (2008) study divides the period into four 5-year sub-periods (see Table 3.7). In the first sub-period, the EU introduced 97 new entities (drugs) followed by Japan with 63. The US ranked third with 52 entities and the rest of the world (ROW) could manage just 5 new entities. In the second sub-period, the EU still led with 90 followed by the US with 66. The Japanese contribution declined significantly to 61 with ROW at 6. In the third sub-period, the US overtook Europe's leadership in developing new drugs. In the final sub-period, the US retained the top spot but productivity in all regions, except the ROW, declined. The ROW output more than tripled the number of new entities over the previous sub-period. At the same time, the Japanese output declined significantly.

Table 3.7: New chemical or biological entities developed (1990-2004)

Region	1988-1992	1993-1997	1998-2004	2003-2007
US	52	66	77	66
Europe	97	90	68	48
Japan	63	61	29	15
ROW	5	6	4	15
Total	217	223	178	144

Source: Based on Scrip News (2005b, p. 3) and EFPIA (2008, p. 24).

The US is appreciated as the leading pharmaceutical market, especially for the sale of new drugs because the US allows high drug prices. The US is tolerated as the lead manufacturer of pharmaceuticals, while this trend might not last long as this function

is shifting[4] to low-cost countries. However, shifting the R&D base to the US has become a worrisome factor for the Europeans. A recent study by Gambardella, Orsenigo and Pammolli (2000) for the European Commission notes:

> ... In particular, the observed concentration of research and innovation in the USA is worrying because Europe risks to be relegated into the fringe of the industry, surviving and even thriving through imitation, generics, marketing, but giving up a large share of the value added and becoming dependent on the USA for the development of new products. (p. 66)

Historically, the Europeans Germany, Switzerland, and the United Kingdom in particular have been the leaders in the development of new drugs. While the EU's stringent patent regime supports innovation, the US offers incentives such as research funding through the National Institutes of Health (NIH) that attracts investors to the US. Should there be a change in the pharmaceutical pricing principles in the US, which is likely following President Obama's recent election, the attractiveness to shift the R&D base to the US might decline. According to Professor Cutler of Harvard University, high drug prices that the US has and the differences in drug prices that currently exist between the US and other major markets especially Canada, are not sustainable in the long run (Cutler 2007). Currently, high prices in the US offer to yield high returns on R&D investments. This incentive is likely to be affected by any changes to the drug pricing mechanism.

3.3.1 The process of drug development

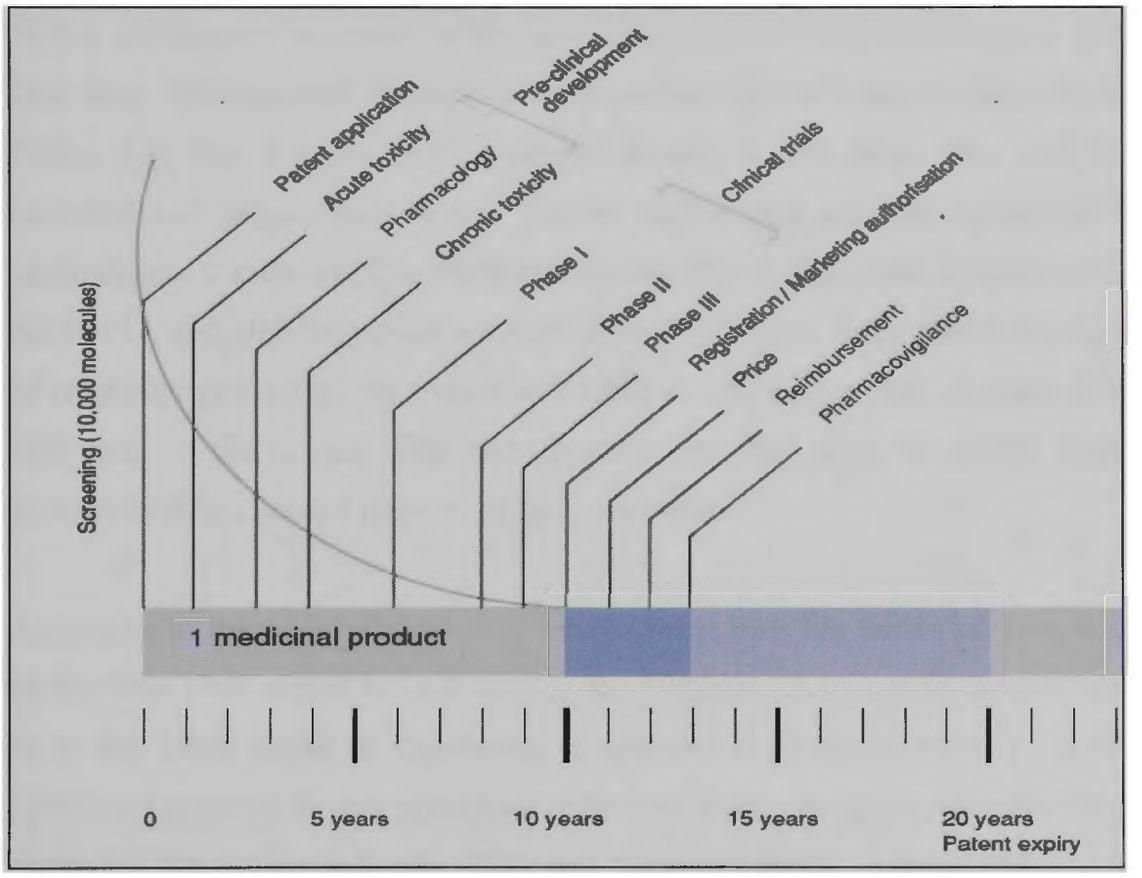
The process of developing drugs involves a number of stages at which candidates (also labelled substances, compounds, molecules) are tested for safety and efficacy. A recent study by the European Federation of Pharmaceutical Industries and Associations (EFPIA) suggests that the drug development begins with the screening of around 10,000 candidates (EFPIA 2008). The number of candidates progressively declines during the testing phases eventually transforming just one of those candidates to a marketable product (see Figure 3.4).

After a successful pre-clinical testing (conducted first on small then on large animals), a manufacturers must first file an investigational new drug application with the FDA in order to undertake the human trials. However, the initiation of human trials can,

[4] According to Pammolli and Riccaboni (2007), the off-shoring of manufacture by the US pharmaceutical firms increased five times between 1996 and 2004.

and often does, occur first outside the US (DiMasi, Hansen & Grabowski 2003). The US Congressional Budget Office (CBO) (1998) defines the three phases of human trials as follows. Phase-I tests the candidate on fewer than 100 healthy volunteers to determine safe dosage level and toxicity. Phase-II tests the new drug on 50 to 200 patients with the disease the drug is expected to combat. This phase determines the safety and efficacy. Phase-III tests the drug on thousands of people to see whether the benefits are statistically significant and to uncover any side-effects. The US Food and Drug Administration (FDA) usually requires two controlled Phase-III trials before approving a new drug. There are also Phase-IV studies that involve post-marketing surveillance looking for adverse drug reactions (ADRs) that may not have been picked up during controlled trials. In case of high incidence of ADRs, the new drug may be withdrawn from the market as it was in the case of Vioxx.

Figure 3.4: Phases of drug development



Source: EFPIA (2008, p. 21).

During the development process, a large percentage of candidates dropout at the pre-clinical stage (see Table 3.8). The share of dropout candidates in Phase-I is around 10 per cent or less. This higher in Phase-II is significantly higher than in Phase-I or Phase-II. This is because Phase-II by design is the first trial to test the efficacy of the drug. By the time, Phase-III trials begin, the efficacy has almost certainly been

established. Table 3.5 shows that over a period of five years, the dropout rate in the pre-clinical testing has declined by more than 25 per cent, while this rate in Phase-II and pre-registration has almost doubled. The late dropouts have implications for the costs of unsuccessful drugs. The later a candidate drops out, the higher the costs that the company would have to write off.

Table 3.8: Percentage of drugs dropped at stages of development (1997-2001)

Year	Pre-clinical	Phase-I	Phase-II	Phase-III	Pre-registration
1997	70	7.2	15	5.4	1.7
1998	66	9.4	15	6.2	2.4
1999	56	10	19	9.4	4.3
2000	61	9.1	17	8.3	3.1
2001	53	11	27	5	3.4

Source: Based on Wilding (2002, pp. 15-6).

3.3.2 Development time

In this sub-section, we examine the time claimed versus the time taken to develop a new drug. The literature appears to be dominated by the industry view (depicted in Figure 3.4) that it takes 10-12 years to develop a new drug. The view is often extended and emphasised through regular studies and seminars sponsored by the pharmaceutical industry. The PhRMA supported by its European counterpart namely the EFPIA and other organisations representing innovator firms justify the high price of originator product on the basis that it takes so long and it costs so much to bring a new drug to the market. The same reasons are also given to justify raising the protection of intellectual property in poor countries.

According to Pfizer (1999), the drug development time has increased from 8.8 years in the 1964-1969 period to 11.0 years in the 1970s to 13.2 years in the 1980s as well as in the 1990s (cited in Gassmann, Reepmeyer & Zedtwitz 2004, p. 4). DiMasi (2001) suggests the development time to be even longer in recent years than the Pfizer estimates. His estimates for the 1960s and 1970s are similar to those of Pfizer. But he suggests that the development time in the 1980s and 1990s to have increased to 14.2 years. The implications of long development period are that the effective patent life (EPL) of the product gets reduced. Patents are taken out at the early stages of the development process. Thus, the clock for patent expiry starts ticking with the filing of the patent application. It is a race against time – the quicker a product can be

developed and marketed, the longer the effective patent life or the exclusive market period a product has. What the Pfizer study suggests is that the EPL or the market period of a patented product has declined by 4.6 years over the 30 years from the 1960s.

Other experts do not agree with the Pfizer/DiMasi view. In contrast, they claim that the drug development time has either remained the same or has in fact decreased significantly in recent years. A US government agency; namely, the Congressional Budget Office (CBO) (1998) finds that the total development time remained 8.2 years for new drugs developed and approved between 1984 and 1995. The CBO concludes that for drugs approved in 1994 and 1995, the approval time was shorter but was offset by longer the clinical testing phase; thus, the total development did not change much. Lloyd (2002) studies the development time of drugs developed over a 15-year period, which he divides into three sub-periods (see Table 3.9). He suggests that the drug development time has reduced from 109 months (9.1 years) during the 1986-1990 period to 71 months (5.11 years) in the 1996-2000 period. Lloyd explicitly notes that there was:

> ... compelling evidence that R&D times have indeed shortened considerably over the past 15 years and this improvement has occurred across all phases of development. In fact, the reduction in time taken to conduct Phase II and Phase III trials in particular is rather impressive. So it would appear that while the industry (if) not doing drug development any better, it is at least doing it quicker (Lloyd 2002, p. 73)

The PhRMA's own industry profile (2004) also suggests that the drug development time (clinical and approval phases) has declined by around two years from the 1980s to 2000s.

Table 3.9: Development time in months (1986-2000)

Development stage	1986-1990	1991-1995	1996-2000
Phase I to Phase II	21	20	15
Phase II to Phase III	31	25	18
Phase III to pre-registration	29	26	18
Pre-registration to Registered	19	15	12
Registered to Launched	9	10	8
Total	109	96	71

Source: Lloyd, (2002, pp. 72-3).

The above findings are also supported by the significant reduction in drug approval time in recent years at the FDA. For example, *Parexel's Bio/Pharmaceutical R&D Statistical Sourcebook 2007/2008* shows that the approval time for new drugs in the

US is as follows (Mathieu 2007). During the 1990-92 period, a total of 64 drugs were approved by the FDA. Of these, 19 new drugs were approved in 1990, 30 drugs in 1991and 25 drugs in 1992. Of these, the approval time on 12/19, 13/30 and 12/25 was more than two years. In fact, it took many years to approve some drugs. Searle's Daypro (122.5 months), Wyeth-Ayerst's Lodine (97.1months), Wyeth-Ayerst's ISMO (96.1 months), Abbott's Prosom (84.2 months), R.W. Johnson's Vascor (84.0 months) and SmithKlineBeecham's Ralafen (70.5 months) some of the examples. Just 11 of the 64 (or 17.2 per cent) drugs were approved within a year. In contrast, 18 new drugs were approved in each year in 2005 and 2006. From the 36 approvals, 22 or 61.1 per cent of the new drugs were approved within a year. According to CBO (1998), it took 2.9 years on average to grant a new drug approval between 1984 and 1995. The recent statistics shows a significant improvement in the approval time effectively increasing the exclusive market period for a new product.

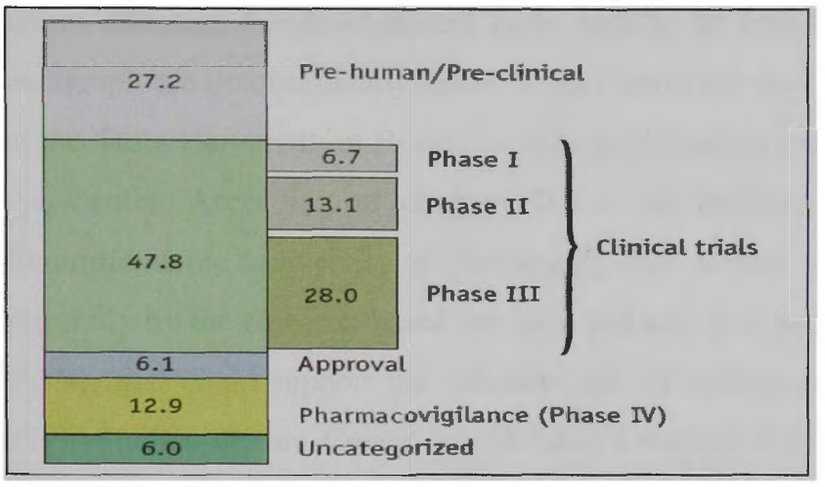
The approval time at the FDA improved significantly after the user pay fees were introduced under the Prescription Drug User Fee Act (PDUFA) of 1992. Under the Act, the FDA could employ more staff to accelerate the approval process. According to the CBO (1998), all new drug applications have to be approved within 180 days, except where agreed upon with the applicant. This change since the early 1990s has reduced the approval time significantly. The industry lobbied strongly for the Act directly and through studies at the Center for the Study of Drug Development at Tufts University. According to Austrom and Howard (1994), the industry wants to bring new drugs to the market faster because delay in launch costs $1 million each day in lost sales. However, a major drawback of this Act is that it places the FDA in a compromising position on the strictness of the approval process.

3.3.3 Development costs

Drug development is an expensive function of the pharmaceutical industry. Broadly, the development costs can be divided into four components. While the pre-clinical component incurs significant costs, clinical trials (human testing) are the most expensive component constituting almost half of the development costs (See Figure 3.5). Phase III alone accounts for more than half of the costs of clinical trials. This phase is basically the final phase before granting marketing approval. As noted

earlier, this phase involves testing the new drug on thousands of people compared to the tests on relatively small populations under Phase I and Phase II. The pre-clinical costs are substantial because of the high rate of dropout candidates.

Figure 3.5: Breakdown of development costs



Source: EFPIA (2008, p. 22).

In dollar terms, the drug developments costs would vary for different types of drugs. For example, costs of developing a drug to treat a chronic disease would be substantially higher than the costs to develop a drug for short-term diseases. Drugs for chronic disease require longer testing periods to determine the efficacy level incurring additional costs. However, the drug development costs also vary significantly between authors representing opposing views. On the one hand, the industry representing innovator pharmaceutical firms and the studies it sponsors come up with one set of figures surpassing $1 billion in 2007. On the other hand, industry experts estimate the costs of a new drug to be no more than $100 million. Hereunder we examine why the development costs are so different.

Hansen (1979) estimates the costs of developing a new drug $54 million in the 1970s. In the 1980s, these costs were estimated at between $70 million and 90 million rising to $125 million in 1986 (Wiggins (1987) as cited in Gambardella 1995). DiMasi (1991) estimates the development costs at $231 million in 1990. DiMasi, Hansen and Grabowski (2003) estimate the costs of bringing a new drug to the market at $802 million that have grown to more than $1.3 billion in 2007 (DiMasi & Grabowski 2007). All these cost estimates include the costs of dropout candidates. However, DiMasi, Hansen and Grabowski acknowledge that in recent years, the widespread use

of new technologies, such as combinatorial chemistry techniques and high-throughput screening may have made the discovery process more cost efficient than before.

While the contribution of the foregoing studies is duly acknowledged, a number of issues affecting the development costs need to be considered. Studies in foregoing paragraph are predominantly based at the Center for the Study of Drug Development at the Tufts University in Boston or they are based on previous studies undertaken at the Center. According to Graham Dukes, an international lawyer and Professor Emeritus at the University of Groningen, this 'Center was from the start financed primarily by the research-based industry and saw it as its mission to undertake policy studies that could support the industry case on various contentious issues' (2006, p. 239). Studies at this Center would have a natural bias toward the research-based industry. In their attempt to expel any doubts of bias in their study, DiMasi, Hansen and Grabowski (2003) explicitly note that 'the authors did not receive any external funding to conduct this study' (p. 183). But it is well established that the Center is financed by the industry. The DiMasi and Grabowski (2007) study does not make any reference to any funding. Instead, the editorial of *Managerial and Decision Economics* by Vernon and Manning (2007) reads that this issue is 'devoted to the industrial organization and political economy of the pharmaceutical industry' and that 'we also thank Pfizer Inc for financial support'.

We now examine how the costs are deliberately distorted to please the industry. First, the cost estimates are based on *confidential* data that may be inflated anyway. In any case, such data can not be independently verified leaving ample room for distortion. Second, DiMasi (1991), DiMasi, Hansen and Grabowski (2003) and DiMasi and Grabowski (2007) calculate the actual outlay for a new drug as follows. In the 1991 study, the actual outlay is estimated at $114 million (49.4 per cent), at $403 million (50.2 per cent) in 2003 and at $452 million (34.3 per cent) of the total development costs including the costs of dropout candidates. The authors then *time-adjust* these costs to derive capitalised costs, which the economists call opportunity costs. According to Goozner (2004), the opportunity cost assumes:

> ... that the money invested in research and development today, which won't have a payoff for many years down the road, could have been spent on other things or turned back to shareholders as additional profit'. (p. 237)

Goozner suggests that it was misleading to include the opportunity costs in the calculation of drug development costs. In the pharmaceutical industry, the R&D investments yield the highest returns in any industry. To suggest that the investors could have invested elsewhere instead is an absurd proposition. Why would investors invest elsewhere expecting a lower rate of return? To inflate the perhaps already exaggerated outlay through their *confidential* questionnaire undermines the integrity of research.

Few other facts not considered (or deliberately overlooked) in the DiMasi and DiMasi et al. studies estimating the costs are as follows. The companies reap significant benefits in tax on R&D investments bringing down the actual costs. Public Citizen (2001) critically analyses the DiMasi studies and also using data on development costs supplied by the industry estimates the costs. After accounting for tax benefits, the costs of a new drug are estimated between $57 million and $71 million in the 1990s including the costs of dropouts. Dr. Marcia Angell, former editor-in-chief of the New England Journal of Medicine points out that the DiMasi estimates were based on a deliberately selected sample of expensive drugs making no allowance for tax rebates to boost the costs. She suggests 'that the real cost per drug is well under $100 million' and 'were it anywhere near the claimed $802 million, the industry would not be so secretive about the data' (2004, p. 46).

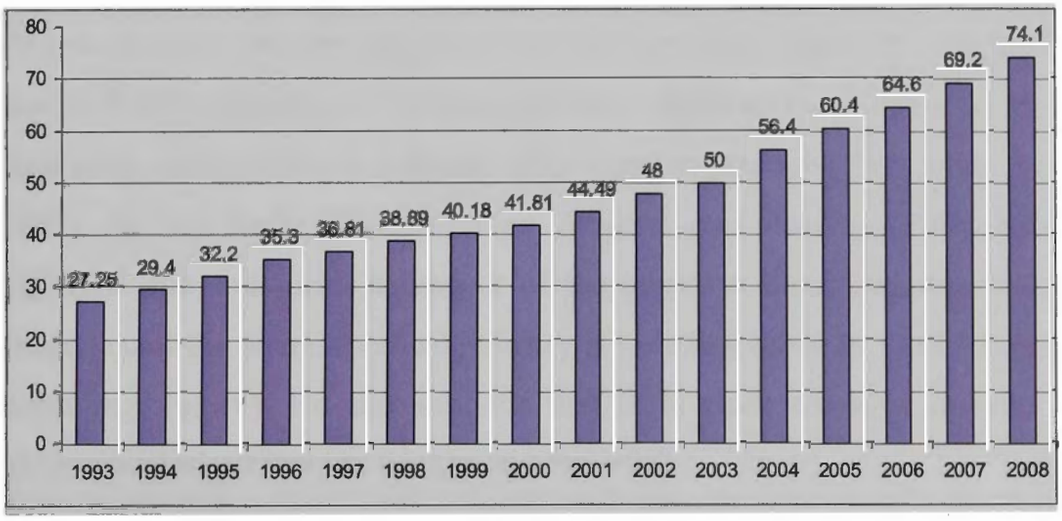
Another fact distorted in the DiMasi studies is the contribution of publicly funded research undertaken at academic and other health institutes. According to Scherer (2000), the National Institutes of Health (NIH) provide considerable financial and technical support to the pharmaceutical research. DiMasi, Hansen and Grabowski (2003) examine the role of NIH but appear to select the drugs to arrive at the predetermined conclusions. They find that 'of the 47 FDA-approved drugs that had reached at least US$ 500 million in US sales in 1999, the government had direct or indirect use or ownership patent rights to only four of them' (p. 157). DiMasi, Hansen and Grabowski (2003) mention in passing that some new compounds investigated by pharmaceutical firms did in fact originate in government or academic institutions underestimating the role these institutions play in research.

In contrast, the NIH (2000) studies the development of 5 drugs (Zantac, Zovirax, Capoten, Vasotec and Prozac) with sales of more than $1 billion in 1995 (cited in Public Citizen 2001). This study finds that 55 per cent of the research was undertaken at the NIH and another 30 per cent at the foreign academic institutes. Only 15 per cent of the research was carried out by the industry. The NIH conclusion usurps all industry claims. The NIH finds that:

> ... public researchers often tackle the riskiest and most costly research, which is basic research, making it easier for industry to profit. The NIH report discovered that only 14 per cent of the drug industry's total R&D spending went to basic research, while 38 per cent went to applied research and 48 per cent was spent on product development. (cited in Public Citizen 2001, p. 10)

The pharmaceutical industry is the most R&D-intensive among industries (DiMasi, Hansen & Grabowski 2003). According to the annual report of the PhRMA (2008a), the industry spent around 16.5 per cent of its global revenue on R&D in 2007. In dollar terms, the industry expenditure was $58.8 billion, which is around $10 billion less than the experts projected for 2007 (see Figure 3.7). Going by the 2007 industry expenditure on R&D, the projection for 2008 can be expected to fall short as well. In absolute terms, the R&D expenditure has more than doubled since 1993. According to Mathieu (2007), after the industry itself, the National Institutes of Health (NIH) is the largest source for funding medical research. In 2007, through its total of 28 institutes, the NIH is estimated to have spent around $29 billion on supporting and conducting research.

Figure 3.7: Global pharmaceutical expenditure on R&D (US$ billion) (1993-2008)



Source: Mathieu (2007, p. 12).

Since the 1980s, the size of the pipeline has enlarged significantly. The top ten companies by pipeline had on average 60-70 new drugs in the development phases in

1985. Ciba-Geigy ranked at the top with 81 new drugs in the pipeline (see Table 3.10). In 2005, Sanofi-Aventis had 215 drugs in the development phase. This increase has mostly been the result of mergers and acquisitions in the industry as noted earlier in the chapter. Ironically however, while the size of the drug pipelines and investments in R&D have increased due to mergers, overall innovation is decreasing (Cruddas & Gannon 2009).

Table 3.10: Top 10 companies by pipeline (1985-2005)

Year	1985		2005	
Rank	Company	Pipeline size	Company	Pipeline size
1	Ciba-Geigy	81	Sanofi-Aventis	215
2	Hoechst	75	GSK	171
3	Bristol-Myers	74	Roche	148
4	Roche	73	J&J	128
5	Merck & Co	68	Merck & Co	127
6	J&J	64	Pfizer	120
7	SmithKline	62	Novartis	120
8	AHP	58	AstraZeneca	101
9	Beecham	57	Wyeth	88
10	Lilly	57	BMS	85

Source: Based on Scrip News (2005d, p. 22).

Pharmaceutical marketing

The pharmaceutical industry emphasises its R&D expenditure at every opportunity to justify the high prices and patent protection for new drugs. What the industry does not appear to be happy to disclose is that it spends significantly more on marketing than it does on R&D. The OECD (2001) *Report on Competition and Regulation Issues in the Pharmaceutical Industry* suggests that the marketing expenditure is around double that of R&D expenditure. On the one hand, pharmaceutical firms are notorious for their perks and freebies to influence physicians to prescribe their medicines (Kassirer 2005). In his book titled *Inventing Disease and Pushing Pills*, Blech (2006), highlights the anti-social behaviour of the industry. Blech suggests that 'for every single doctor the pharmaceutical industry is spending 8,000 to 13,000 Euros a year on marketing' (p. 16). He also suggests that GSK alone employs an army of 17,000 pharmaceutical advisers in Europe and in the US.

Firms in this industry engage in unethical practices to promote the products they want to sell. In 2005, the Canadian Pharmaceutical Industry Association introduced rules to

place on probation, suspend or even expel companies not meeting its marketing standards (Scrip News 2005a). In Canada, companies can also be fined for breaching its code of conduct Can$10,000 for the first offence, Can$15,000 for the second, and C$25,000 for the third breach with any additional violations rising to C$50,000. According to Scrip News (2005a), AstraZeneca was placed on probation for series of breaches of the code. On the other hand, the industry is not forthcoming with all the facts when marketing new products. Harvey (2005) suggests that the industry distorts the promotion process through selectively promoting the benefits of the latest and most expensive drugs and withholding information about the side effects, contradictions and opportunity costs.

3.3.4 Direction of pharmaceutical research

This is the most critical part of drug research directly affecting access to medicines in the poor countries. Priority-setting by decision makers primarily at large MNCs determines the direction of pharmaceutical research. At present, there is a 10/90 research gap. This term refers to the fact that only 10 per cent of the biomedical research funding is targeted to the diseases accounting for 90 per cent of the global disease burden (Barry 2003). This gap was first identified by the Global Forum for Health Research (1999). This gap was an unknown concept in 1990 but it is widely recognised now (Global Forum for Health Research 2004). Implications of this gap are 'the vast divisions in the health status of the relatively high - and low income groups within a society' (Commission on Macroeconomics and Health 2001, p. 22). Mortality rate among children in the poorest quintile, in developing countries such as Bolivia, Turkey and India, is significantly higher than those in the richest quintile. Murray and Lopez (1996) study the global burden of disease and project the possible causes of deaths to year 2020. In their study, projections in Tables (7.4, 7.5 and 7.6) represent the base-, the optimistic- and the pessimistic view of the top ten causes of deaths worldwide to year 2020. Tuberculosis appears on all three lists suggesting that this disease is certainly one of biggest killers of humans. While tuberculosis is common in poor countries, it is almost non-existent in the developed world. Despite the large number of people dying and projected to die over the next two decades, large MNCs do not appear interested to commit research funding in this direction.

Global Forum for Health Research (2004) estimates that the private pharmaceutical industry now accounts for 42 per cent of all health research spending (p. 112). Public funding of high income and transition economies (47 per cent), public funding of low- and middle income economies (3 per cent) and Non-Governmental Organisations (NGOs) (8 per cent) account for the rest of the funding. Yet, there appears to be no change in the direction of pharmaceutical research. According to Labonte and Schrecker (2006), 'public funding agencies in many industrialized countries are linking priorities to the anticipation of commercial returns' (p. 25). One would expect the pharmaceutical industry in the developing countries to set priorities to meeting the needs of the poor. However, the Indian pharmaceutical industry is also focused on developing products to serve the wealthy markets of the developed world, simply because the poor lack the purchasing power. Priority-setters in the pharmaceutical research appear to have forgotten the advice from one of the founding fathers of the pharmaceutical industry. In the often cited visionary quotation, George W. Merck says, 'Medicine is for people. It is not for the profits. The profits follow, and if we have remembered that, they have never failed to appear' (see for example, Dr. Reddy's 2004; Hawthorne 2003).

The governments in the poor countries need to develop and introduce equitable healthcare programmes that include access to medicines. Programmes of such type are more important in the poor countries, where medicines constitute a significantly large share of health expenditure relative to developed countries. The model for India in Chapter 7 is an example other countries could replicate. This model has been developed taking into account India's health and industry requirements. Under the model, India's entire population would have access to medicines, which would encourage research-based companies to invest into drugs for the diseases of the poor.

3.4 Conclusions

This chapter set out to examine the role of pharmaceutical industry in developing new drugs. In the preceding discussion it has been noted that the global pharmaceutical industry is dominated by the large MNCs that are principally based in the EU, Japan and the US. These companies hold most of the pharmaceutical patents worldwide.

Through mergers and acquisitions, the MNCs are progressively getting larger and typically have much larger new product pipelines than ever before.

In particular, the US dominates global pharmaceutical industry in its capacity as being both the largest single manufacturer and the largest single consumer of pharmaceuticals. The recent shift of R&D from Europe to the US is a disturbing development for the Europeans who until recently were the leaders in pharmaceutical innovation. Japanese output in drug development has also declined over the last 10-15 years, while the rest of the world has increased its share of new drugs.

The pharmaceutical research is expensive involving a process spanning over several years. However, the industry's own claims regarding R&D costs and the time required for developing new drugs appear to be gross exaggerations. The methodology used in the studies on which these claims are based has been widely criticised for inflating the costs. The real costs of bringing a new drug to the market are likely to be significantly lower than the figures suggested by the industry and the industry-sponsored research.

As noted above, global pharmaceutical industry has enjoyed consistently high rates of growth in output and sales revenues for many years. Global pharmaceutical sales increased from US$356 billion in 2000 to US$643 billion in 2006. In 2004, the global pharmaceutical sales crossed the half a trillion dollar mark for the first time. The world market growth recorded annually around 9.5 per cent in 2001 and 2002, peaked at 16.4 per cent in 2003 and declined to 12.5 per cent in 2004. The growth has slowed down to less than 8 per cent since then.

The critics have pointed out that while pharmaceutical firms ask for patent protection to recover their developmental costs, the industry spends significantly more on marketing that it does on R&D. The critics also point out that if ethical standards were effectively enforced, the methods employed by pharmaceutical firms to promote new and expensive drugs would breach these standards in most countries. It is common knowledge that firms in this industry often provide perks to physicians in return for prescribing their medicines.

Private firms in the pharmaceutical industry account for less than half of the R&D expenditure. Governments, NGOs and other agencies provide the rest of the funding. In recent years however, even the public institutes have become more focused on research with a potential for great returns. The 10/90 research gap is widely accepted but continues, because the poor lack adequate resources to pay a price that the industry expects. Governments in developing countries need to consider new models to provide equitable healthcare, including access to medicines that would encourage research-based companies to develop medicines for the diseases of the poor.

The development strategy of the large pharmaceutical MNCs has also shifted in recent years towards developing the so-called 'blockbuster' drugs. These blockbuster drugs have become the backbone of the large MNCs for recouping their R&D investments. It was noted in the preceding discussion that on average, sales of blockbuster drugs have increased from $1.79 billion in 2000 to $2.20 billion in 2006. The increasing concentration of the large companies on blockbuster drugs has the worrying implication that the industry is ignoring the development of those drugs that are badly needed by the populations of the developing countries, simply because the sales revenues from these drugs are not as high as from selling the blockbusters.

Chapter 4

Development of India's Pharmaceutical Industry

4.1 Introduction and background

The development of global pharmaceutical industry was discussed in the previous chapter, where it was noted that development of new drugs was a long-term process that required large sums of investment and that returns on such investment were secured through legal protection of patents, enabling the innovator companies to charge monopoly prices. Large multinational companies (MNCs) dominated in patented products globally, but faced substantial competition from the generics manufacturers after the patents had expired. The development of India's pharmaceutical industry (India pharma[5]) that has rapidly grown to become one of the world's leading generics producers is discussed in this chapter. Also discussed are the role of foreign direct investment (FDI) and the emerging business models in the Indian pharmaceuticals industry. The role of FDI into the pharmaceutical industry is considered against its past development and the recent changes made to India's patent regime under the TRIPS agreement. The emerging business models provide some indications of the future directions of the domestic pharmaceutical industry.

The development of India's pharmaceutical industry has also been important in boosting the availability of pharmaceutical drugs in the domestic market (Swain et al. 2002), and the enhanced capability of the Indian industry to manufacture less expensive generic drugs for both domestic and foreign markets. With significantly lower manufacturing costs relative to those of the manufacturers in the developed countries, Indian companies were able to lower the prices of medicines and increase access to medicines in India and in other countries. Since the late 1980s, India has also become almost self-sufficient in meeting the entire domestic demand for formulations and around 70 per cent of the bulk drugs.

[5] Unless otherwise specified, it refers to indigenous pharmaceutical industry.

The remainder of the chapter is set out as follows. Section 4.2 briefly describes the significance of the pharmaceutical industry in the wider healthcare sector in India. Section 4.3 examines the India pharmaceutical drugs exports and imports. Exports of India's pharmaceutical products significantly increased access to medicines in other countries. In particular, the role of Indian pharmaceutical manufacturers in supplying antiretrovirals (ARVs) at affordable prices in the poor countries is discussed from the view point of improving access to medicines. An examination of India's imports of pharmaceuticals is also conducted to identify the emerging strategic shift from European countries to China as the main source for Indian supplies. Section 4.4 examines the foreign direct investments (FDI) in the pharmaceutical industry. The significance of the FDI into the pharmaceutical industry is that the investment may increase the research and development (R&D) and/or the manufacture of drugs for the Indian market. Section 4.5 examines the emerging business models of the domestic and foreign pharmaceutical companies in India, indicating an important emerging shift in the pharmaceutical industry. The final section (4.6) provides the main conclusions of the chapter.

4.2 The development of Indian pharmaceutical industry

India has developed a large pharmaceuticals industry that now plays a vital role in the country's economy. This industry employs around 500,000 directly and 1.9 million indirectly (Organisation of Pharmaceutical Producers of India 2003). In broad terms, the total industry output accounts for 1.3 per cent of the world market by value and around 8 per cent by volume (Nanda & Khan 2005). The difference in market share by value and by volume suggests that the products India pharmaceutical manufactures are priced low relative to the rest of the products in the global market. India's pharmaceutical industry has become the world's largest producer of off-patent generics.

In 2006, the total industrial product of India's pharmaceutical industry was around US$12 billion with exports accounting for US$3.8 billion leaving US$8.2 billion for the domestic market (Government of India 2006a). This is a significant increase from US$333 million domestic sales in 1970 and US$1,816 million in 1980 (Pradhan 1983). In Rupee terms, figures in Table 4.1 show that the total industry product

increased significantly over the 30-year period from Rs. 4,900 million in 1974-75 to Rs. 354,710 million in 2003-04. The share of bulk drugs remained small relative to the share of formulations throughout this period. The last column in Table 4.1 shows the percentage change over the preceding year. The second last row shows the sum of all percentage changes over the 30-year period and the last row shows the annual average over the same period.

Table 4.1: India's pharmaceutical industry output (Rupees million)

Category	Bulk			Formulation			Total		
Year	Product	Change		Product	Change		Product	Change	
	Rs.	Rs	%	Rs.	Rs	%	Rs.	Rs	%
1974-75	900			4,000			4,900		
1979-80	2,260	1,360	151.11	11,500	7,500	187.50	13,760	8,860	180.82
1984-85	3,650	1,390	61.50	18,270	6,770	58.87	21,920	8,160	59.30
1988-89	5,500	1,850	50.68	31,500	13,230	72.41	37,000	15,080	68.80
1989-90	6,400	900	16.36	34,200	2,700	8.57	40,600	3,600	9.73
1990-91	7,300	900	14.06	38,400	4,200	12.28	45,700	5,100	12.56
1991-92	9,000	1,700	23.29	48,000	9,600	25.00	57,000	11,300	24.73
1992-93	11,500	2,500	27.78	60,000	12,000	25.00	71,500	14,500	25.44
1993-94	13,200	1,700	14.78	69,000	9,000	15.00	82,200	10,700	14.97
1994-95	15,180	1,980	15.00	79,350	10,350	15.00	94,530	12,330	15.00
1995-96	18,220	3,040	20.03	91,250	11,900	15.00	109,470	14,940	15.80
1996-97	21,860	3,640	19.98	104,940	13,690	15.00	126,800	17,330	15.83
1997-98	26,230	4,370	19.99	120,680	15,740	15.00	146,910	20,110	15.86
1998-99	31,480	5,250	20.02	138,780	18,100	15.00	170,260	23,350	15.89
1999-00	37,770	6,290	19.98	158,600	19,820	14.28	196,370	26,110	15.34
2000-01	45,330	7,560	20.02	183,540	24,940	15.73	228,870	32,500	16.55
2001-02	54,390	9,060	19.99	211,040	27,500	14.98	265,430	36,560	15.97
2002-03	65,290	10,900	20.04	241,850	30,810	14.60	307,140	41,710	15.71
2003-04	77,790	12,500	19.15	276,920	35,070	14.50	354,710	47,570	15.49
Total for 30 years	453,250	76,890	553.75	1,921,820	272,920	553.72	2,375,070	349,810	553.79
Annual average	15,108.33	2,563	18.46	64,060.67	9,097.33	18.46	79,169	11,660.33	18.46

Source: Government of India, various years, Annual Reports, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, New Delhi; Pharmaceutical & Drug Manufacturers (2007); and Chaudhuri (2005).

The implementation of economic reforms in 1991 laid the foundation for industrial de-licensing in a range of industries including pharmaceuticals. Subsequently, the annual growth rate in the pharmaceutical industry increased to around 25 per cent for two years and since then, the industry has been growing at around 15 per cent annually. India's pharmaceutical industry is expected to maintain its rate of growth at more than 10 per cent per annum over the next few years. This rate compares with the growth estimated for the pharmaceutical industries of the US at 5-6 per cent and of Europe at 3-4 per cent (Cygnus 2007).

The significance of the increased industry output is that it helped India become almost self-sufficient in formulations and reduce dependency on previously imported bulk drugs. India now manufactures around 350 (around 70 per cent) of the bulk drugs used in the domestic production of formulations (Pharmaceutical & Drug Manufacturers 2005a; Swain et al. 2002). It is imperative that the industry product and the growth be kept in its true perspective. The industry product is measured in monetary value, which in India's case is known to be low relative to other countries. A major drawback with the value data is that it clubs together the expensive medicines with the low cost drugs distorting the data on access to medicines. The data on volume sales would provide more accurate data on access to medicines in terms of the number of patients served.

4.2.1 The significance of the small pharmaceutical firms

After the restrictive measures were introduced in the 1970s, government subsidies encouraged the development of small manufacturing units resulting in a high market fragmentation (Swain et al. 2002). It is estimated that around 8,000 manufacturing units belonging to the small-scale[6] industry (SSI) category accounted for around 50 per cent of the market by volume and 29 per cent by value in 2005 (Government of India 2007e). Considering the substantial rise in India's market size, this is a significant increase on the 15 per cent share by value held by the 2,179 SSI units in 1980-81 (Pradhan 1983) (Bhagat 1982). This comparison also demonstrates the importance of the small pharmaceutical firms at the low end of the market.

Access to medicines has increased from 15-20 per cent in 1980-81 (Bhagat 1982) to 35 per cent of the Indian population in 2001 (WHO 2004b). India had a population of 683 million in 1981 of which 15-20 per cent means that the number of Indians with access to medicines was around 102-136 million. In 2001,360 million Indians had access to medicines (at 35 per cent of the 1029 million population). This means that an additional 224-258 million people had gained access to medicines in during the period between 1981 and 2001.

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[6] Certain drugs are reserved for manufacture by the SSI, for which to qualify, the total outlay must not exceed Rs.10 million ($222,000). This limit is currently in the process of being increased to Rs. 50 million ($1.15 million).

Several studies suggest that small scale firms are likely to have significantly contributed to extending the access to medicines in India, as the brand-generics manufactured by the large pharma companies are significantly more expensive than the generic-generics manufactured by the small firms. The first study by Medico Friends Circle (2006) reported that Aventis charged Rs. 95 for a tablet of Levofloxacin compared with the same drug offered by a domestic manufacturer for only Rs. 7. Another study (cited in Gupta, AS 2004) found that the wholesale price of a generic-generic 10 tablet strip of Nimesulide 100mg was as low as Rs.1.20 compared with the retail price of Rs. 38.61 charged for Nise by Dr. Reddy's Labs. The third study by Das, Mandal and Mandal (2007) reported after examining the wholesale prices of 20 drugs that significant mark-ups were charged by the big brand firms relative to the small manufacturers (see Table 4.2 for details).

Table 4.2: Price differences between brand-generics and generic-generics

		Price in Rs.		Difference from lowest		Most sold brand			Price difference	
1	2	3	4	5 (3-4)	6	7	8	9	10 (8-4)	11
Name	Dose (mg)	Highest	Lowest	Rs.	%	Brand	Price (Rs.)	Company	Rs.	%
Diazepam	5mg	1.76	0.29	1.47	506.9	Valium	1.76	NPML	1.47	506.9
Dexamethasone	0.5mg	0.31	0.15	0.16	106.7	Decdak ST	0.16	Wockhardt	0.01	6.7
Prednisolone	10mg	1.47	0.84	0.63	75.0	Wysolone	1.34	Wyeth	0.50	59.5
Ibuprofen	400mg	0.68	0.51	0.17	33.3	Brufen	0.67	Abbott	0.16	31.4
Ibuprofen+ Paracetamol	400mg+ 500mg	1.33	0.68	0.65	95.6	Flexon	0.68	Aristo	0.00	0.0
Valdecoxib	20mg	5.50	0.80	4.70	587.5	Valto	3.50	NPML	2.70	337.5
Amoxycillin	500mg	7.72	3.09	4.63	149.8	Wymox	7.72	Wyeth	4.63	149.8
Amoxicillin+ Clavulinic acid	500mg+ 125mg	34.50	19.69	14.81	75.2	Clavam	34.50	Alkem	14.81	75.2
Doxycycline	100mg	6.20	1.55	4.65	300.0	Doxy-1	3.96	USV	2.41	155.5
Ciprofloxacin	500mg	12.58	3.75	8.83	235.5	Cifran	8.96	Ranbaxy	5.21	138.9
Azithromycin	500mg	78.29	16.50	61.79	374.5	Aziok	25.80	Not listed	9.30	56.4
Cefotaxime	250mg	28.50	14.25	14.25	100.0	Taxim	27.69	Alkem	13.44	94.3
Ranitidine	150mg	1.90	0.51	1.39	272.5	Rantac	0.53	JB Chemicals	0.02	3.9
Omeprazole	20mg	3.99	0.58	3.41	587.9	Omez	3.98	Dr. Reddy's	3.40	586.2
Metronidazole	400mg	0.83	0.63	0.20	31.7	Metrogyl	0.63	JB Chemicals	0.00	0.0
Albendazole	400mg	12.25	7.25	5.00	69.0	Zentel	12.25	GSK	5.00	69.0
Propranolol	40mg	2.00	0.50	1.50	300.0	Inderal	1.80	NPML	1.30	260.0
Nifedipine	10mg	2.35	0.89	1.46	164.0	Nicardia	0.92	JB Chemicals	0.03	3.4
Amlodipine	5mg	4.81	0.49	4.32	881.6	Amtas	2.05	Intas	1.56	318.4
Losartan	50mg	7.00	1.70	5.30	311.8	Losacar	4.40	Zydus Medica	2.70	158.8

Source: Based on Das, Mandal & Mandal (2007, Table 2).

It is clear from Table 4.2 that the largest difference between highest and lowest price was for Amlodipine – a difference of more than 881 per cent, Amtas, the *most sold* brand was manufactured by Intas, one of the leading Indian firms with a price more than 318 per cent higher than the lowest priced product in the same category. Dr. Reddy's Labs (DRL) was charging over 580 per cent more for Omez than the lowest priced product in that category. With the exception of Aristo and JB Chemicals, all large firms including Nicholas Piramal (NPML), Ranbaxy, USV, Wyeth and GSK had priced their products significantly higher than the lowest priced products in their respective categories.

All the drugs in these studies were off-patent generics. The *most sold* brands at higher pricing levels suggest significant marketing power that the large manufacturers exert relative to the small firms. This market power in the drug industry is characterised by strong promotional competition rather than price competition (Bhagat 1982; Medico Friends Circle 2006). Blech (2006) suggests that the pharmaceutical companies offer a range of perks to influence the doctors in return for prescribing their brand names. In contrast, cost-effective generics are rarely promoted (Harvey, KJ 2005). Minwalla (2003) believes that if generic[7] names were used in prescribing instead of brand names, it could limit the influence of marketing power of the pharma companies. In India, generic prescribing was first recommended by the Hathi Committee in 1975 and also considered by The Sen Committee (2005). The drug industry remains opposed to the concept and generic prescribing remains unimplemented (Scrip News 2005c). The drug industry claims that generic prescribing would shift the choice of medicines from doctors to chemists, which would be inappropriate for consumer interests (Roy & Madhiwala 2003). It can be concluded that generic prescribing in India could further increase access to medicines, because generic prescriptions would give the patients freedom to choose low cost products over more expensive brands prescribed by the doctors, arguably under the influence of the manufacturers. However, the switch to generic prescribing policy would require adequate regulatory safeguards to ensure that generic drugs are bio-equivalence with the originator drugs (McLachlan, Ramzan and Milne 2007).

[7] The actual drug or salt used in the formulation (e. g. the drug Paracetamol used in Panadol).

4.2.2 Growth of the India pharmaceutical industry

The number of firms in India's pharmaceutical industry grew from 2,257 in 1969-70 to around 23,000 units in 2004 (see Table 4.3), although estimates of the exact number varies from 5,700 (Essentialdrugs 2004; The Expert Committee 2003) to 10,000 (Organisation of Pharmaceutical Producers of India 2006) and to 23,000 (Galpalli 2004). A number of official documents refer to 20,000 pharmaceutical manufacturers (Government of India 2002c, 2006c; WHO 2004b); hence, this particular number has been used as a point of reference for this thesis.

Table 4.3: Estimates of manufacturing units 1969-70 to 2004

Period	Year	No. of units	Growth %
1	1969-70	2,257	
2	1979-80	5,156	128.4
3	1989-90	16,000	210.3
4	1999-00	20,053	25.3
5	2004	23,000	14.7

Source: Based on Galpalli (2004); Pharmaceutical & Drug Manufacturers (2005b); and Pradhan (1983).

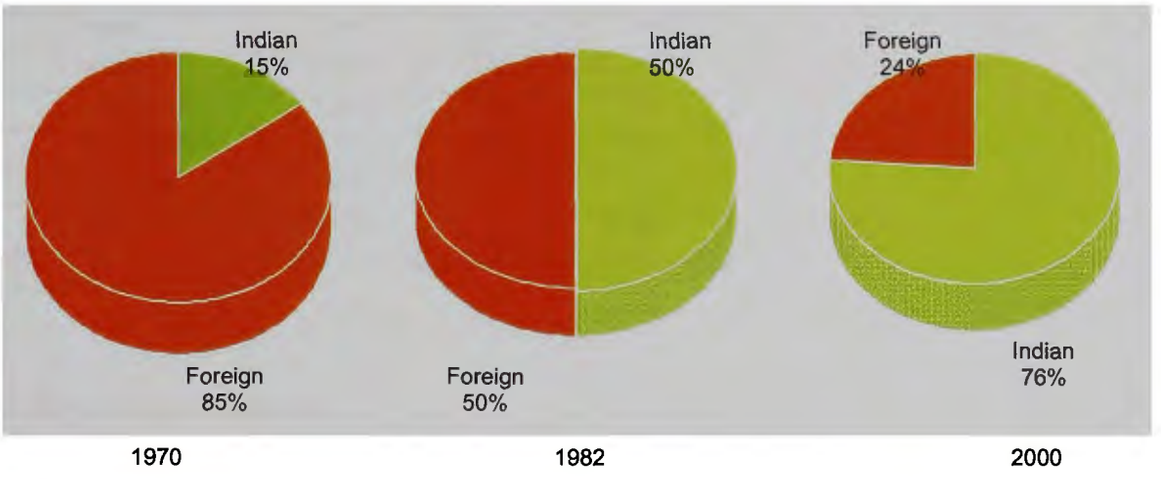
While the decadal growth in number of manufacturing units from 1970 to 1980 was substantial, the subsequent decade registered the highest growth at over 210 per cent. The principal reason for this growth was a range of industrial policies introduced in the 1970s. These policies restricted the movement of foreign exchange and placed special conditions on firms with more than 40 per cent foreign equity. At the same time, by abolishing product patents and granting only process patents, the Patent Act 1970 broke the monopoly of the patent holders. The MNCs held 99 per cent of the drugs and pharmaceutical patents in India between 1947 and 1957 (Aggarwal 2004). Given the low innovative skills of the domestic industry in the pre-1970 period, it would be safe to assume that the MNCs' domination in patents would not have diminished before the introduction of Patent Act 1970.

It is shown in Figure 4.1 that in 1970, the MNCs dominated the Indian market and the domestic firms had only 15 per cent of the market share. Following India's introduction of restrictive measures, the number of overseas pharma companies in India declined from 63 in the 1970s to 32[8] in 2004, reducing the market share of the MNCs to 50 per cent in 1982 (Chaudhuri 2005). The new industrial landscape created

[8] In today's terms, the total number of MNCs would be 26 because of mergers and acquisitions.

opportunities for domestic firms to acquire innovative skills in order to develop new processes to manufacture patented drugs (see Table 4.5 for a snapshot of India pharma development). The share of indigenous manufacturers increased and since the 1990s, India pharma has dominated the domestic market.

Figure 4.1: Composition of share of the Indian pharmaceutical market



Source: Shah (2003).

Indian firms now account for more than three quarters of the Indian market. The top ten domestics firms had a collective share of over 30 per cent in 2004 (see Table 4.4). Cipla was the leading Indian firm, followed by Ranbaxy and Nicholas Piramal with 5.5 per cent, 4.5 per cent and 4.2 per cent of the market shares respectively.

Table 4.4: Leading domestic pharmaceutical companies in India

Rank	Company	Sales 2004 (Rs million)	Market share (%) 2004
1	Cipla	11,285	5.5
2	Ranbaxy	9190	4.5
3	Nicholas Piramal	8720	4.2
4	Sun Pharma	6738	3.2
5	Dr Reddy's	4988	2.4
6	Zydus-Cadila	4959	2.4
7	Aristo Pharma	4760	2.3
8	Alkem Labs	4477	2.1
9	Lupin	4165	2.0
10	Wockhardt	3776	1.8
Total of the top ten		63,058	30.4%

Source: Compiled from various company reports; and (Cygnus 2005).

The top ten foreign firms accounted for less than 19 per cent of the Indian market (see Table 4.5). With over 5 per cent market share, GSK is the largest foreign pharma

company in India. The Table 4.5 also shows that in 2003-04, AstraZeneca had the highest growth, while Pfizer, Wyeth, and Merck recorded negative growth.

Table 4.5: Leading multinational pharmaceutical companies in India (2003-04)

Rank	Company	Sales (Rs million)	Growth rate %	Market share %
1	GSK	10,962	2.0	5.6
2	Pfizer	5,899	-5.4	3.0
3	Abbott	4,428	2.9	2.2
4	Aventis	4,350	3.8	1.8
5	Novartis	3,656	3.3	1.8
6	Wyeth	2,483	-4.1	1.3
7	Merck	2,286	-4.3	1.2
8	AstraZeneca	1,454	15.1	0.7
9	Janssen Cilag	1,124	3.0	0.6
10	Infar India	988	0.4	0.5
	Total of the top ten	37,630		18.7

Source: Novartis (2004).

4.3 Exports and imports

This section examines the growth of India's pharma exports and imports in recent years, and argues that by exporting low priced generics to a number of developing countries, including some of the poorest African countries, Indian exports of medicines have helped to increase access to medicines. Also noted is the irony that although India's exports have increased access to medicines in other countries, the vast majority of India's own population still remains without access to medicines. The section also notes the shift in recent years in the principal sources of India's pharmaceutical imports.

4.3.1 Exports

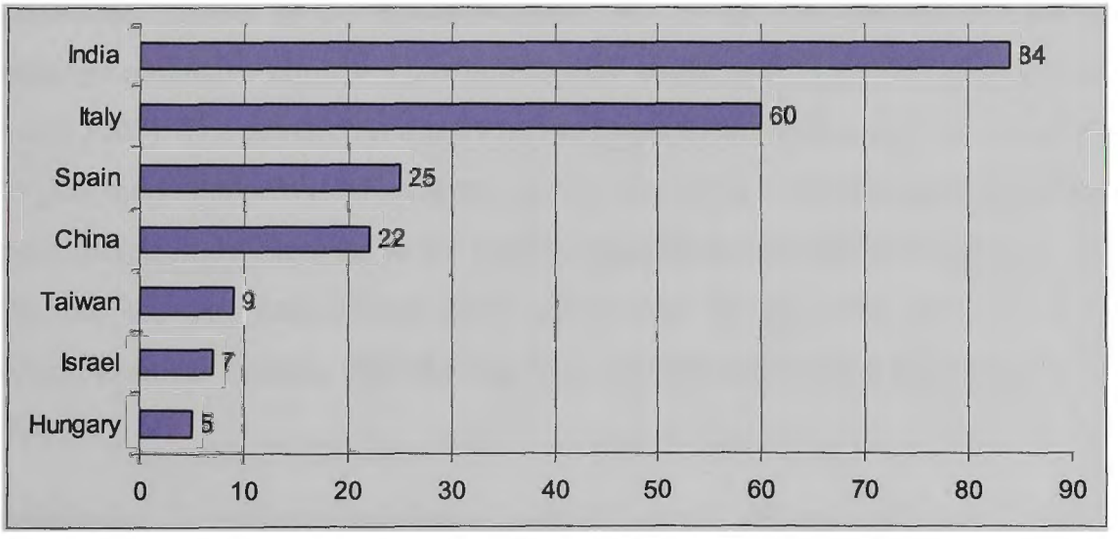
Indian pharmaceutical industry started from a low manufacturing base with exports of drugs and pharmaceuticals constituting less than three per cent of the industry product from 1970 to 1980 (Bhagat 1982). In subsequent years, exports grew significantly and in 2005-06, accounting for almost a third of the industry product (Government of India 2006a). In the late 1980s, India turned from a net importer of pharmaceuticals to a net exporter, with its products now selling in more than 170 countries (Aggarwal 2004). With continuous growth in exports, India's trade surplus in pharmaceuticals

has increased from €370 million (~$520 million) in 1997-98 to €2 billion (~ 2.8 billion) in 20007-08 (Perlitz 2008).

Two recent factors have contributed to improving the drug quality and boosting the India pharma exports. First, following the report of the Expert Committee (2003) on drug regulatory issues and spurious drugs, the Government of India introduced new measures to raise manufacturing standards in the pharmaceutical industry. Under Schedule M of the Drugs and Cosmetics Act 1940, Good Manufacturing Practices (GMP) developed by the World Health Organization (WHO) were made mandatory for all pharma manufacturing units from 1 July 2005 (Government of India 2007e).

Second, a significant number of manufacturing units have obtained in recent years compliance certification by the national authorities for exports to those specific markets. Authorities in other countries have set significantly higher than the WHO-GMP standards and the number of Indian manufacturers meeting these standards is increasing. For example, India has 84 units approved by the United States Food and Drugs Administration (USFDA), which is the largest number of manufacturing units approved by the agency outside the US (see Figure 4.2). A significant number of India pharma units are also approved by other regulatory authorities such as the MHRA (UK), TGA (Australia), and ANVISA (Brazil). The significance of these certifications is a compliance guarantee for quality assurance providing an impetus for its pharma exports to highly regulated markets.

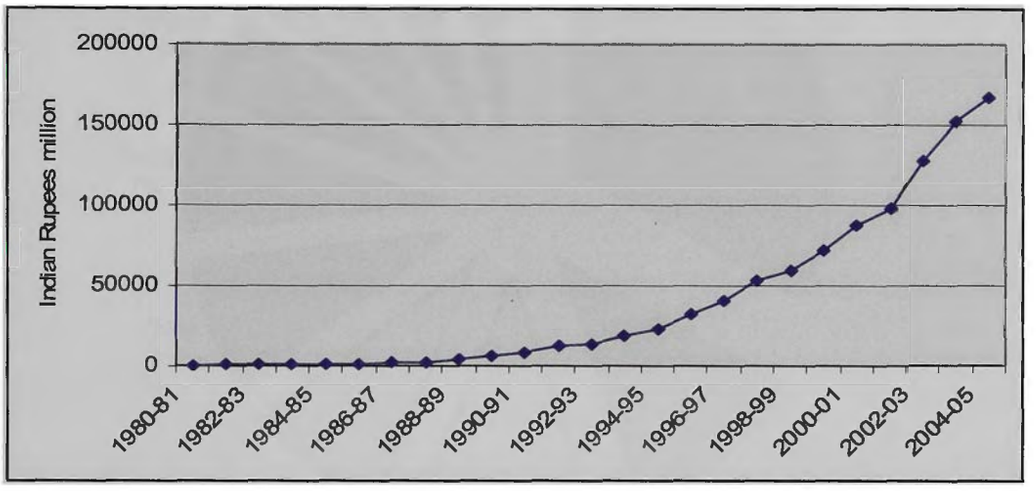
Figure 4.2: Number of FDA approved manufacturing units outside the US



Source: Based on KPMG (2006b); FICCI (2005) and Knowledge at Wharton (2006).

India's pharmaceutical exports remained relatively low until 1988-89 and began to increase after that (see Figure 4.3). Two periods distinctly mark this increase. The first period relates to the years from around 1994-95, when exports increased sharply. This period coincided with the signing of the WTO agreements by the Indian government in 1994, providing an easy access to the developed markets such as the US. The pharmaceutical exports further accelerated from around 2002 onwards, after an increasing number of Indian manufacturers received compliance certifications from overseas regulatory authorities, such as the FDA.

Figure 4.3: Trends in India's exports of medicinal and pharmaceutical products (1980-81 to 2004-05)



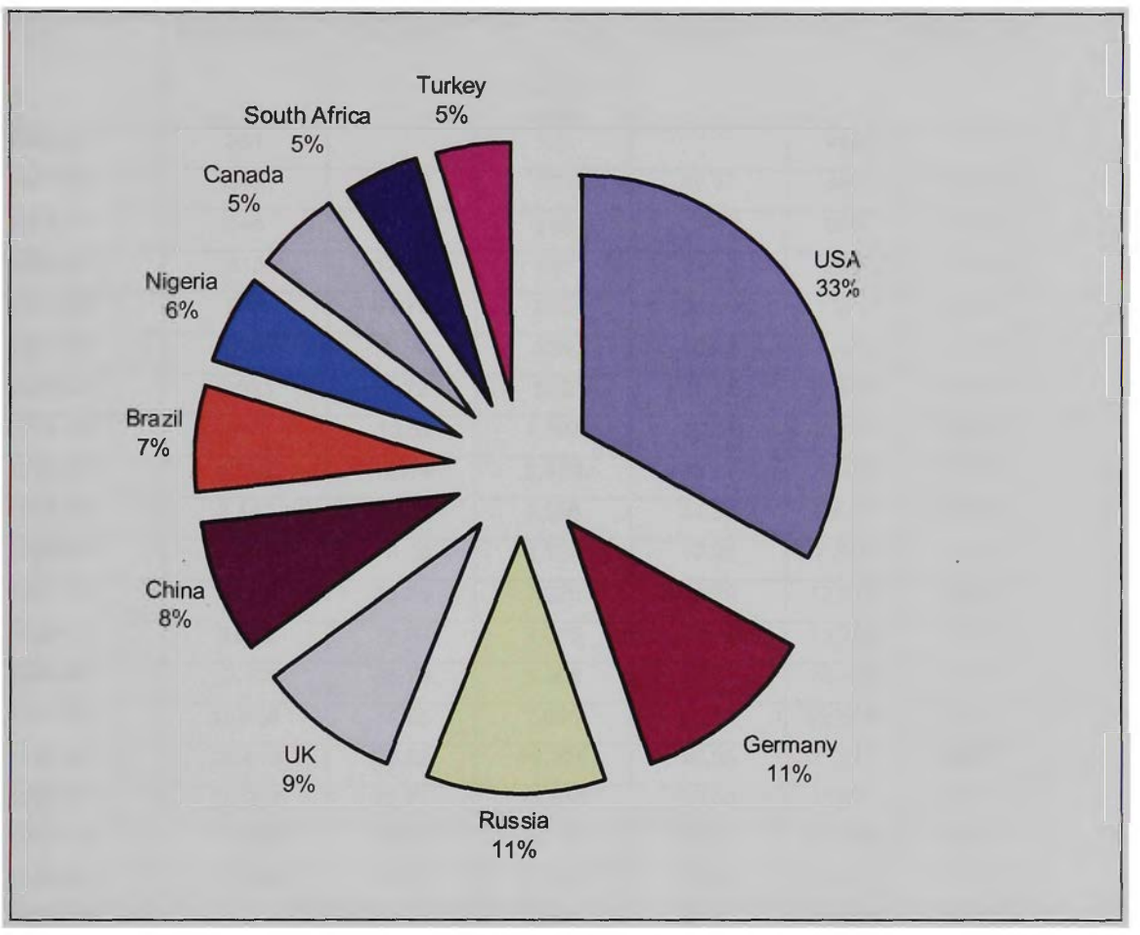
Source: Based on Government of India, various years, Annual reports, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, New Delhi; and Pharmaceutical and Drug Manufacturers (2007).

The initial focus of the domestic industry was on exports to the developing countries, erstwhile Soviet Union, and Commonwealth of Independent States (CIS). After the introduction of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act in the US, generics did not have to undergo extensive clinical trials before they could sold in the US market (Bower & Sulej 2007). The generic producers had to prove bioequivalence to the originator drug to gain market approval. During the last decade, India's pharmaceutical products have been increasingly exported to the highly regulated markets including the US. In 2005-06, the top ten destinations made up around 43 per cent of the total India's pharmaceutical exports, with the regulated markets dominating (Government of India 2007e).

Figure 4.4 shows that in 2005-06, the US was the largest single destination for India's pharmaceutical exports. Five out of the top ten destinations were OECD countries

collectively accounting for almost two thirds of the value for top ten destinations. The significance of exports to the highly regulated market is that the domestic industry feels confident and is capable of producing drugs that meet the world's highest standards.

Figure 4.4: Top ten destinations of India's pharmaceuticals exports (2005-06)



Source: Government of India (2007e, p. 125).

India's exports have grown substantially since 1980. While the growth from 1980-81 to 1992-93 fluctuated considerably, the annual growth has been relatively steady since 1993-94 (see Table 4.6). Pharmaceutical exports increased from Rs. 464 million in 1980-81 to Rs. 249,420 million in 2006-07. Over the 27 years study period, the exports averaged positive annual growth of 27.3 per cent compared with the average growth in the industry product at 15.41 per cent during the similar period. Consequently, the exports as a share of the industry product have been continuously rising. In 2004, the government established Pharmexcil, a high level body to assist the pharmaceutical industry to explore the export potential by organising networking opportunities in India and abroad (Government of India 2005e). Patents on a significant number of lucrative drugs including Lipitor, the world's top selling drug,

are due to expire in the next few years providing ample opportunities for Indian firms to boost exports. In dollar terms, patents worth up to $100 billion are expiring in the next 3 to 4 years meaning $1/6^{th}$ of global sales or $1/4^{th}$ of the US sales will disappear for large MNCs (The Wharton School 2008).

Table 4.6: India's exports of drugs and pharmaceuticals in Rupees million (1980-81/ 2005-06)

Year	Formulations	Change %	Bulk drugs incl. Quinine salts	Change %	Total	Change %
1980-81	351		113		464	
1981-82	693	97.44	155	37.17	848	82.76
1982-83	546	-21.21	113	-27.10	659	-22.29
1983-84	615	12.64	185	63.72	799	21.24
1984-85	995	61.79	293	58.38	1,288	61.20
1985-86	1,066	7.14	334	13.99	1,400	8.70
1986-87	1,021	-4.22	872	161.08	1,893	35.21
1987-88	883	-13.52	1,397	60.21	2,280	20.44
1988-89	1,573	78.14	2,429	73.87	4,002	75.53
1989-90	3,142	99.75	3,505	44.30	6,647	66.09
1990-91	3,714	18.20	4,134	17.95	7,848	18.07
1991-92	5,585	50.38	7,226	74.79	12,811	63.24
1992-93	9,655	72.87	4,095	-43.33	13,750	7.33
1993-94	13,108	35.76	5,308	29.62	18,416	33.93
1994-95	15,055	14.85	7,601	43.20	22,656	23.02
1995-96	20,448	35.82	11,329	49.05	31,777	40.26
1996-97	25,092	22.71	15,811	39.56	40,903	28.72
1997-98	31,800	26.73	21,730	37.44	53,530	30.87
1998-99	31,949	0.47	27,641	27.20	59,590	11.32
1999-00*	n.a.	n.a.	n.a.	n.a.	72,302	21.33
2000-01*	n.a.	n.a.	n.a.	n.a.	87,575	21.12
2001-02*	n.a.	n.a.	n.a.	n.a.	98,347	12.30
2002-03*	n.a.	n.a.	n.a.	n.a.	128,379	30.54
2003-04*	n.a.	n.a.	n.a.	n.a.	152,132	18.50
2004-05*	n.a.	n.a.	n.a.	n.a.	178,578	17.38
2005-06*	n.a.	n.a.	n.a.	n.a.	215,790	20.84
2006-07*	n.a.	n.a.	n.a.	n.a.	249,420	15.58

Source: Based on Pharmaceutical & Drug Manufacturers (2007); and Government of India, various years, Annual reports, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

4.3.2 TRIPS, India's pharmaceutical exports and access to medicines

Two questions are addressed in this sub-section. First, how do India's exports increase access to medicines? Second, how are India's pharmaceutical exports likely to be affected in the wake of apprehensions that the implementation of TRIPS?

The case of antiretrovirals (ARVs) used in HIV/AIDS treatment illustrates the contribution made by India's pharmaceutical industry to significantly reduce the price and extend access to medicines. The case, in which 39 pharma MNCs instituted legal proceedings against South Africa for allowing the sale of cheaper versions of ARVs, is well documented in the literature and in the media the world over. In the wake of widespread global demonstrations, the pharma companies withdrew the case. In 2001, Cipla, an Indian manufacturer offered to supply a generic version of ARVs at $800 per patient-a-year compared with the price between $10,000 and $15,000 charged by the MNCs for the same supply (Shiva, M 2005; Weissman 2007). The Cipla offer was later revised down to $350 per patient-a-year to supply the ARVs to South Africa (Global-Challenges 2008). Cipla is now the world's largest manufacturers of ARVs by volume and at $150 per patient for a year's supply of ARVs, around 40 per cent of the HIV/AIDS patients worldwide undergoing the ARV therapy take Cipla drugs (Wikipedia 2008). Other Indian companies such as Ranbaxy have also joined in to extend access to medicines in the poor countries through low cost supply of HIV/AIDS drugs. A number of Non-Government Organisations (NGOs), including the Clinton Foundation, Global Fund to Fight AIDS, Tuberculosis and Malaria, and the UNAIDS program significantly depend on the low cost supplies from India.

The Indian pharmaceutical Industry also contributed to increasing access to medicines in the developed countries. The core business of India's pharmaceutical exports to the highly regulated markets has been the off-patent generics and the level of competition after patent expiry has resulted in significant reductions of the originator price. For example, after the patent on Ciprofloxacin expired in the US, eleven generic versions were launched in the market the next day. The intense competition led to a 97 per cent drop from the price the originator had charged (Kamath 2004). Dr. Reddy's labs (DRL), one of the Indian firms to launch the generic version for Ciprofloxacin claimed that 'even at the price, we made 50 per cent profit' (cited in Mukreja 2004). By 2005, the DRL version of Ciprofloxacin had captured around 17 per cent share of the US market (Dr. Reddy's 2005). DRL has 50 Drug Master Files (DMFs)[9] in Canada, 128 in the US, and 71 with the European agency (Dr. Reddy's 2008). Collectively, India's pharmaceutical firms accounted for around 35 per cent of the

[9] Filed to obtain approvals for bulk drugs.

DMFs filed in the US in 2005 (Government of India 2007e). India's firms also accounted for over 20 per cent of the Abbreviated New Drug Applications (ANDA[10]s) in filed the US in 2006 (IBEF 2007).

It can be concluded that the Indian pharmaceutical industry has contributed, and continues to contribute, significantly to lowering drugs prices in the importing countries. Leading Indian firms draw significant proportion of their sales revenues from overseas markets. Ranbaxy, DRL and Cipla respectively generate around 70 per cent, 60 per cent and 50 per cent of their sales revenues in overseas markets (company annual reports). Other firms including Sun Pharma, Torrent, Wockhardt, Nicholas Piramal, Lupin, and Zydus Cadilla collect a substantial share of their sales revenues from overseas. With its products selling at low prices, India's pharmaceutical industry is contributing to extend access to medicines in more than 170 countries.

Now we return to the second issue raised at the beginning of this section, namely the likely impact of TRIPS on India's pharmaceutical exports. There are two distinct groups of countries that import India pharmaceutical products from India. The first group consists of the highly regulated markets of the US and other developed countries with stringent patent regimes. Implementing TRIPS will not affect India's ability to continue to export to this group of countries, because only off-patent products are exported to these markets and the export of such products remains unaffected under TRIPS, as the legal restrictions in these countries did not allow the import of imitated versions of patented drugs. The second group consists of the developing countries and the least developed countries, which have relatively lax patent regimes. This group of countries has been the main importers of India's supply of generic versions of on-patent drugs.

To determine the degree of impact TRIPS might have on India's drug exports to the second group of countries, an analysis of India's pharmaceutical exports was undertaken, using dollar value of every single drug exported for three years (2000-01 to 2002-03). The purpose of this examination was to assess which exports might be affected after 2005.

[10] Filed to obtain approvals for generic versions of formulations.

As India did not provide product patents pre-2005, exports data was examined for patent expiry at the destination country. South Africa was chosen as a country of reference for patent expiry. South Africa has the largest number of people with HIV/AIDS virus and where access to medicines is a major issue. India is the largest supplier of low cost antiretrovirals (ARVs) used in the treatment of HIV/AIDS.

The exports data from the Office of the Directorate General Commercial Intelligence and Statistics (DGCIS) showed that India exported 249 drugs grouped into 309 items under the category of drugs and pharmaceuticals during the period of inquiry (see Appendix A for details). A significant number of items had more than 3-4 drugs grouped together under the same item number.[11]

The following method for examination of exports data was applied. Each drug was separately checked for the date of patent expiry with reference to the first year of inquiry being 2000. For example, if a drug was found to be patented in South Africa until 2000 or beyond, the whole item[12] was regarded as patent-protected and was included in the calculation. If, however, the patent expired in 2000, this item was included only for one year (i.e. 2000-01), and similarly for the other years[13]. Of the 309 items India exported during the study period, a total of 26 drugs (grouped under 14 items – see total-1 Table 4.7) in were patent protected in 2000 or beyond in South Africa. Data on patent expiry on 3 items are not available. These items are listed separately in the table, but considered as patent protected in the grand total. Patents on 6 of these drugs had expired before 2000, and were due to expire on another 4 drugs in 2000, 6 drugs in 2001, and 3 drugs in 2002. Accordingly, these drugs were included in our examination only for that part of the period when they were under patent, but excluded from calculations for the subsequent period. The remaining 7 drugs had patent protection beyond 2002. Table 4.7 shows the export value of the items under patent protection in South Africa during the study period. The item

[11] It should be noted that the data examined relates to India's pharmaceutical exports to all countries [presumed developing] and not just to South Africa.

[12] No breakdown of the export value of each drug was available separately. The value of the whole item was used in calculation.

[13] Item no. 211 had four drugs, of which patents on all but paclitaxel had expired. Paclitaxel is a natural molecule, thus a product patent would not be applicable to it *per se*. However, considering that a patent on its 'method of working' exists in South Africa till 2013, the whole item was included in the examination, as its export may be affected by the new patent regime in India.

numbers in the first column correspond to the items numbers in the original table included in Appendix A. The data in Column 3 in Table 4.7 shows that the total value of exports affected by the implementation of the new regime would be $17.18 million for the year 2000-01. For the years 2001-02 and 2002-03, this value would be $16.68 million and $18.88 million respectively. In order to translate these values into relative terms, we consider India's total pharmaceutical exports, which stood at $1.95 billion, $2.18 billion and $2.65 billion for 2000-01, 2001-02, and 2002-03 respectively. Thus, India's exports of imitations of patented drugs as a share of its total pharmaceutical exports that could be affected by the new regime, would amount to 0.91 per cent, 0.77 per cent and 0.71 per cent for the respective years.

Table 4.7: Drugs and pharmaceuticals with patent expiry in 2000 or beyond

Original item no.	Product	Export value (US$ million)		
		2000-01	2001-02	2002-03
43	Captopril (1994), lisinopril (1999), enalapril (1999)			
	ramipril (2001), perindopril (2001), benzepril (2002) - formulations thereof in tablets, etc.	$0.9767	$2.0792	$2.1802
48	Cefixime and its salts (2000)	$1.2236		
56	Cetirazine - formulations thereof (2002)	$0.5851	$0.6107	$0.5041
95	Famotidine - formulations thereof in tablets, etc. (2000)	$0.4690		
98	Fluticasone - formulations thereof in tablets, capsules, etc. (2001)	n/a	$0.0290	
145	Lansoprazole - formulations thereof in tablets, etc. (2005)	$0.3771	$0.5935	$0.4615
150	Lomefloxacin (2004)	$0.0580	$0.0647	$0.3452
151	Loratadine - formulations thereof (2001)	$0.7121	$1.0176	
186	Norfloxacine- Frmltns thereof in Caps etc (2002)	$5.7380	$2.2532	$2.2319
187	Ofloxacin (2001)	$0.0359	$0.1409	
211	Other Carcino-Chemotherapeutic Drugs (E.G.Cyclophosphamide, chlorambucil, paclitaxel (2013), tamoxiphen, etc.)	$0.9364	$1.3763	$1.4316
256	Roxythromycin (2000), Azithromycin (2008) Clarithromycin (2005 Taisho and 2013 AstraZenecca)) in capsules, injections, etc.	$3.0088	$2.4282	$3.8423
258	Simvastatin (2001); lovastatin (2000); atrovastatin (2007)	$0.2691	$1.9269	$4.3967
309	Zidovudine - formulations thereof (2006)	$0.0640	$0.3348	$0.8683
Total - 1		$14.4538	12.855	16.2618
No data available on patent expiry on the following items				
55	Cephaloridine	$0.4023	$0.9936	$0.1500
87	Dxamtasne Tblts etc incl. Eye/Ear Drops etc	$2.9199	$2.8304	$2.4342
272	Syntocinone Injection	$0.0407	$0.0018	$0.0355
Total - 2		$3.3629	$3.8258	$2.6197
Grand total		$17.8167	$16.6808	$18.8815

Source: Author calculations based on IndianData.com (2005); data on patent expiry from IMS-LifeCycle (2004) and Government of India (2007b).

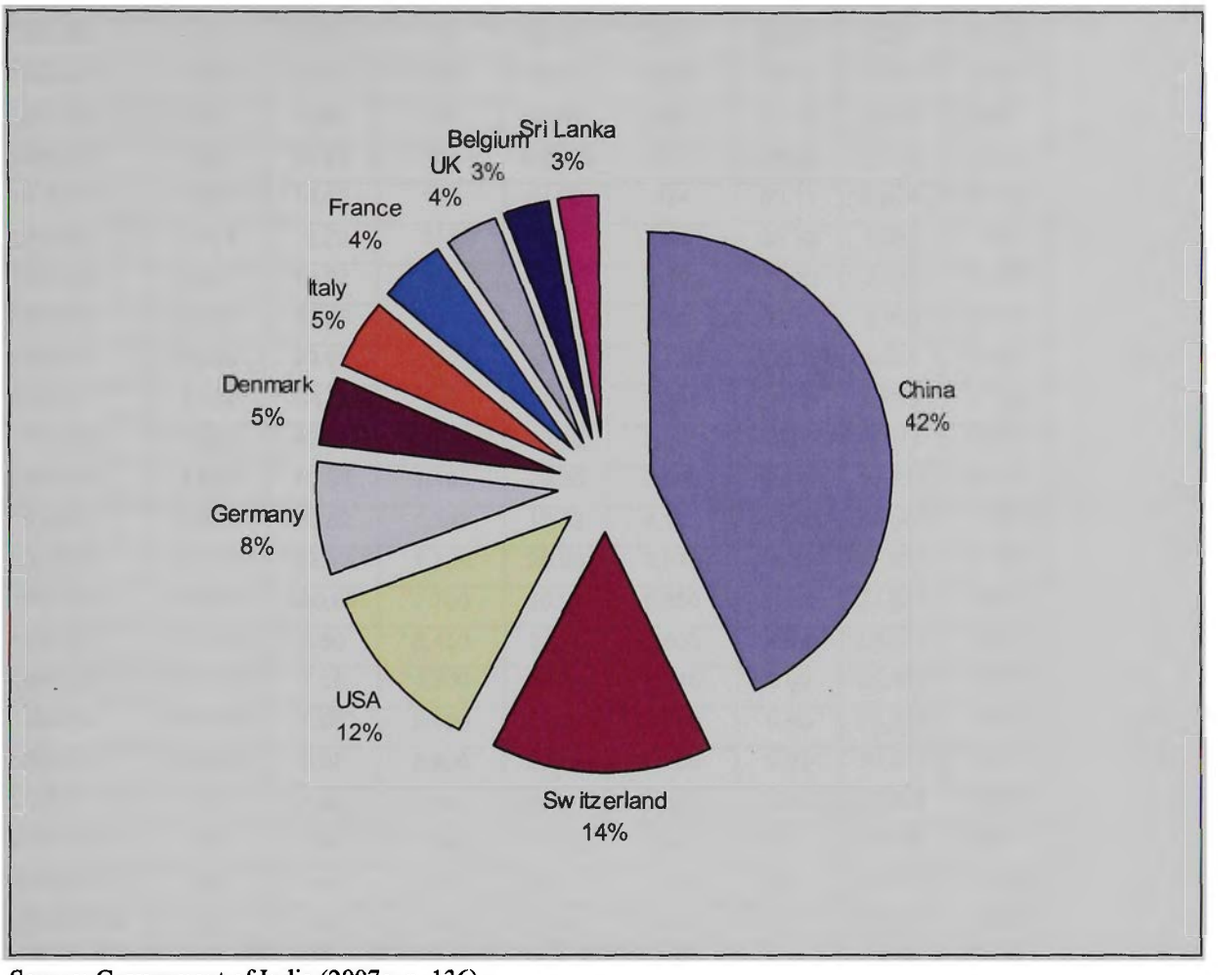
Based on the data examined, it can be concluded that in terms of value of exports, the impact of the implementation of the TRIPS agreement on India's exports is likely to be quite small - only around 1 per cent of India's pharmaceutical exports may be in jeopardy due to TRIPS. However, the overall impact may be greater if the number of patients who benefit from India's low-priced exports of drugs is considered, especially in the area of HIV/AIDS. Moreover, as pointed out in Malhotra (2008), the implementation of the new patent regime would close all future opportunities to develop new processes for providing cheaper generic drugs (Malhotra 2008). This loss would adversely affect access to medicines for the poor not only in India, but also in the other developing countries. Thus, the overall impact of TRIPS on potential exports and patient welfare is likely to be considerably greater than simply the value of exports lost. This difference arises due to two reasons. First, India's drug prices among the lowest in the world. So, the dollar value is likely to under-represent significantly the scale of populations that would be denied access to medicines after the regime change. Second, as noted above, the implementation of TRIPS has closed all future opportunities for India's domestic industry to develop new processes and provide cheaper alternatives to expensive innovator drugs. This loss would adversely affect access to medicines for the poor in India as well as in other developing countries.

4.3.3 Imports

Initially, India was heavily dependent on imports from Germany, France, Switzerland and the UK (Chaudhuri 2004). With the development of its pharmaceutical industry, India became almost self-sufficient in manufacturing formulations as noted earlier. Thus, India's import requirements were confined to importing bulk drugs mainly from European countries including Italy the world leader in bulk drugs (Roumeliotis 2006). The Chinese accession to the WTO in 2001 changed the global landscape for bulk drugs providing Indian firms with a wider choice of suppliers. India's pharmaceutical imports from China now rank ahead of any other country. In 2005-06, the top ten countries accounted for over 81 per cent of India's total pharmaceutical imports. While the developed countries dominated the list of top ten suppliers of Indian

imports, China alone contributed to around 42 per cent of the total of the top ten suppliers of pharmaceutical products to India (see Figure 4.5).

Figure 4.5: Top ten suppliers of India's pharmaceuticals imports



Source: Government of India (2007e, p. 136).

With the rapid development of the domestic pharmaceutical industry, India's drugs imports have also increased significantly. India's pharmaceutical imports grew from Rs. 1,125 million in 1980-81 to Rs. 44,272 million in 2005-06 (see Table 4.8). The imports grew every year, except for 1990-91 and 2000-01 when a negative growth was recorded. The first negative growth was just before the industrial restrictions were relaxed under the economic reforms introduced in 1991. The second negative growth could be attributed to the different sources used for data, highlighting the problems of obtaining reliable accurate data. The growth in pharmaceutical imports has not been stable throughout the period. The highest annual growth was recorded in 1995-96 after the signing of the WTO agreements.

Table 4.8: India's imports of drugs and pharmaceuticals (Rupees million) (1980-81/2005-06)

Years	Bulk drugs	Change %	Formul-ations	Chan-ge %	Interm-ediates & others	Chan-ge %	Total	Chan-ge %
1980-81	872		96		157		1,125	
1981-82	1,051	20.53	19	-80.21	293	86.62	1,363	21.16
1982-83	1,156	9.99	54	184.21	275	-6.14	1,485	8.95
1983-84	1,231	6.49	34	-37.04	369	34.18	1,633	9.97
1984-85	1,784	44.92	102	200.00	271	-26.56	2,156	32.03
1985-86	2,081	16.65	158	54.90	434	60.15	2,674	24.03
1986-87	2,075	-0.29	218	37.97	583	34.33	2,876	7.55
1987-88	2,341	12.82	214	-1.83	939	61.06	3,494	21.49
1988-89	3,284	40.28	354	65.42	831	-11.50	4,469	27.90
1989-90	4,256	29.60	551	55.65	1,714	106.26	6,521	45.92
1990-91	3,226	-24.20	849	54.08	1,965	14.64	6,040	-7.38
1991-92	4,585	42.13	961	13.19	2,528	28.65	8,074	33.68
1992-93	5,084	10.88	1,195	24.35	5,095	101.54	11,374	40.87
1993-94	6,127	20.52	1,383	15.73	4,155	-18.45	11,665	2.56
1994-95	8,114	32.43	1,730	25.09	3,843	-7.51	13,687	17.33
1995-96	16,300	100.89	2,700	56.07	5,050	31.41	24,050	75.71
1996-97	17,050	4.60	3,450	27.78	5,555	10.00	26,055	8.34
1997-98	18,270	7.16	4,300	24.64	6,110	9.99	28,680	10.07
1998-99	19,180	4.98	5,400	25.58	6,700	9.66	31,280	9.07
1999-00	20,250	5.58	6,800	25.93	7,360	9.85	34,410	10.01
2000-01* #	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	17,015	-50.55
2001-02* #	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	20,266	19.11
2002-03* #	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	24,771	22.23
2003-04* #	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	29,580	19.41
2004-05* #	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	35,960	21.57
2005-06* #	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	44,272	23.11

Note: * A breakdown of figures not available for these years.

Multiplied by the exchange rate[14] to convert these figures from US$.

Source: Pharmaceutical and Drug Manufacturers (2007) and Government of India, Annual Reports (various issues), Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

While imports are generally discouraged by Indian policy-makers, the pharmaceutical imports have played a significant role in the development of the Indian pharmaceutical industry over the last three decades. Before the industry began to manufacture bulk drugs in India, imported bulk drugs were used to manufacture formulations for the domestic and overseas markets. India still imports around 200 of the approximately 600 bulk drugs used in the manufacture of formulations. This means that even today, the total Indian demand for bulk drugs could not be met without the contribution of the imports. Since the Indian law treats the foreign

[14] Exchange rate obtained from the Ministry of Commerce website.

companies at par with the Indian firms and the special conditions forcing the MNCs to manufacture in India now abolished, imports are likely to increase in the future. Imports are also likely to play significant role in the availability of patented medicines in India. The pharma MNCs holding most of the patents worldwide are unlikely to manufacture the patented drugs, because the MNCs tend to import these drugs from the parent company rather than produce them in India (Phadke 2000).

Notwithstanding the negative impact perceived by India's policy makers, imports have played a vital role in the development of India's pharmaceutical industry. Using imported bulk drugs, the industry gained experienced to manufacture formulations Around 30 per cent of the bulk drugs are still imported to manufacture formulations. With progressive increase of patented drugs to be launched in the Indian market, imports are likely to rise substantially in future.

4.4 Foreign direct investment

This section examines foreign direct investment (FDI) in the Indian pharmaceutical industry with a view to determine the importance of intellectual property rights (IPRs) in attracting the FDI. The significance of this examination is to assess if implementing TRIPS is likely to increase FDI into India's pharmaceutical sector. This investigation is based on the five-yearly FDI data from Shah (2003) for the 25-year period from 1975 to 2000. Using the average exchange rate[15] for each five-year period, the data is converted from Indian Rupees to US dollars, because the US$ is the standard format used for FDI all over the world. Using the CPI index from the World Bank database, the data was then converted from current value to constant 2000[16] value providing a common denominator for the data in different five-year blocks.

As noted earlier, under the restrictive measures introduced in the 1970s, foreign equity in the pharmaceutical industry was reduced to 40 per cent or less. Companies

[15] The average exchange rate of Rs. 8.38, 10.00, 14.29, 26.77 and 38.97 for the five-year periods starting 1975, 1980, 1985, 1990 and 1995 respectively derived from the yearly exchange rates obtained from IMF database.

[16] For Rupees, CPI index for India was 15, 22.5, 33.6, 52.8 and 82.8 for respective five-year periods with 100 being for the year 2000. For US$, the CPI index for the US was 35.8, 55, 66.6, 81.2, and 92.8 for the respective five-year periods with 100 being for the year 2000.

with more than 40 per cent foreign equity were treated as FERA[17] companies and as such, were subject to special conditions (Reserve Bank of India 2005). Following the economic reforms introduced in 1991, foreign equity in the pharmaceutical industry has been progressively raised to 100 per cent (Government of India 2002d) and the Indian law now treats foreign companies at par with domestic companies (Smith 2000).

Based on a recent study, it could be argued that the significance of FDI into the pharmaceutical sector is that FDI is likely to contribute to industry development and increase drug supply in the market. Feinberg and Majumdar (2001) suggest that technology spillovers from foreign direct investment contributed to the development of India's domestic pharmaceutical industry. These spillovers enhanced productivity of domestic manufacturers through efficiency gains in human capital, R&D capabilities, and infrastructure development, argue Feinberg and Majumdar.

The discussion in this section challenges the assertion made in a number studies that there is a positive correlation between stronger intellectual property rights (IPRs) and higher levels of investment in pharmaceutical industry (for example, Lippoldt 2006; Mansfield 1995; Maskus, KE 2000; Seyoum 1996). These studies seem to suggest that strong protection of IPRs was instrumental in attracting foreign direct investors into the developing countries, particularly in industries, such as the pharmaceutical industry. Their assertion is based on the basic premise that theft or unauthorised use of intellectual property was a perceived threat to global investors. The degree of this threat depended on the stage of development of the industry and other characteristics, such as manufacturing and R&D capabilities, infrastructure and skilled labour in the host country (Nunnenkamp & Spatz 2003). A recent survey of the knowledge-intensive industries including pharmaceutical industry suggests that around 35 per cent of global investors consider IPRs as a challenge to India's future competitiveness (A T Kearney 2004). The findings of the same survey could also be interpreted, however, to suggest that around two thirds of global investors did not consider IPRs was an issue in India. In the light of this contradictory evidence, a systematic examination was conducted in this study of FDI in India's pharmaceutical industry

[17] Foreign Exchange Regulation Act (FERA).

over a period of 25 years (1975-2000).[18] The results are then used to assess whether or not the implementation of TRIPS would impact the level of FDI in India in general and in the pharmaceutical industry in particular.

In constant value, the level of FDI into the pharma sector was the highest in the 1975-80 period (see Table 4.9). The level of investment in Period 1 was higher by all measures than the sum of Period 2 and Period 3. In constant Rupees terms, the investments in Period 5 were close to but lower than the level of Period 1. The final period relates to time when India had already signed the WTO agreements including the TRIPS agreement. In contrast, Period 1 followed the introduction of restrictive measures in India, during which, the investments (US$ constant) constituted around 93 per cent of the total sum of the rest of the study periods.

Table 4.9: FDI into the Indian pharmaceutical sector in Rs. million (1975-2000)

No.	Period	Rs. (current)	Rs. (constant 2000)	US$[19] (current)	US$ (constant 2000)
1	1975-80	3,050	20333.33	$364	$1,016.76
2	1980-85	1,200	5333.333	$120	$218.18
3	1985-90	2,000	5952.381	$140	$210.21
4	1990-95	5,300	10037.88	$198	$243.84
5	1995-00	15,200	18357.49	$390	$420.26

Source: Based on Shah (2003), slide 16.

The highest investments in the Indian pharmaceutical industry relate to the five-year block, following the introduction of the Patent Act 1970 and the Foreign Exchange Regulation Act (FERA) 1973. The investments significantly reduced following the introduction of Drug Price Control Order 1979 and the Drug Policy 1978 revised in 1986. Table 4.11 shows that foreign investments continued in the pharmaceutical industry even after product patents were abolished in India. A number of other countries had a similar experience, where the FDI rose after a weak patent regime was introduced. For example, after Turkey abolished patenting of pharmaceutical processes and products in 1961, the level of FDI increased significantly (Seyoum 1996). In Brazil, the level of FDI in the pharmaceutical industry also increased substantially after the country abolished product patents (UNCTC 1993). In contrast,

[18] The significance of this period is that it covers the period of restrictive measures of the 1970s as well as the period following economic reforms in 1991.
[19] For the years obtained from the IMF database and average for each period derived.

Nigeria's introduction of stringent protection of intellectual property rights (IPRs) did not translate into FDI increase (Aderibigbe 1990; Adikibi 1988).

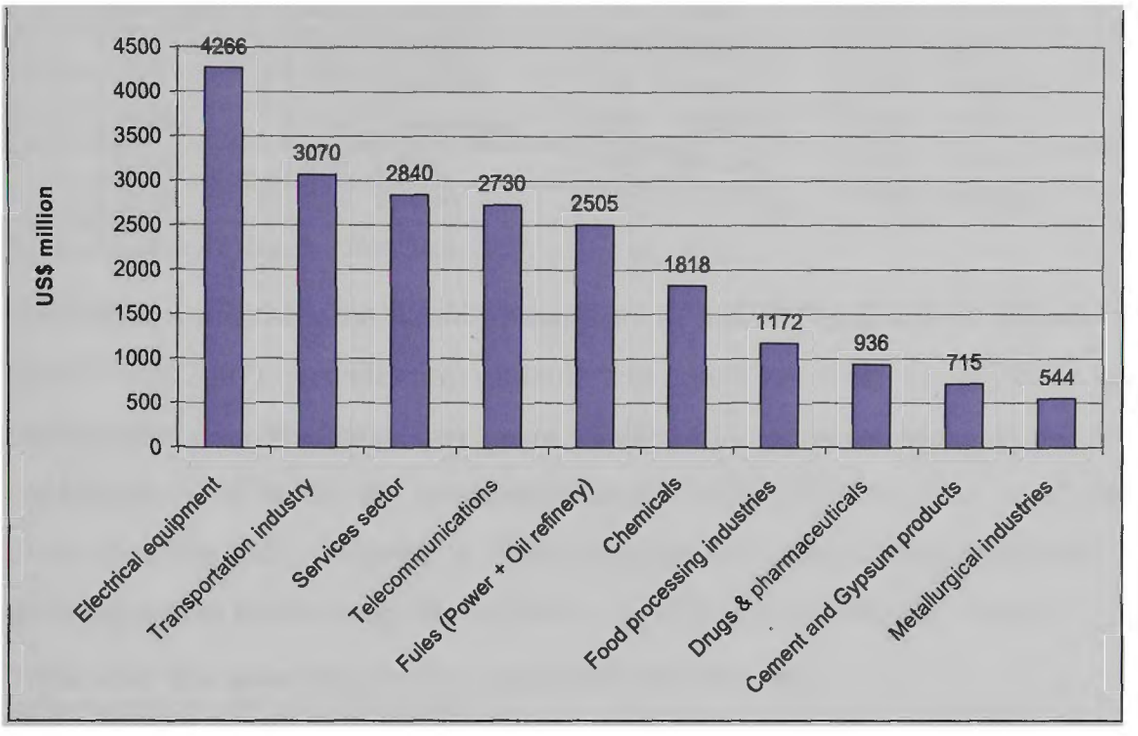
These findings would suggest that FDI is not necessarily based on IPRs alone, other factors also play a significant role in investment decisions. For example, availability of human resources or more specifically skilled labour is a crucial determinant of FDI (Schneider & Frey 1985). In India's case, its human capital is arguably one of its biggest strengths of comparative advantage and a significant pull factor in attracting FDI (Palit & Nawani 2007). While the low-cost human capital was also available in the 1980s, there is no explanation for the significant drop in FDI in the 1980-85 period, other than a delayed reaction by the foreign investors to India's weakened patent regime. India's introduction of good manufacturing practices (GMP) and the approval of a large number of manufacturing units by the FDA and other regulatory in recent years have significantly improved India's reputational value at the international level. These factors have added to the investors' confidence in the post WTO era.

After economic reforms were introduced in India in 1991, foreign direct investment into the pharma industry began to increase pushing the pharma sector into the top ten sectors attracting FDI. Figure 4.4 shows top ten sectors by FDI for the 15-year period (1991-2005). The drugs and pharmaceutical sector attracted US$936 million compared with $1,818 million invested in the chemical sector and more than $4.2 billion invested in the electrical equipment sector during the study period. More than 38 per cent of all investments made into the pharmaceutical sector during 1991-2005 period were made in 2004, which was possibly in anticipation of the patent regime change from 2005 (Chadha 2006).

There are a number of reasons for the increase in the FDI in recent years since 2000 in particular. One of the reasons is the broadening of the definition of FDI. The earlier definition of FDI was confined to equity inflows through the automatic approval route schemes earmarked for Indian expatriates, the government route (approved by Foreign Investment Promotion Board), and acquisition of non-residents in Indian companies under the Foreign Exchange Management Act (FEMA) of 1999. Since 2000-01, equity capital of unincorporated bodies, reinvested earnings (retained earnings) and inter-corporate debt transactions between FDI entities are also

considered FDI (Reserve Bank of India 2008b). The previous definition resulted in underreporting of FDI and the new definition conforms to the international standards (Palit & Nawani 2007).

Figure 4.7: Top ten sectors attracting FDI in India (US$ million) (1991-2005)



Source: Government of India (2006j)

India specific factors also play a significant role in investment decisions. Factors such as low manufacturing and R&D costs, a large of pool of highly skilled English speaking work force, a market of 300 million middle class, and a proven record of economic growth are significant considerations boosting the investor confidence. Table 4.10 shows top ten countries by investor confidence for the 2003-07 period[20]. The Table shows that China retained the top spot for investments throughout the entire period. The investor confidence for India improved significantly from rank 6 in 2003 to rank 3 in 2004, which was ahead of Germany, France and Australia. In 2005 and 2007, India ranked second ahead of the US, and the UK.

[20] The FDI confidence index was not available for 2006.

Table 4.10: Ranking of economies by FDI confidence index (2003-07)

Rank	2003		2004		2005		2007	
1	China	1.97	China	2.03	China	2.197	China	2.21
2	US	1.63	US	1.45	India	1.951	India	2.09
3	Mexico	1.06	India	1.40	US	1.420	US	1.86
4	Poland	1.06	UK	1.25	UK	1.398	UK	1.81
5	Germany	1.06	Germany	1.17	Poland	1.363	Hong Kong	1.78
6	India	1.04	France	1.03	Russia	1.341	Brazil	1.78
7	UK	1.02	Australia	1.00	Brazil	1.336	Singapore	1.75
8	Russia	0.99	Hong Kong	0.99	Australia	1.276	UAE	1.72
9	Brazil	0.94	Italy	0.98	Germany	1.267	Russia	1.70
10	Spain	0.94	Japan	0.97	Hong Kong	1.208	Germany	1.70

Source: Based on AT Kearney (2004, 2005, 2007).

What does it mean for the future investments in India? The *World Investment Report* (UNCTAD 2007) provides an outlook that could be used as guide to size up investments over the next two years. Table 4.11 provides ranking and investor confidence level in the top investment destinations. China was the most preferred destination for FDI, followed by India and the US. India's continued hold on the second position shows a significant level of confidence in investors' minds.

Table 4.11: The most attractive locations for FDI (2007-09)

Rank	Countries	% of respondents
1	China	52
2	India	41
3	United States	36
4	Russian Federation	22
5	Brazil	12
6	Viet Nam	11
7	United Kingdom	10
8	Poland	7
9	Germany	7
10	Australia	6

Source: UNCTAD (2007, p. 30).

Investments into manufacturing or into R&D are made through acquiring an existing facility or developing a new facility from scratch known as green-field investments. In 2004, India and China together accounted for around half of all green-field and expansion projects in developing countries (UNCTAD 2005). In the pharmaceutical industry, a number of MNCs have recently invested into R&D facilities in India. Astra-Zeneca started a large R&D facility for research on tuberculosis in Bangalore in 2003 that was later expanded to include pharmaceutical development. Pfizer started clinical research in India back in 1995 and expanded to include a biometrics unit in

1998 along with formulation development in 2004. By June 2005, Eli Lilly, Sanofi-Aventis, Novartis and GlaxoSmithKline had started clinical research units and Novartis and GlaxoSmithKline had biometrics centres in India (Mukherjee 2005).

What impact is the FDI into the pharmaceutical sector likely to have on access to medicines? Our conclusion is that unlike exports, FDI is not expected to significantly increase access to medicines. There is no doubt that if the new FDI goes into new facilities to develop and/or manufacture medicines for the domestic market, the drug supply would increase. However, this would not necessarily increase the affordability of medicines. This is because if the new investment goes into acquisition of an existing firm or facility, there would be no net increase in the supply of drugs on the market. Furthermore, new investments are unlikely to be made into the development of new drugs for tropical diseases prevalent in India and in other developing countries. Generally, it is understood that nearly 90 per cent of the global R&D is directed to developing new drugs for the 10 per cent of the world population. This is because the other 90 per cent lack the purchasing power to generate adequate returns on investment (Moran 2001; Scherer, FM 2001), a trend unlikely to change in foreseeable future.

It should be clear from the discussion in this section that the level of FDI into the pharmaceutical sector actually rose after product patents were abolished in India. The investments into the pharmaceutical sector were the lowest from 1980 to 1990 but started to rise following the economic reforms in 1991. Today, the pharmaceutical sector in India is one of the top ten sectors to attract the FDI. Globally, India ranks second behind China, but ahead of the US and the UK, in respect of investor confidence. From the perspective of access to medicines, however, the poor consumers are unlikely to gain much from FDI into the pharmaceutical sector.

4.5 Emerging business models in the pharmaceutical sector

This section discusses the emerging business models in the pharmaceutical sector in India, as the future of India's industry will be shaped by the emerging new business models. The recent changes, such as the new investment policies and the reintroduction of product patents, have changed the industrial landscape in India, and

the pharmaceutical industry stands at critical crossroads – looking back at one path stemming from its traditional strategies, and looking ahead at another path characterised by new emerging business models (Heinen & Perry 2006). The industry, as a whole, is going through an unprecedented transformational process through mergers and acquisitions, strategic alliances and outsourcing of major functions such as research and development, manufacturing and marketing. The outlook for the future is that this process of consolidation is likely to stabilise the market environment with greater concentration of market power and with fewer competitors in the pharmaceutical market (Madanmohan & Krishnan 2003).

The increased global interdependency, advances in information and technology, and the falling costs of telecommunication and global travel have changed significantly the way businesses operated. These changes have also affected the operations of the large MNCs, as summed up in the following statement:

> ... Globalization has resulted in increasing fragmentation of production networks of multinational enterprises. Several functions, which used to be performed in one location, are now getting dispersed over multiple countries for maximising benefits offered by specific features of different locations. (Palit & Nawani 2007, p. 4)

The return of 'big pharma' companies, such as Merck & Co, after 20 years to India indicates the beginning of new dawn in the Indian pharmaceutical market. A significant number of MNCs have set up their manufacturing and/or R&D operations in India. Under mounting pressure of rising costs, an increasing number of global pharmaceutical companies are seeking alliances with their competitors. Even core competencies, such as R&D and clinical trials, are now being outsourced to specialist firms in low-cost economies, including India (Chataway, J, Tait & Wield 2007). For example, in 2005 alone, there were 39 co-development and co-marketing deals as well as 129 licensing agreements signed worldwide (Scrip 2006). The recent changes in the industrial sphere have had a profound impact on the mindset of India's pharmaceutical industry forcing domestic firms to reconsider their business strategies. The strategies recently adopted by leading Indian firms suggest a shift from 'inward looking to outward looking' mindset (Malhotra 2005). The emerging forces of globalisation have led a large number of Indian pharmaceutical companies to form alliances with other domestic or foreign enterprises. Dr Reddy's Labs describes the new industrial landscape as a place of:

> ... networks of innovative alliances – between boutique R&D companies and pharmaceutical players, between different pharma companies, between pharma players and clinical research

> organisations – many of which are mediated by third party risk capital of venture capital enterprises. (Dr. Reddy's 2005, p. 3)

The changing business models in the pharmaceutical industry represent only a fraction of the changes taking place across the business sphere India wide. In a broader economic context, the Indian industry in general referred to as India Inc in the media, has been revising its business models. Using the strong economic growth in the domestic market as a stable platform, Indian companies are rapidly launching themselves in the overseas markets. For example, between 2003 and 2006, India Inc acquired 307 overseas firms worth more than US$20 billion (Aiyer 2006) and Indian investors invested close to $40 billion in the four years to 2007-08 (Reserve Bank of India 2008a, p. 154). These investments suggest that the Indian businesses are increasingly becoming global thinkers indicating a significant shift in the mindset of Indian entrepreneurs, including the pharmaceutical industry.

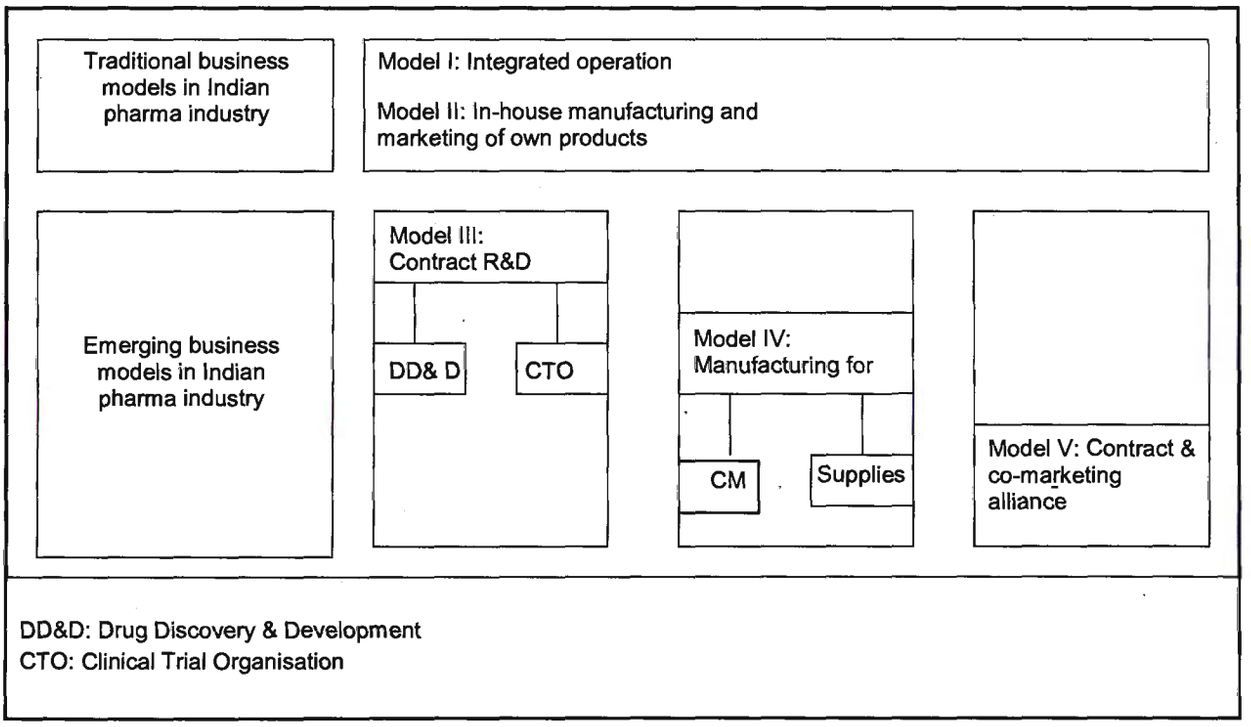
Domestic pharmaceutical companies have adopted a range of models to fit the new industrial landscape. While a dozen or so leading Indian companies have embarked upon drug discovery with a view to fully integrate into the global pharmaceutical industry, their business models vary significantly. On the one hand for example, Ranbaxy and Dr. Reddy's Labs (DRL) are pursuing a competitive model with aggressive marketing and patent challenges to the MNCs in a number of markets, the US in particular. Both companies have had success in securing 6-months exclusive access as a generic supplier to the US market after patent expiry. Both companies have also entered into alliances with MNCs and signed lucrative deals as a result of these challenges. However, this is a high risk business model with high rewards for successful challenges. For example, Ranbaxy spent US$25 million in 2004 and US$30 million in 2005 on fighting patent litigations (Bisserbe 2006).

In a recent study, Bower and Sulej (2007) suggest that the business models of the internationally successful Indian pharmaceutical companies are significantly different from those of the biotech firms in the US and Europe. They suggest that the Indian business model made more financial sense and provided more stability than that of their EU and US counterparts. The Indian firms follow a 3-step strategy for steadily increasing their cash generative capability. The first step is to make generics for the

home market to become financially secure. The second step is to target the generics markets in the US and Europe to provide a financial boost through increased sales revenue. The final step is to develop in-house capability in drug discovery and development. In contrast, the Western biotech firms start with an initial discovery capability, attract finance and complementary expertise through strategic alliances with pharmaceutical companies, venture capital and public equity finance, and become profitable at a much later stage (Bower & Sulej 2007).

The base of the model adopted by Indian firms is what Prahalad describes as the 'fortune at the bottom of the pyramid' with some of the most effective sales occurring at the lowest threshold of consumer markets (Prahalad 2005). For example, despite being in the top ten firms in the domestic market, Ranbaxy and DRL both draw more than half of their sales revenue from overseas markets, where the potential of lucrative returns is significantly higher than in India. However, in the rapidly changing industrial landscape, different Indian firms are likely to adopt different business models. Based on Ernst & Young (cited in FICCI 2005), Figure 4.8 shows different business models adopted by Indian pharmaceutical companies.

Figure 4.8: Changing business model of India's pharmaceutical industry



Source: Based on Ernst & Young cited in FICCI (2005).

Model-I represents the fully integrated companies with capability to undertake drug development, manufacturing and marketing. A number of leading Indian firms pursue

this strategy. For example, DRL is fully integrated company with subsidiaries in the US, UK, Germany, Brazil, Russia, New Zealand, Turkey and Mexico, and joint ventures in Australia, China, and South Africa (DRL website). Companies such as Ranbaxy and DRL have now enhanced their capabilities to conduct original research. Biocon, a leading Indian biotech firm, launched BIOMAb EGFR for cancer in 2006. This is the first indigenously developed medicine in India (Mazumdar-Shaw 2007).

Model-II describes companies with their own facilities to reverse engineer and manufacture, and market off-patent generics. This model is less capital intensive relative to Model-I, because it does not require investments for developing new drugs. The primary business of companies pursuing this model remains the manufacture and export of generics. A large number of domestic firms pursue this strategy and serve the local, regional and overseas markets.

Model-III describes the typical contract research organisations (CROs) specialising in undertaking research and development functions on contract from other firms. The services of a typical CRO include providing pre-clinical leads and conducting clinical trials. These contracts could take different forms, such as licensing deals with milestone payments or royalties upon successful development of a drug. Anticipating significant growth in contract research, a number of Indian companies have floated separate entities dedicated to R&D. For example, Biocon's Syngene for pre-clinical discoveries and Clinigene for clinical trials, DRL's Aurigene Discovery Technologies and Sun Pharma's Sun Pharma Advanced Research Company (SPARC) are separate business entities dedicated to contract research (CROs) (Kamath 2007).

Recently, Ranbaxy and GSK signed a co-development agreement under specific conditions. GSK will provide Ranbaxy the leads on compounds to screen them for optimisation and conduct pre-clinical tests and GSK will take care of the human trials. The two firms will co-promote the product in India while GSK will retain exclusivity in the developed markets. Other major contracts include AstraZeneca and Torrent, Biocon owned Syngene with BristolMyerSquib (BMS), Dyax Corp with Glenmark, and Johnson & Johnson with The Chatterjee Group (TCG) (company websites).

Revenue of India's pharmaceutical research industry has been growing at 40-50 per cent annually and is expected to reach $1 billion by 2008 (FICCI 2005). This is due to a significant number of 'big pharma' companies engaging in R&D agreements in countries, where the costs of developing of a new drug are significantly lower than in the developed countries. An analysis of the R&D expenditure by FICCI (2005) reveals the level of potential savings if the work was carried out in India. In 2005, an estimated US$60 billion was spent globally on pharmaceutical R&D comprising US$21 billion for discovery and development and US$39 billion for clinical testing. According to FICCI, if outsourced to Indian firms this would translate into US$7 billion (at one third of $21billion – the US/EU costs) and US$7.8 billion (at one fifth of $39 billion – the US/EU costs) at Indian prices representing a potential savings of more than $45 billion (FICCI 2005, p. 6). Other experts estimate the R&D and manufacturing costs in India to be even lower. For example, international observers such as KPMG (2006b) estimate the discovery and development costs in India to be about one eighth and the clinical trials around one tenth of western levels.

Shifting drug development to India also has a number of other reasons. India has a large pool of patients with diverse range of diseases. India's regulatory framework with regards to clinical trials is significantly less complex than the frameworks in the US and other developed markets (Heinen & Perry 2006). With the recent advances in information and technology, India offers low-cost streamlined data management facilities. After the US, India also has the second largest English speaking highly skilled workforce employable at around one fifth to one sixth of the cost that in the US. For example, a chemist with PhD costs $15,000 p.a. compared with $100,000 in the US (Bower & Sulej 2007, p. 616). Under the current framework, drugs developed in India are free of price controls for the life of the patent (Government of India 2005a). This provides incentives to develop new drugs in India and charge monopoly prices. The Indian law also provides a 150 per cent weighted tax deduction on in-house R&D expenditure (Government of India 2002d).

Pfizer, Novartis, and AstraZeneca have established their own R&D facilities in India with a focus on clinical trials. DuPont is investing over $22 million in a biotech research centre at Hydarbad. Pfizer is involved in 20 clinical trials while Eli Lilly in 17, and GSK in 7, and the clinical trials market in India could be worth $300 million

by 2010 (KPMG 2006b). An industry report on India's leading 100 pharmaceutical companies indicates that 57 companies are engaged in drug discovery, 41 companies in contract manufacturing, 22 companies in clinical trials, and 26 companies in contract research (Cygnus 2005). However, these figures suggest that some of the companies pursue mixed strategies and engage in all of the above activities.

Model-IV describes companies undertaking contract manufacturing. With the governments worldwide trying to contain the escalating healthcare costs, the pharma industry is forced to reduce to the R&D and manufacturing costs. It is not surprising that an increasing number of MNCs are outsourcing drug manufacturing to India, because the manufacturing costs are significantly cheaper in India than in the US/EU (KPMG 2006b). According to KPMG (2006a), the global size of contract research and manufacturing (CRAM) was estimated to be around $48 billion in 2007. Selected contract manufacturing agreements are shown in Table 4.12. This model has significant advantages for both parties. The Indian firms are confined to manufacturing and not concerned with the product sales or market fluctuations. The overseas partners could neutralise the low-cost advantage Indian firms have developed and compete in the US and European markets against other Indian firms. This could intensify the competition and lower the prices increasing access to medicines in the respective markets in the short term. In the long term however, this intensification could also drive Indian firms out of those markets and reduce access to medicines.

A number of factors are hampering the small pharma companies from tapping into the lucrative contract manufacture business. First, small companies are likely to have the capability but not the capacity to contract manufacturing of large volumes for the big pharma companies. Second, it is unlikely that the small manufacturing units would have compliance certification from the regulatory authorities, such as the US FDA (US), TGA (Australia), or MHRA (UK), hindering manufactured products from being exported. The small manufacturers are also unlikely to have Good Manufacturing Practices (GMP) compliance certification forfeiting the potential for contract manufacture for the supply to the domestic market.

Model – V represents companies forming alliances for co-marketing products in new markets. These collaborations are designed to help manufacturers with promising product lines but lacking distribution and marketing strengths to launch products in the global market (Mathew, J 2006). In 2006, Ranbaxy acquired a 10 per cent stake in the Hyderabad based Zenotech Labs to launch the latter's injectible oncology products under its own label in the international markets.

Table 4.12: Select contracting manufacturing agreements with Indian companies

Indian company	Overseas partner	Outsourced products
Cadila Healthcare	Altana	Intermediates for Altana's on-patent molecule protonix (pantoprazole)
Hikal	Degussa	Intermediates and active pharma ingredients (APIs)
Nicholas Piramal	AMO	Neutralizing tablets and sterile FFS apcks
Nicholas Piramal	Allegan	APIs for Levobunol (Betagen) and Brimondine (Alphagen and Alphagen-D)
Nicholas Piramal	Pfizer	7 year agreement related to R&D under which NPML will provide process development
Dishman Pharma	Solvay	6 projects: the main one for base material and advanced intermediate for Tevetan.
Dishman Pharma	AstraZencea	Intermediate for Nexium (esomeprazole)
Dishman Pharma	Merck	Intermediate for Losartan
Shasun Chemicals	GSK	Ranitidine API
Shasun Chemicals	Eli Lilly	Nizatidine, Metohexital and cycloserine APIs

Source: Based on KPMG (2006b).

Leading Indian companies are becoming MNCs themselves with acquisitions of overseas firms incorporating global marketing opportunities into their business model. Table 4.13 below shows a selection of overseas acquisitions by Indian firms. It should be noted that the main focus of all the acquisitions has been generics expansion into wealthy markets. While the size of the Indian acquisitions is relatively small compared with that of the big pharma companies, it provides the Indian companies a foothold into the wealthy markets. The acquired firms have established sales revenue, experience in the local markets and infrastructure for marketing the acquirer's products.

There is yet another business model emerging in the Indian pharma industry and may become quite important in the wake of the TRIPS agreement. As noted above, under the TRIPS agreement, the least developed countries (LDCs) have till 2016 to implement the agreement meaning that the reverse-engineering model can be continued to manufacture and export cheaper versions of patented drugs out of these 49 countries (Chadha 2006). Consequently, Indian pharma companies may shift their manufacturing bases from India to LDCs (Mueller 2007b). Sun Pharma, one of the leading Indian firms recently inaugurated its manufacturing facility in Bangladesh.

Another Indian company, the Ahmedabad based Cadila Pharma was expected to set up its manufacturing plant in Ethiopia in 2007 (Babu 2007). This model provides significant advantages at least till 2016 over the current regulatory environment in India.

Table 4.13: Select foreign acquisitions by India pharma

Year	Acquirer	Target	Country	Transaction value US$ million
1995	Ranbaxy	Ohm Labs	United States	n.a.
1997	Sun Pharma	Caraco	United States	7.5
1998	Wockhardt	Wallis	United Kingdom	9
2000	Ranbaxy	Basics	Germany	8
2000	Ranbaxy	Veratide	Germany	5
2001	Zydus Cadilla	German Remedies	Germany	n.a.
2002	Ranbaxy	Signature	United States	n.a.
2002	Unichem	Niche Generics	United Kingdom	5
2002	Dr. Reddy's	BMS	United Kingdom	16
2003	Wockhardt	CP Pharma	United Kingdom	20
2003	Zydus Cadilla	Alpharma	France	6.6
2003	Sun	Caraco	United States	42
2004	Ranbaxy	RPG Aventis	France	84
2004	Glenmark	Lab Klinger	Brazil	5
2004	Dr. Reddy's	Trigenesis	United States	11
2004	Jubilant Organosys	PSI group	Belgium	16
2005	Dishman	Synprotec	United Kingdom	n.a.
2005	Malladi	Novus	United States	19m Euro
2005	Matrix	22% of Docpharma	Belgium	217m Euro
2005	Torrent	Heumann Pharma	Germany	n.a.
2005	Strides Acrolab	NA	Poland	8
2005	Strides Acrolab	>50% of Beltapharma Spa	Italy	1.9
2005	Sun	Valeant	Hungary	n.a.
2006	Dr. Reddy's	Betapharm	Germany	$570

Source: Based on various company reports; Kaul (2004); Kamath and Krishnan (2004); Taylor (2005) and FierceBiotech (2006).

The regulatory changes made to the patent regime in India have created an environment in which the previous business models are being modified or discontinued. Some large firms have opted for full integration into the global pharma, while others have adopted a mixed strategy. A number of firms have opted for forming alliances with large MNCs for drug development and marketing arrangements. The number and size of the Indian firms with a potential for full integration into the global pharma is quite small. The Indian pharma industry appears to be settling for a subservient role to the MNCs that have significant marketing power and large capital. One risk of these changes occurring in the industrial

landscape is that the longer-term future of the small Indian manufacturers, which can play a crucial role in the supply of low cost drugs, may be jeopardised.

4.6 Conclusions

This chapter has painted a picture of how India's pharmaceutical industry developed initially under the protection of the anti-competitive government policies introduced in the 1970s, and subsequently continued its rapid growth even after the introduction of industrial de-licensing as a part of the economic reforms in 1991. Today, the Indian pharmaceutical industry has grown into a globally competitive indigenous industry that is increasingly integrating into the global industry through not only imports and exports, but also via FDI, outsourcing and contracting arrangements with overseas partners. While overseas MNCs once dominated the Indian pharmaceutical market, they now account for less than a quarter of the domestic market. Leading domestic firms generate significant share of their revenues in overseas markets. But the industry has a large number of small manufacturing firms that account for around half of the domestic supply by volume.

A net importer of pharmaceuticals until the late 1980s, India is now a net exporter of pharmaceuticals. The economic liberalisation and the reforms to industrial policies introduced since 1991 provided a boost to India's exports of pharmaceuticals. The highly regulated markets, including the US, are the top ten destinations for India pharmaceutical exports. India's pharmaceutical industry has also contributed significantly to increase access to medicines in the developing countries as well as in the industrialised markets.

Access to medicines has also increased from less than one-fifth of India's population in 1980 to more than one-third by 2001. While this is an impressive achievement, two-thirds of India's population still remains without access to medicines. It was noted in the preceding discussion while the large number of small pharmaceutical firms have played an important role in expanding access to medicines in the domestic market, the large firms have helped the situation in other countries by exporting less expensive medicines.

China now accounts for around a third of India's pharmaceutical imports, suggesting a shift away from the traditional suppliers of Germany, France, the UK and the US. In the wake of the patent regime change, imports are likely to increase as patented drugs are likely to be introduced but not manufactured in India. With the revocation of the policy that forced the MNCs to manufacture bulk drugs and formulations in India, the MNCs are likely to increase imports leading to higher drug prices.

It has been suggested that foreign direct investment (FDI) into the pharmaceutical industry is not only influenced by the protection of intellectual property rights (IPRs). Other factors, including R&D and manufacturing costs, availability and costs of skilled labour, exports potential, and compliance certification for quality also play a significant role in investment decisions of overseas firms. While the pharmaceutical sector has become one of the top ten industries to attract foreign investments in recent years, it is unlikely that foreign investments would lead to developing medicines for tropical diseases.

In the wake of the recent changes to the industrial landscape, India pharmaceutical firms have adopted a mixture of new business models. Leading Indian pharmaceutical companies are expanding through overseas acquisitions and exports now constitute a significant share of their annual sales revenue. Other firms are opting for alliances and contract manufacturing roles. There are indications that some Indian firms may relocate their manufacturing operations to the least developed countries (LDCs) to take advantage of the delayed implementation of TRIPS in those countries. The survival of small manufacturers could be jeopardised by the changing dynamics in the market, which would be counterproductive from the access to medicines perspective. With the abolition of highly protective measures that once favoured the domestic Indian pharmaceutical industry, the new industrial landscape foreshadows significant challenges for the indigenous players.

Chapter 5

TRIPS and the Indian Patents Regime

5.1 Introduction

This chapter discusses the recent amendments to India's patent regime as a consequence of the implementation of the TRIPS agreement. Also examined is the general apprehension that the new patent regime might put an end to India's supply of low cost imitations of patented drugs, which have helped in extending access to medicines in the poor countries. A systematic examination is undertaken of India's exports to assess the impact of the new regime on India's ability to continue the exports of low-cost drugs.

As a continuation of the government's policy shift towards economic liberalisation in 1991, India signed the WTO agreements in 1994, including the TRIPS agreement. As noted in chapter 4, the developing countries were given till 2000 to amend their patent regimes (Article 65.2)[21] and a further five-year period was given to those countries that did not previously grant product patents (Article 65.4). India fell into the latter category and, therefore, was required to comply with the TRIPS agreement by 1 January 2005.

The rest of the chapter is set out as follows: Section 5.2 describes the changes made to India's patents regime in the wake of TRIPS and discusses their impact on the pharmaceutical industry in India. Because the new patent regime involves a large number of changes, including several flexibilities, such as compulsory licensing and parallel imports, Section 5.2 has become quite a long section. Section 5.3 discusses the impact on innovative activities with a focus on research and development of the Indian pharmaceutical sector, including the role of the government in promoting innovation. Section 5.4 provides the main conclusions.

[21] Articles refer to the TRIPS agreement.

5.2 India's Patents Regime and its impact on the pharmaceutical industry

India's patent regime is fairly young relative to the developed world. Venice enacted its first patent statute in 1474, Germany issued its first patent in 1484, and colonial India first introduced patents protection in 1856. Since then, India's patent regime has undergone a number of reforms to reflect the government policy on the industrial framework (see Table 5.1). The first Act relevant to the modern pharmaceutical industry was the Indian Patents and Designs Act 1911. This Act provided patents for pharmaceutical *products* and *all known* and *possible processes* for 16 years extendable by another 10 years if the patent had not generated sufficient returns for the patent holder (Lalitha 2002).

Before the World War-I, India had less than a dozen indigenous companies. The Indian Patents and Designs Act 1911 restricted growth of the indigenous industry by denying opportunities to participate in the manufacture of new drugs. By granting patents on all *known* and *possible processes* to manufacture the patented drug, this Act denied further innovation around the patented drug that is common to the pharmaceutical industry. For example in recent years, Eli Lilly, a large MNC took out 56 patents in the US on the known processes to manufacture Cefaclor. Ranbaxy, a leading Indian firm successfully developed a non-infringing process to manufacture the same drug and licensed the process back to Eli Lilly for a substantial remuneration (Rangnekar 2005). A series of 50:50 joint ventures followed in the wake of Eli Lilly's recognition of Ranbaxy's superior research capabilities (Lanjouw, J 1998). Opportunities for this type of follow-up innovation were denied under the Patents and Designs Act 1911 till the Patent Act 1970 was introduced in India.

The most significant change to shape the indigenous pharmaceutical industry model was the introduction of the Patents Act 1970 (the 1970 Act). In contrast to its predecessor, the 1970 Act (enacted April 1972), abolished product patents for drug (and food and agricultural products) and pharmaceuticals, and recognised only a single process actually used in the manufacture limiting the protection to seven years from date of filing or five years from date of grant whichever was shorter (Government of India 1972). The 1970 Act effectively meant that every drug was potentially generic and firms could manufacture new drugs using a different process

immediately after a patent was granted. Indian firms developed skills to copy new drugs by 'reverse engineering' and reproduce the same drug using a different production method.

Table 5.1: History of Indian patent system at a glance

1856	The Act VI of 1856 on protection of inventions of innovators based on the British Patent Law of 1852. Certain exclusive privileges granted to inventors of new manufacturers for a period of 14 years.
1859	The Act modified as Act XV; Patent monopolies called exclusive privileges (making, selling and using inventions in India and authorizing others to do so for 14 years from the filing date).
1872	The Patents & Designs Protection Act.
1883	The Protection of Inventions Act.
1888	Consolidated as The Inventions & Designs Act.
1911	The Indian Patents & Designs Act.
1972	The Patents Act (Act 39 of 1970) effective from 20 April 1972.
1999	The Patents (Amendment) Act (1999) retrospective from 1 January 1995.
2002	The Patents (Amendment) Act (2002) effective from 20 May 2003.
2005	The Patents (Amendment) Act (2005) of 5 April 2005 retrospective from 1 January 2005.

Source: Based on Government of India (2006d).

The rapid growth of the domestic pharmaceutical industry attracted a large number of new entrants resulting in increased industry competitiveness and lowered drug prices not only in India but also in other countries. With a large pool of English speaking low cost manpower skilled in engineering and chemistry in India, the elimination of product patents provided ample opportunity for capacity building in pharmaceutical innovation and increase efficiency. Low manufacturing costs made it possible to significantly reduce the prices of copies of on-patent drugs in India as well as in developing countries with weak patent regimes. The Indian pharmaceutical industry enhanced institutional capabilities to manufacture processes for simple antibiotics to complex drugs used in treating HIV/AIDS, cancer, and cardiovascular diseases.

Before 1984, the United States Food and Drug Administration (USFDA) did not allow generic manufacturers applications for marketing approvals to rely on the test and other data submitted for a new drug application by originator companies (Baker 2008). With the introduction of Hatch-Waxman Act 1984 in the US, the generic manufacturers could submit an abbreviated new drug application (ANDA) with the proof of bioequivalence to the originator drug (Clements 2007-08). This change in the US law saved generic manufacturers significant costs of conducting their own tests and created opportunities for early introduction of generics. On the one hand, Indian manufacturers began entering the markets of developed countries with generic versions of blockbuster drugs at very low prices (Lanjouw, J 1998). The industry began to realise the enormous potential and shifted its focus from manufacturing

reverse-engineered copies of patented drugs to producing generics for off-patent drugs for exports to lucrative markets such as the US (Malhotra 2008).

On the other hand, India was supplying low-cost imitations of on-patent drugs to a large number of poor countries. The role of India's pharmaceutical industry in lowering the drug prices and increasing access to medicines in both developed and developing countries became particularly evident in the supply of antiretrovirals (ARVs) used for treatment of HIV/AIDS (Narrain 2005). For example, Indian firms supply 84 per cent of the AIDS drugs used by Medecin Sans Frontiere (MSF) to treat thousands of patients across 30 countries (Mueller 2007a) (more details are provided in Chapter 4).

As a signatory to the WTO agreements signed in 1994, India was obliged to change its patent regime by 1 January 2005. India adopted a three step approach to make its regime TRIPS compliant. In accordance with the conditions set out for the Transitional Arrangements in the TRIPS agreement, India introduced the [first] Patents (Amendment) Act 1999 to provide a mailbox for filing product patent applications. While the actual processing of these applications did not begin until after the introduction of product patents in 2005, the mailbox was designed to establish the filing dates for patent applications. Under the [first] Amendment, companies applying for product patents through the mailbox could also apply for Exclusive Marketing Rights (EMRs) for a period of up to five years or till the date of grant or rejection of the patent application whichever was shorter. Under the conditions set out in the TRIPS agreement, the EMRs would be granted provided a patent for the drug was obtained in a WTO member state after 1995 (when TRIPS came into effect), as well as marketing approval for the drug was also obtained in that country (Article 70.9). The EMRs practically had the same effect as a patent driving existing generics out of the market and supplying the drug under monopoly prices. See the case of Glivec for example in Box 5.1.

Box 5.1: Exclusive Marketing Rights (EMRs) in India

India grants first EMRs
Novartis became the first company to obtain EMRs in India. Under Patent application No. 1602/Mas/98, Novartis filed a patent application for Glivec (imatinib mesylate) with the Indian authorities on 17 July 1998. Glivec is used to treat Chronic Myeloid Leukemia (CML) and was launched in India in 2002. In November 2003, the company was granted EMRs for five years for Glivec and a notification was published in the Gazette of India on 13 December 2003. The cost of Glivec at Rs 1,20,000 per month compared with the price of generic versions of the same drug already in the market at around Rs10,000 per month (Jatania 2004). After EMRs were granted, Novartis obtained an injunction from the Madras High Court barring domestic firms including Ranbaxy, Cipla, and Sun Pharma from producing andr marketing the generic versions of Glivec. The grant of EMRs to Novartis was challenged by a number of parties including NATCO an Indian manufacturer of the generic version, the Indian Pharmaceutical Alliance (IPA) representing leading domestic firms including Ranbaxy, and the Indian Drug Manufacturers' Association (IDMA). The challengers argued that the patent on the active pharmaceutical ingredient (API) imatinib mesylate was filed before the deadline of 1 January 1995; namely in the US on 28 April 1994 and in Canada on 1 April 1993 (Narula 2004). It was argued that Glivec was a modified form of an existing compound; therefore the subject matter was neither patentable in India and nor eligible for EMRs. The Mumbai based Cancer Patients' Aid Association (CPAA) also filed a writ petition in the Supreme Court of India challenging the grant of EMRs to Novartis. It was argued that the absence of low cost generics would effectively mean denying the Right to Life enshrined in the Article 21 of the Indian Constitution. The government is responsible to its people and hence, must maintain control over the prices of life-saving drugs, suggested the CPAA. After considering the arguments of various parties, the Controller on 25 January 2006 rejected the patent application and terminated the EMRs granted to Novartis (Government of India 2006h). Novartis appealed against the termination and was awaiting the outcome.

Source: Based on authors cited in the Box.

The grant and revocation of EMRs for Glivec raise a number of questions for different stakeholders. First, the domestic firms were locked out of the market as a result of EMRs granted to Novartis in the above case for more than two years. Consequently, the domestic firms incurred loss of potential sales and income. Currently, there is no provision for automatic compensation for loss of potential sales/income for the barred generic manufacturers. If the generic manufacturers were to take a collective action, who would be responsible for compensating the domestic companies? Would it be Novartis as the beneficiary of the EMRs, or the Indian State as the administrator of the framework and grantor the EMRs? Second, the drug price in this case was raised 10-12 times of pre-EMRs scenario forcing patients and their families into unnecessary hardship. Healthcare costs are one of the major reasons for household indebtedness often resulting in sale of family assets (Government of India 2006e). If the monopoly price of Glivec charged under the EMRs led to the sale of such assets, who would be responsible to compensating the families and restoring the rightful ownership of the sold family assets? Under the provisions for drug price controls, India collects the over-charged amount from the pharmaceutical companies and places these amounts in a special account. India could consider introducing a similar framework to collect the difference between the lowest priced generic and the price actually charged by the right holder, and distribute the amount among the rightful stakeholders. This method

may not deter all frivolous claims, but it would provide a framework to reclaim the over-charged price. Provision of such a framework would be expected to avoid or at least minimise recurrence of Glivec like situations under grant of patents.

The [second] Patents (Amendment) Act (2002) introduced changes to patentable subject matter, extended the term of protection to twenty years, and changed conditions for compulsory licensing. This amendment also shifted the onus to the alleged infringer in patent infringement disputes. The first and second amendments laid the ground work to introduce the final amendment.

The third and final amendment to the Patent Act 1970 was delayed, because the Indian Parliament got dissolved in early 2004 in preparation for general elections. Initially, the coalition partners in the new government under Prime Minister Manmohan Singh could not agree on the terms of reference for the final Bill. Consequently, a President's Ordinance was issued in December 2004 to ensure India became TRIPS compliant from 1 January 2005. In March 2005, after reaching consensus, the [third] Patents (Amendment) Act (2005) was passed through both Houses of the Indian Parliament (Bill No. 32-C of 2005).

The Patents (Amendment) Act 2005 introduced product patents for pharmaceuticals and drugs. The Patents Act, as it stands now, has the following implications. The domestic industry's previous practice of reverse engineering and manufacturing of imitations of patented products has been disallowed. Consequently, the absence of market competition is likely to raise the drug prices and restrict access to medicines. The extension of patent term from 7 years to 20 years will delay the entry of generics. The so-called 'Bolar provisions' under the current Act allow generic manufacturers to conduct necessary tests and prepare for the drug launch. However, the actual launching of generic versions of a patented drug cannot take place until the patent expires. Under the new Act, the onus of proof for non-infringement rests with the alleged infringing party in a patent litigation. Under the previous regime, the alleger (patent holder) had to prove the infringement by the alleged party. Now the alleged infringer has to provide burden of proof, which is a significant departure from the doctrine of 'presumption of innocence'. Under fear of prosecution, the domestic companies could stop engaging in innovative activities that may involve the risk of

potential patent litigation. The major differences between the pre- and post-TRIPS Patent Act are summarised in Table 5.2. Other main points covered by the amendments are considered below.

Table 5.2: Major differences in the pre- and post-TRIPS Patent Act

	Pre-TRIPS		*Post-TRIPS*	
Category	Patent Act 1970	Implications	Recent amendments	*Implications*
Product patents	No	Able to reverse engineer and reproduce.	Yes	*Reverse engineering disallowed*
Process patents	Patent granted on a single process actually used for manufacturing	Easy to follow up with a new process	Multiple processes patentable	*Difficult to develop a non-infringing process*
Patent term	7 years from date of filing or 5 years from date of grant whichever is shorter	Relatively short term	20 years from date of filing	*Relatively long term for monopoly rights*
Pre grant opposition	Yes	Allows the opportunity to object before patent granted	Yes	*Allows the opportunity to object before patent granted*
Post grant opposition	No	N/A	Yes, within 12 months of grant of a patent any person can submit/lodge a claim disputing/objecting the patent	*Allows the opportunity to raise concerns after patent has been granted*
Compulsory licensing (CL)	After 3 years of grant of patent	Practically unrestricted applicability	After 3 years of grant of patent under specific conditions	*Only for domestic market supply*
Exports under CL	Unrestricted	For domestic or exports	Under Section 92A (1) conforming to 30 August Decision of the WTO	*Only under specific conditions including labelling to prevent re-export*
Data protection	N/A	N/A	Yes, against unfair commercial use. No data exclusivity	*Possible disputes with delays to introducing generics*
Patent infringement disputes	*Onus on the patentee to prove the infringement*	*No or few disputes*	*Onus on the alleged infringer to prove non-infringement*	*Escalation of disputes. Small domestic firms likely to shy away from innovation*

Source: Based on Government of India (1972, 1999, 2002b, 2005d).

The Patents (Amendment) Act (2005) provides product and process patents for food, drugs, and pharmaceuticals. The new Indian regime provides patents for any invention granted under this Act. Patentable inventions must involve an inventive step defined as '*a feature of an invention that involves technical advance as compared to the existing knowledge, or having economic significance, or both*' (Section 2 (1)(ja). The expression '*economic significance*' in the new law is neither a classical patentability criterion nor does it have anything to do with inventions (Ram 2006). Under this principle, the Patents Controller assesses the economic significance of an invention based on the data furnished by the patent applicant. This practice places a question mark on the application of the principle itself. This is because there is no evaluation of the application based on the input of any independent data. The data

supplied by the applicant itself is likely to have a bias favouring the application that is likely to influence the Controller's decision.

The following subject matter is not patentable under the new regime:

> ... The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of the substance or the mere discovery of any new property of new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. (Section 3(d))

The provisions of Section 3(d) have the following implications. A new use or a new form of a known substance as such would not be patentable. It is not uncommon for pharmaceutical companies to find new uses or new forms of existing drugs and seek patent extensions on the basis of these discoveries in a number of countries including Australia, but such extension is not a TRIPS requirement. For example, the first patent on Zidovudine, one of the antiretrovirals, was filed in 1964. Counting 20 years from date of *first* filing, the patent should have expired in 1984. Yet, the patent on the drug in a large number of countries, including the US, is technically still valid (Shah as cited in Hiddleston 2007). This is because the patent holders keep finding new ways to extend the patent term. According to IMS (2004), patent on the combination of Zidovudine, Lamivudine, and Indinavir in most countries, including Australia, is due to expire in 2016 or later. In the US, the patent on Merck's Crixivan (combination of the three drugs) is due to expire in 2021 with a possibility of further extension (IMS Health 2004). The Orange Book of the Food and Drug Administration shows that there is no patent on Zidovudine as such. Patents on Lamivudine and Indinavir are due to expire in 2011 and 2012 respectively (FDA 2008). Yet, the manoeuvrability permitted under the US law allows companies to add around ten years of patent rights on a combination of the three drugs. This is because countries such as the US and Australia grant patent extensions for new uses (indications) of existing drugs. This type of perpetuation of patents would not be possible under the Indian law.

The process of seeking patent extensions based on such manoeuvrability is known as ever-greening in the literature (House of Commons Health Committee 2005). Section 3(d) is designed to prevent ever-greening. But there are practical difficulties in implementing the provisions of this clause. For example, Section 3 (d) requires evidence of enhancement of known efficacy of the substance. Proving the difference

in efficacy at the time of filing a patent application is not practical. Patents are usually filed at the early stages of drug discovery. The efficacy of a drug is established during clinical trials. The process of clinical trials (on human subjects) follows the pre-clinical testing (on animals). It takes several years for the entire process of clinical trials to establish efficacy.

Novartis, a Swiss MNC, alleges that India's Section 3(d) breaches the TRIPS agreement. Under the TRIPS agreement, member countries are required 'to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability' *(*Article 27.1*)*. What constitutes an invention is not however defined in the agreement. India does not provide patents for 'the mere discovery of any new property of new use for a known substance or of the mere use of a known process' (Section 3(d)). India views these discoveries frivolous and denies patents. Novartis alleges that this denial by India contravenes the requirements of the TRIPS agreement.

A number of studies support the Indian view. In the early part of the 20th Century, a committee was established by the United Kingdom Government to examine issues related to patent medicines. The findings of the Select Committee on Patent Medicines (1914) included:

- that the [patented] remedies are of a widely differing characters, comprising (a) genuine scientific preparations; (b) unobjectionable remedies for simple ailments; and (c) many secret remedies making grossly exaggerated claims of efficacy;

- that this last-mentioned class (c) of [patented] remedies contains none which spring from therapeutical or medical knowledge, but that they are put upon the market by ignorant persons, and in many cases by cunning swindlers who exploit for their own profit the apparently invincible credulity of the public; and
- that this [practice] constitutes a grave and widespread public evil … (House of Commons Health Committee 2005, p. 7)

The above findings suggest that even at that time, firms in the pharmaceutical industry did not hesitate from trying to obtain patents on frivolous claims. While the firms and the industry have changed significantly since then, the will to exploit the consumer to the maximum, has only intensified. House of Commons Health Committee (2005), when the patent on a product expires, the originating company is deemed to have been rewarded for risks of innovation. Yet, originators keep inventing new ways to extend the periods of exclusivity. Almost 100 years after the first inquiry in the UK, the industry is better equipped and more aggressive than ever to test the regulatory framework and extend the monopoly rights well beyond the intention of the law. For example, the European Commission recently launched an investigation into the pharmaceutical industry, because the Commission had information indicating that the industry competition may be restricted or distorted. The preliminary report suggests that the innovator companies use 'a tool-box of instruments aimed at ensuring continued revenue streams for their medicines' (European Commission 2008, p. 401). In some cases, up to 1,300 patents were filed for a single drug as a strategy to keep competitors out of the market, notes the Commission. Strategies such as these make a mockery of the spirit of rewarding innovators for disclosing their innovations to public. In the name of promoting innovation, this blatant abuse of the system is, in fact, harming the future of innovation. In light of the reports of the House of Commons Health Committee and the European Commisson, the Indian law appears to be rightfully proactive in preventing the frivolous claims.

Novartis filed a writ challenging the Section 3(d) of the Patent Act in the Madras High Court[22] in 2005. The challenge was widely viewed as a test case between the MNCs and India. The writ attracted worldwide condemnation of the company action by health activists, NGOs and a significant number of countries including Norway and Germany. More than 420,000 people worldwide, including Nobel Laureate Archbishop Desmond Tutu and the former Swiss president and health minister Ruth Dreifuss, signed a petition calling upon Novartis to drop the case (Bidwai 2007). In February 2007, the European Parliament in a written declaration called upon Novartis to 'withdraw its complaint in order to guarantee continued access to affordable

[22] The High Court is the highest court in a state/province. The Supreme Court is the apex court of India.

generic medicines for all' (European Parliament 2007, p. 2). Mueller (2007a), a legal expert opines that Section 3(d) of India's Patent Act 'does not necessarily impose stricter requirements than are used elsewhere', (p. 543) negating the Novartis writ. Basheer (2008), a renowned expert on intellectual property also suggests that every country needs to calibrate the pharmaceutical patent protection in accordance with its own national circumstances and Section 3(d) is, in many ways, an example of that calibration by India (cited in Kumar 2008). In August 2007, the Madras High Court rejected the Novartis legal challenge. The Court held that the arguments put forward by Novartis would limit competition and reduce access to medicines, especially for the poor who cannot afford the expensive drugs for cancer and other diseases. Novartis has now lodged an appeal with the Supreme Court of India.

Provisions to oppose the grant of patents

The patent applications can be opposed before or after the patent is granted. Under the Patents and Designs Act 1911, India first introduced the provisions for pre-grant opposition to pending patent applications. The provisions for pre-grant opposition were carried forward into the Patents Act 1970 and have also been retained in the 2005 amendments. After a patent application has been published and the patent has not yet been granted, *any person* can submit an application opposing the grant of such patent. Along with Brazil and Jordan, India remains one of few countries to have pre-grant opposition provisions (Mueller 2007b).

Under the President's Ordinance in 2004, India also introduced provisions for post-grant opposition and retained these provisions under the 2005 amendments. The post-grant opposition has to be filed within 12 months of the grant of patent. The post-grant opposition applications would be heard by a three-person Opposition Board that must not include the original patent examiner. Should the patent be revoked, the patent holder may appeal to the Appellate Board.

At this stage of development of India's pharmaceutical industry, the industry lacks patent literacy.[23] Pre-and post-grant opposition to patents provides additional opportunities for the domestic firms and other stakeholders to file counter claims. Pre-

[23] Defined as mastering the ability to read patents 'in such a way that you can bypass someone's invention,' and to write patents in such a way that nobody can bypass you'(Mashelkar 2003)..

grant opposition has an advantage over the post-grant opposition. Pre-grant opposition provides an opportunity to stop the patent before it is granted. Once the patent is granted and the product is launched in the market, the price is going to be considerably high under monopoly rights. Under post-grant opposition, the patients continue paying high prices while the case is waiting to be heard. The submission of pre-grant objections eliminates that possibility and shortens the period of monopoly prices even where companies may have obtained exclusive marketing rights pending their patent applications. Pre-grant opposition was instrumental in the rejection of patent application and revocation of the exclusive marketing rights granted to Novartis for Glivec (noted in Box 5.1).

Inserting the words *'any person'* in the opposition to grant of patents has provided opportunities for other stakeholders, such as NGOs and health activists, to lodge their objections with the Indian Patent Office. For example, the pre-grant opposition by the Positive Women's Network and the Indian Network for People Living with HIV/AIDS resulted in the rejection of the patent application filed by the German pharmaceutical company Boehringer Ingelheim for nevirapine syrup, used in the treatment of children living with HIV/AIDS. The opposition argued that the syrup formulation of nevirapine was a new form of a known drug first invented in 1989, and thus older than the 1995 cut-off date that India's Patents Act considers eligible for patenting (MSF 2008). A pre-grant opposition has also been filed against a patent application by GlaxoSmithKline (GSK) for its fixed dose combination of two AIDS drugs; namely, zidovudine and lamivudine or AZT/3TC (Combivir). This submission is based on a different technicality. A combination of known drugs is not an invention under the Indian law, and hence should not be granted a patent, argue the Indian Network for People Living with HIV/AIDS, the Manipur Network of Positive People, and the Lawyers Collective opposing the patent application (IP-Watch 2006). Cipla challenged GSK' patent on Combivir in the United Kingdom on the basis of 'lack of novelty' and Cipla won the case in 2004, but GSK's patent application for Combivir remains in the mail box in India (Gehl Sampath 2006).

In March 2006, Roche was successful in beating off the opposition and becoming the first company to obtain a product patent under India's new patent regime for Pegasys (peginterferon alpha-2a), which is used for treating hepatitis C (Jyothi-Datta 2006).

Wockhardt, an Indian drug maker has lodged a post-grant opposition challenging the Pegasys patent (Jyothi-Datta 2007). In December 2007, Pfizer obtained a patent on Maraviroc, first patent in India on an anti-AIDS drug. A number of NGOs, such as Lawyers Collective, were also considering a post-grant opposition to the Maraviroc patent (Managing Intellectual Property 2007).

Rising litigations

With the implementation of the new regime, patent litigations have emerged in India in growing numbers. In the short history of product patents in India, the number of litigations has been rising, as patent applications from the Mail Box are progressively published. The Indian situation is not uncommon however. Because 'with any new legislation, changes in terminology will likely result in uncertainty and litigation' (McEwan 2005, p. 62). In the initial stages of a new regime, litigations are a part of the evolutionary process. Litigants on both sides do everything in their power to set a precedent to favour their interests.

In India's case, the originator companies and the generics manufacturers are testing how different provisions of the Patent Act are interpreted. The originator companies are trying to impose their own interpretations of TRIPS in order to raise the protection level that of developed countries. The interests of the generic manufacturers lay in keeping the protection level to the minimum. If litigations focused on outcomes to provide certainties to encourage innovation, the litigations could be considered beneficial in the long run. But in recent years, originator litigants have become more focused on blocking the development of a new competing product rather than protecting an invention of their own (European Commission 2008). This development is counter-productive.

Dr. Hamied, Chairman of Cipla, warns that 'the new patent legislation will certainly lead to numerous litigations. It will herald an era of monopoly in vital and life-saving drugs in general that would be detrimental to the interest of the consumer' (cited in Cipla Annual Report 2004-05, p.9). The experience in the US shows that the launch of the first blockbuster drug Tagamet in 1976 changed the mindset of the industry, leading to a sharp increase in patent litigations in the US. The number of lawyers per

thousand population in the US, which had remained fairly stable between 1900 and 1970, tripled between 1970 and 1998 due to a boom in litigations (Caplow, Hicks & Wattenberg 2006), lending further indirect evidence to the argument advanced by Dr Hamied of Cipla. India already has a significant backlog of cases before the courts and does not need further increase in the number of cases. An expert estimates that India has over 38 million cases pending in courts and at current rates it would take nearly 320 years to dispose them (Debroy cited in Government of India 2007d). An escalation of the patent litigations would only add to the existing pile. Even if the patent related cases were given priority because of public health issues, further delays would occur to the cases in the queue to be heard.

India's Patent Act is still evolving and the country should consider including some measures to lessen the number of litigations. Perhaps consideration should be given to introducing a clause similar to that in Australia, where Section 26C of the Therapeutic Goods Act 1989 (as amended following the signing of the Free Trade Agreement (FTA) between Australia and the US) provides for the imposition of penalties of up to A$10 million for unnecessarily delaying the entry of generics in the market with frivolous claims. The aim of the amendment was to ensure that legal 'proceedings are not otherwise vexatious or unreasonably pursued' (Section 26C(4)(c)).

Introduction of a similar clause in the Indian legislation should have prevented the filing of several patents, including those filed by Novartis for Glivec and by Boehringer Ingelheim for Nevirapine. Both companies knew that the drugs they were trying to patent were registered elsewhere pre-1995 and would not qualify for a patent in India. Under the proposed clause, GSK would also be unlikely to apply for a patent on Combivir knowingly that *a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance* would not be patentable in India (Patent Act 1970, Chapter 2, Section 3). In a recent case, the High Court in Gujarat in Cadila Pharmaceuticals Limited v. Instacare Laboratories Pvt Ltd. [2001(21) PTC 472 (Guj)] held that 'development of a combination medicine by a pharmaceutical company does not amount to patentable invention' (Embassy of the United States 2008). Moreover, the UK court's ruling against the GSK would be a discouraging factor in lodging a patent application if India introduced a deterrent clause.

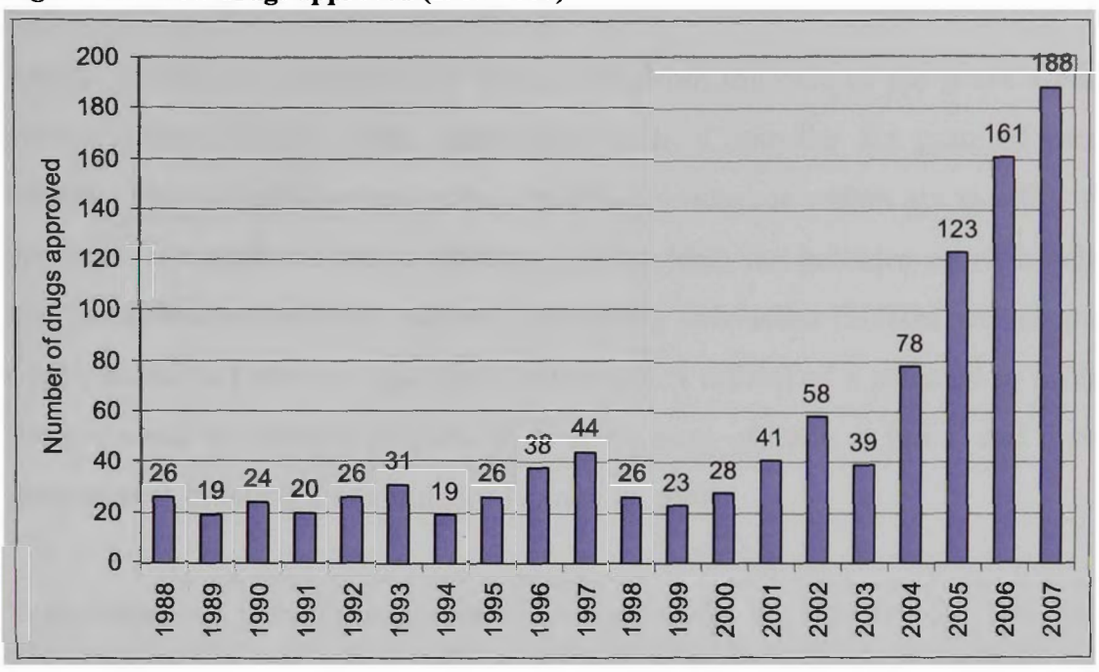
Companies already engaged in copying a product now under patent

Until 2005, Indian pharmaceutical companies reverse engineered patented products and produced imitations thereof. This was possible because India did not provide patents for pharmaceutical products as noted earlier. Under the regime introduced since 2005, copying a patented product and reverse engineering is disallowed. Prior to 2005, a large number of Indian firms were manufacturing drugs, for which patent applications have been filed under the new regime. Before the new regime was introduced, there was uncertainty in these manufacturers' ability to continue in the post-2005 scenario. However, according to the new regime, these manufacturers may continue to manufacture imitations of the patented product under conditions noted below.

A large number of the foreign patent applications in the mail box are expected to be for products the Indian companies had been copying under the pre-TRIPS regime. Under India's new patent regime, companies that had made significant investments and were already engaged in producing and marketing of copied versions of patented drugs prior to 2005 may continue without the fear of being prosecuted (Section 11A (7)). Nevertheless, the patent holders shall be entitled to receive a 'reasonable royalty' from the [Indian] enterprises. Up to year 2000, the number of new drugs approved was almost static, except for 1996 and 1997 when it slightly increased (see Figure 5.1) A significant rise in the number of new drug approvals can be observed from 2000 and a further rise from 2004 onwards.

Domestic companies took advantage of the transition period and launched as many products as possible before the 1 January 2005 deadline. By some estimates, there are over 12,000 patent applications submitted via the mail box (NISTADS 2005). More than 80 per cent of these applications belong to foreign MNCs (Ram 2006). In the absence of firm data, new drug approvals since 2005 shown in Figure 5.1 are expected to be the marketing approvals for drugs with patent application pending.

Figure 5.1: New drugs approved (1988-2007)



Source: Based on Government of India (2008c).

Compulsory Licensing

Compulsory licensing refers to a practice when a government allows someone else to produce the patented product or process without the consent of the patent owner (WTO 2006b). The TRIPS agreement does not use the term 'compulsory licensing', but refers to 'use without authorization of the right holder' (Article 31). Under the TRIPS agreement, compulsory licensing is one of the flexibilities and an important instrument for governments to provide patented drugs at lower prices and increase access to affordable healthcare (Abbott 2005). Under Article 31, reaffirmed by the Doha Declaration on TRIPS and Public Health, member states are free to determine the grounds for granting compulsory licences. India considered its TRIPS obligations and the requirements of its pharmaceutical industry in developing the grounds for compulsory licensing. Mueller (2007b) opines that India has 'the world's most elaborate compulsory licensing scheme' (p. 504). The provisions for compulsory licensing in the Indian Patent Act are representatives of India's interests and suitable to its industry needs. Moreover, these provisions are well within the guidelines for flexibilities provided under the TRIPS agreement.

Granting compulsory licences

Any time after the expiration of three years from the date of the grant a patent, *any person* interested may make application to the Controller for grant of compulsory licence. The Controller must grant compulsory licences within six months where the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions without any success. According to Mueller (2007b), certain provisions of the Indian act are so vague that 'virtually any refusal of a patentee to [voluntarily] licence could be deemed prejudicial to some form of trade in India' and result in the government granting a compulsory licence (p. 590).

With respect to granting compulsory licences under the new regime, two issues need to be considered. First, observers such as Ram (2006) argue that adding six months to grant the compulsory licence unnecessarily extends the waiting period from three years to three and a half years before the product can be supplied to the market. The waiting period could be shortened by allowing applications for compulsory licences before the three years period expires. This would allow the processing of applications within the three years. Alternatively reducing the six months period to grant the licence to a 30-day period would expedite the product to the market.

Second, the expressions 'reasonable terms and conditions' used in connection with voluntary licensing are not defined in the Patent Act. This omission leaves the terms open to different interpretations creating uncertainties. As the following example illustrates, in the past, this ambiguity has caused significant delays for compulsory licensing (Chaudhuri 2005, p. 94).

The Neo-Pharma Industries, an Indian firm sought licence from Parke-Davis to manufacture one of its patented drugs. The Indian subsidiary and the US-based parent company took more than two years to decide, as to who would negotiate with the interested party. When the negotiations eventually began, the parent company did not formally refuse, but just sat over the proposal. The government finally granted a compulsory licence to Neo-Pharma but was stayed on a court order obtained by Parke-Davis. This example illustrates how the omission of specificity in the Act could

unintentionally contribute to significant delays in the granting of compulsory licences, effectively defeating the purpose of compulsory licensing.

By comparison, Canada simplified its procedure for compulsory licensing as far back as 1969 by placing the time limit of two months for the patent holders to file counter claims. This change enabled authorities to grant over 613 licenses between 1969 and 1992 compared with just 22 compulsory licences granted between 1923 and 1969 when the country did not have a time limit in place (Chaudhuri 2005) (Box 3.2). Similarly, Norway has a limit of 30 days for the patent holder to respond.

It is clear from these examples that India should consider a similar time limit to increase the efficiency and certainty in the industry. Under ordinary circumstances, India would not be expected to issue a compulsory licence before 2009/2010. This is because the first product patent under the new regime was not granted until 2006. And only after the expiry of three years can India begin the process to grant compulsory licences.

Under specific circumstances, the government may issue compulsory licences anytime after granting a patent. In cases of national emergency, extreme urgency, public non-commercial use including public health crisis, compulsory licence can be issued immediately after a patent has been granted (see Figure 5.2). Under the TRIPS agreement, compulsory licensing is designed 'predominantly for supply of the domestic market' (Article 31 (f)). However, the Indian Patent Act also provides for compulsory licensing for the purpose of exporting patented pharmaceutical products to least developed countries (LDCs) countries with no or insufficient pharmaceutical manufacturing capacity. These provisions correspond to the Waiver Decision of 30th August 2003 of the WTO (later adopted as Article 31*bis* of the TRIPS agreement) allowing countries with no or insufficient pharmaceutical manufacturing capacity to import patented drugs from a low cost supplier. A number of countries including Canada and the EU have also enacted similar provisions for exports of generic versions of patented drugs in accordance with the WTO decision.

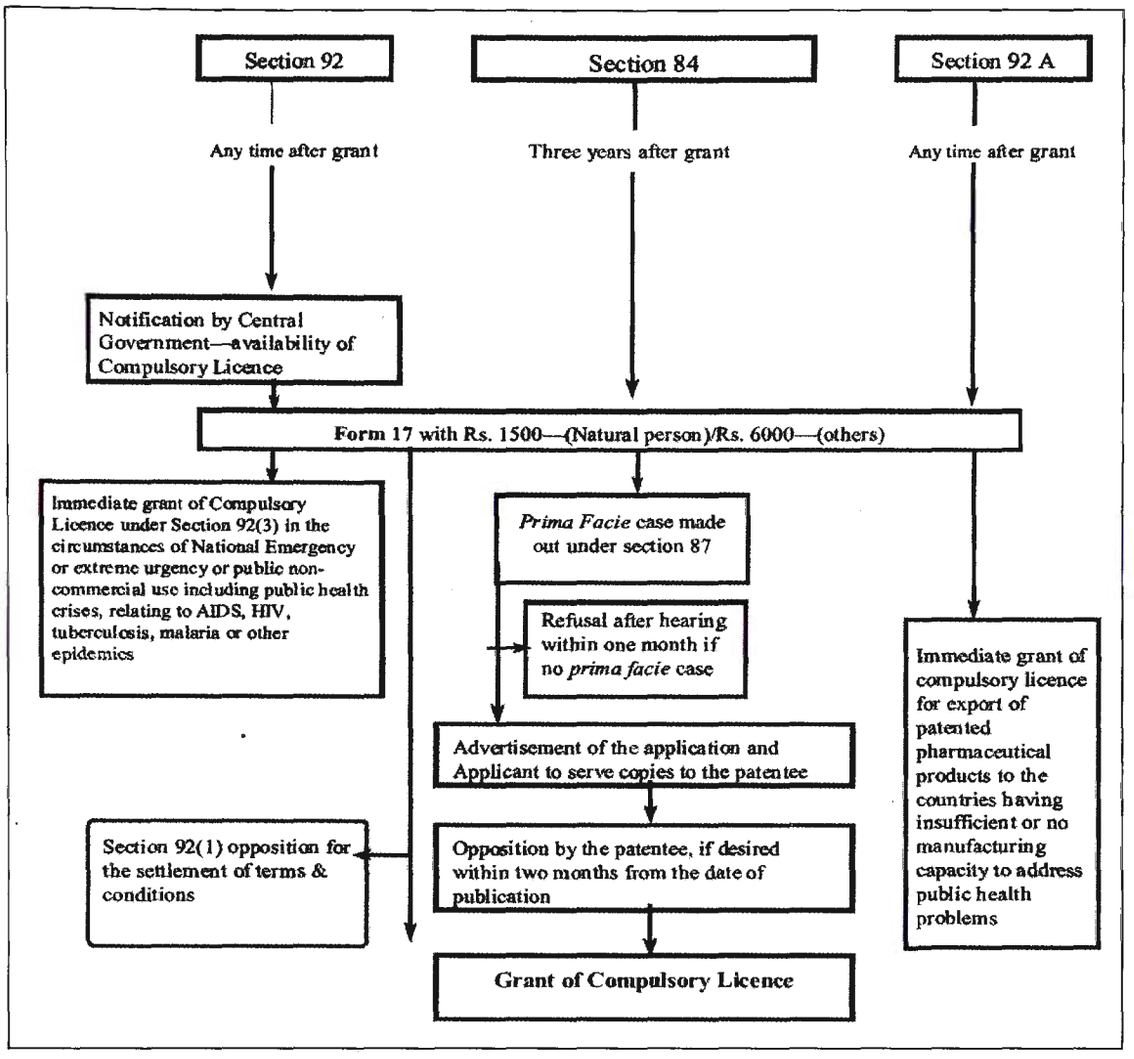
However, the process to issue a compulsory licence for exports is extremely complex. For example, India may grant a compulsory licence, if the importing country has

issued compulsory licence for that product, provided that the product is patented in that country and/or the importing country has, by notification or otherwise, allowed importation of the patented product from India (Abbott 2003). Despite the provisions built into India's Patent Act, frequent use of these provisions to issue compulsory licences is unlikely at least in the foreseeable future. There are two reasons for this. First, the process to import medicines under the Waiver Decision of the WTO is highly complex and time-consuming. Second, the fear of retaliatory measures by the first world nations prevents the third world nations from using these provisions. This perhaps explains why Rwanda, in May 2008, became the first country to use the provisions of the Waiver Decision and import the imitations of AZT+3TC+NVP for HIV/AIDS patients from Canada. The whole process is so cumbersome that it took four years of sustained effort to achieve this single use of the WTO decision. Moreover, Apotex, the Canadian manufacturer involved in the process has indicated its reluctance to use the process again (Elliott 2008).

The words *any person interested* in the Indian Patent Act[24] allow the filing of applications for compulsory licences by any of the stakeholders. While the domestic firms may apply for compulsory licensing to enter the market, the inclusion of *any person* allows other stakeholders such as health activists and NGOs to also make applications for compulsory licensing to increase access to medicines. Singh (2008) provides an example of the Cancer Patients Aids Association (CPAA) seeking compulsory licensing for around cancer 20 drugs patented by large drug MNCs including Roche, Pfizer, AstraZeneca, GSK, and Novartis. The main reason for making these applications is that these drugs are priced too high for the Indian patients. Singh also notes that Roche charges Rs. 130,000 and Rs. 100,000 for an injection of Herceptin and Mabthera respectively. These prices are far too high for most of Indians to afford.

[24] (Chapter XVI, Section 84(1)).

Figure 5.2: Procedure for compulsory licensing under the Patent Act 1970 (2005)



Source: Based on Intellectual Property India (2005, p. 97).

Response of domestic firms

Domestic firms in the industry have reacted differently to the new patent regime. On the one side are some firms prepared to take significant risks and test the new regime, while on the other side, some firms adopt a rather safer approach. In January 2008, Cipla, a leading Indian drug company and a known opponent of the TRIPS regime, launched Erlocip, an imitation of Taraceva, on which Roche was granted a patent in India in 2007. Taraceva is used to treat lung cancer, and Cipla has lodged a post-grant opposition. Roche's appeal for an injunction to stop Cipla from manufacturing was rejected by the Delhi High Court in March 2008, citing public interest and the significant price difference between the two brands of the same drug as the reasons (Cipla 2008). Taraceva is priced at Rs. 4,800 a tablet compared with Rs. 1,600 for Erlocip. In the wake of the High Court ruling, Ranbaxy, DRL and Sun Pharma may also adopt the same path as Cipla.

Encouraged by the Delhi High Court ruling, Cipla launched an imitation of Roche's anti-infection drug Valcyte in September 2008. Valcyte is priced at more than Rs. 1,000 a tablet compared with Rs. 245 for Cipla's Valcept (Mathew, JC 2008). Roche holds a valid patent in India for Valcyte and has initiated legal proceedings against Cipla for infringement of patent and trademark. A number of companies including Ranbaxy and Cipla as well as the Delhi Network of Positive People (DNP+) living with AIDS have filed post-grant opposition against the patent that is yet to be heard.

Other companies have adopted different approach to the new industrial landscape. Natco, a Hydrabad based small firm has applied for a compulsory licence for Taraceva. The company already manufactures the drug and sells it in Nepal at Rs. 1,400 a tablet. Nepal is among the least developed countries (LDCs) and as such not obliged to comply with TRIPS till 2016. From the limited data available since the implementation of the new regime, it would appear that large Indian companies with capabilities to manufacture patented products are prepared to take the large MNCs head on while smaller firms appear to adopt a risk avert approach.

The Cipla approach to enter the market with Erlocip and Valcept offers considerable price reductions relative to the patented products. The Delhi High Court decision not to issue an injunction against Cipla is likely to encourage other large Indian companies to follow the same path. The High Court decision would be disappointing for the patent holder, but the decision reflects the flexibilities within the framework of the Indian law. In view of public interest, the intention of the decision clearly is to keep drug prices at a level closer to that of income of vast majority of Indians.

Appeals against the Indian Patent Office decisions

Until recently, appeals against the decisions of the Indian Patent Office could be filed at the High Courts. This appeals process was recently changed and there are two reasons for it. First, as noted earlier, the courts have a significant backlog of cases to be heard. Lodging an appeal with the courts would unnecessarily delay the hearing. Second, patent litigations require specialised skills for examination of the matter put before the court. Under the recent amendments to the Patent Act, an Intellectual

Property Appellate Board (IPAB) has been established to hear appeals against the decisions, directions, or orders made by the Indian Controller of Patents. The IPAB became operational on April 2, 2007 and pending appeals in the High Courts were transferred to the Appellate Board (MedIndia 2007). The establishment of the IPAB is expected to expedite the appeals process, and the decisions made by the IPAB would be rendered as final. Except for writ petitions on 'patent illegality', 'miscarriage of justice', or 'a question of law that merits attention', no further direct review of the Appellate Board decisions will be available through the Indian court system (Mueller 2007b). The non-availability of 'further review' of the IPAB decisions could be considered a good thing eliminating the lengthy delays under the previously available 'almost endless' appeals process. The fact that the IPAB decisions will be final brings certainty in the industry.

Uncertainties and ambiguities

In the wake of such a major change as implementing the TRIPS compliant regime in India, some uncertainties and ambiguities would be expected and they are part of the evolutionary process. Different interest groups have different interpretations of the provisions introduced in the recent amendments to the Indian Patent Act. The following areas remained contentious between different stakeholders including different sections of the government that have difference of opinions:

- If it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps (examination of Section 3(d));

- If it would be TRIPS compatible to exclude micro-organisms from patenting;

- What steps should be taken with regards to data protection in the context of Article 39.3 of TRIPS Agreement; and

- Whether data protection can be offered under the existing legal provisions or an appropriate new dispensation is required.

Two separate committees were established to examine the above issues. A Technical Expert Group on Patent Law Issues under the Chair of Dr. Mashelkar, India's chief scientist at the time, examined the issues 1 and 2. In the interest of the pharmaceutical industry in general and more specifically, in the wake of Novartis' challenge, the investigation of the first issue was very significant. This group submitted its final report in December 2006, but subsequently withdrew the report due to alleged plagiarism and the issues remain unresolved.

The issue of *data protection* versus *data exclusivity* has also been a bone of contention between those who support a stringent patent regime and those who prefer minimum protection. This debates hinges on protecting undisclosed test or other data submitted by the first applicant (originator) to the regulatory authorities to obtain marketing approval for pharmaceutical or agricultural chemical products. The generation of such data takes several years and incurs considerable costs. If the subsequent applicants (generic manufacturers) can provide bioequivalence to the originator drug, no further test data are required (Sauer & Sauer 2007). Under *data protection*, the authorities can, without disclosing it to third parties, rely on the originator data saving the subsequent applicants significant costs. *Data exclusivity* refers to confidentiality of the regulatory file submitted to regulatory authorities for a specific period (Morag-Sela et al. 2004) Under *data exclusivity*, the reliance on the originator data is prohibited during the period of exclusivity forcing subsequent applicants to conduct their own tests and effectively barring the generics entry until the exclusivity period expires. This debate is a consequence of the ambiguities of Article 39.3 of the TRIPS agreement stating that:

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

The terms *unfair commercial use, considerable effort* and *disclosure* are not described in the TRIPS agreement, and hence, have been interpreted differently by different interest groups. Furthermore, the TRIPS agreement does not mention how long this protection be provided for or how this protection be carried out. An independent study finds that Article 39.3 does not create property rights, nor a right to prevent others

from relying on the data for the marketing approval of the same product by a third party, or from using the data except where unfair (dishonest) commercial practices are involved (Commission on Intellectual Property Rights Innovation and Public Health 2006).

The International Federation of Pharmaceutical Manufacturers and Associations suggests that data exclusivity is an intellectual property right not be confused with the protection provided by other rights, especially patents (IFPMA 2004). There are significant differences between the rights under data exclusivity and under patents. While data exclusivity does not prevent other firms from conducting their own trials, the prohibitive costs effectively stop generic manufacturers from doing so. Unlike patents, data exclusivity is automatic (similar to copyrights), does not incur additional costs or renewal fees, and has no provisions for exceptions such as compulsory licensing (Clift 2007). Yet, the data exclusivity creates a patent-like barrier on the drugs outside the patent protection and prevents generics entry for the entire period of exclusivity (So 2004). For example, Taxol was derived from natural extracts; hence, could not be patented. The US National Cancer Institute discovered Taxol in 1962 and licensed it to Bristol-Myers-Squibb (BMS) for commercial development in 1991. BMS kept generics out of the market through data exclusivity (Pugatch 2004).

Internationally, the debate on the interpretation of Article 39.3 has divided the world into two distinct groups; namely, the developed countries with advanced research capabilities and the developing countries with less developed pharmaceutical industries. The former group of countries views the provisions of Article 39.3 as mandating data exclusivity. The interpretation of the latter group of countries in contrast appears to be along the lines of data protection. The developed countries led by the US have, though other means, such as bilateral or regional agreements and the use of Special 301, forced a significant number of poor countries to adopt data exclusivity potentially jeopardising healthcare in those countries (Malhotra & Grewal 2008; Timmermans 2007) (see Chapter 2 for more details). The promotion of data exclusivity appears to be, in part, large MNCs' attempt to nullify or minimize the benefits of early introduction of generics gained under the Hatch-Waxman Act 1984.

In India, the pharmaceutical MNCs, some research-oriented Indian firms, such as Nicholas Piramal, and the Planning Commission of India favour data exclusivity. Most Indian firms, Ministry of Health and Family Welfare and other sections of the government as well as the NGOs such as Oxfam and Médecins Sans Frontières (MSF) argue that TRIPS obliged India to provide data protection against unfair commercial use and not to data exclusivity. The difference of opinions remained and the issue was handed over to an Inter-Ministerial Consultative Committee (IMCC) under the chair of Mrs. Reddy, Secretary, Department of Chemicals and Petrochemicals.

The IMCC used a consultative approach to gain the views of concerned departments, field experts, industry delegations, NGOs, and other stakeholders and submitted its report in May 2007. The report suggests that under Article 39.3, the regulatory authorities are free to rely upon the data submitted by first applicant to grant marketing approvals to subsequent applicants without disclosing the data to them. However, the report finds that the current Indian law does not meet the minimum requirements of the TRIPS agreement for data protection. The report makes recommendations in three key areas; namely, pharmaceuticals, traditional medicines, and agrochemicals. With the limited scope of this project, only the recommendations relevant to the pharmaceutical industry are considered hereunder.

The IMCC recommended a two-step approach to data protection. The first step relates to *data protection* during a transitional period not specifically defined in years or with a fixed date. The transitional period would end once the Central Drug Authority (CDA), an autonomous body under the Ministry of Health and Family Welfare is established. During the transition period, India should adopt the 'trade secret' form of protection and take appropriate steps to safeguard non-disclosure of undisclosed data. However, the generics may be approved by relying on the data submitted by originators.

In the second step, the IMCC recommended a five-year *data exclusivity* under the following conditions. First, the data exclusivity would be provided only to post - 1995 molecules and only to those not yet introduced in India. This exclusivity would be provided to undisclosed data and not extended to data already published or publicly

available. The data exclusivity for patented drugs should under no circumstances extend beyond the 20-year period of patent protection in India.

Second, the marketing approval becomes invalid if the product is not launched within six months of its grant and if not marketed for twelve consecutive months anytime thereafter. Under these circumstances, the authorities can grant marketing approvals to subsequent applicants by relying on the original data, even though the data exclusivity period may not have expired.

Third, the period of data exclusivity may be counted from the date of the first marketing approval anywhere in the world, if the originator applies for marketing approval in India within 24 months of that date. Generics producers may apply for marketing approval with the express consent of the originator within the above-stated 24-month period or without the originator's authorisation after this period. However, should the generics applicant apply within this 24-month period for tentative[25] marketing approval, the application would become final on the day after the expiry of the 24-month period, provided the originator does not apply for a marketing approval within this period. In case, the originator applies within this period, the tentative approval will not become final until after the expiry of the 5-years data exclusivity period counted from the date of the first launch anywhere.

Fourth, in accordance with the provisions of the Patent Act, compulsory licensing would override the data protection, so that data protection does not jeopardise the spirit of compulsory licensing. Finally, activities under the 'Bolar provision' would be exempted from data protection. Under the Bolar provisions, companies undertake drug testing to prepare for a market launch after the protection period expires.

The IMCC recommendations, if implemented, would force the originator companies to launch their products in the Indian market with a shorter lag than in the past. In the 1970s and 1980s, the drug lag in India measured against the first approval granted by the USFDA has in some cases been more than 12 years (Keayla 1996). Most of the new drugs post-1970 were introduced by the domestic manufacturers rather than the

originator companies. Under the IMCC recommendations, Indian companies would use the Bolar provisions to prepare for the timely launch of generics in the post data protection period. Unlike a significant number of countries under contractual obligations disallowing them to use compulsory licensing, India would be able to override data exclusivity when granting compulsory licensing. This provision is important for India being the leading supplier of generics and low-cost imitations of patented drugs to the developing world.

Access to medicines and the new patent regime

How does the new patent regime impact on access to medicines? Considering the similarities between the post-2005 and pre-1970 patent regimes, it could be assumed that the impact would be to push drug prices higher. There is one significant difference between pre-1970 and post-2005 situation, however. In the pre-1970 period, India's domestic pharmaceutical industry was virtually non-existent, compared to the world class industry of the post-2005 period. Yet, this difference may not be sufficient reason to rule out the widely held apprehension that in the post-TRIPS world drug availability and drug prices are likely to put medicines beyond the reach of the poor people, as witnessed in the following comment:

> If I were a hapless citizen of India, I would hope for the TRIPS system in the WTO to collapse; and for the development of some alternative form of rewarding innovations in medicines that matter to me, my family and my country. (Srinivasan 2008, p. 68)

The TRIPS compliant regime has been in force in India for four years now. During this short period, India has had a number of drugs introduced such as Glivec, where the originator has priced the drug significantly beyond the affordability of common Indians, The pre-1970 domestic industry was not developed sufficiently to offer alternatives and India was paying the highest drugs prices. The post-2005 domestic industry however is in a strong position to manufacture and supply low cost generics. The case of Cipla to produce copies of Taraceva[26] shows the preparedness of domestic companies to play their role in lowering the drug prices. The Delhi High Court decision not to grant injunction against Cipla demonstrates that the courts are ready to back up the domestic industry in its attempt to increase access to medicines. Under its international obligations, India has implemented the TRIPS agreement,

[26] As noted earlier, Roche has a patent on Taraceva in India.

which, appears to be a hindrance to the access to medicines. India needs to devise new strategies fro broadening the access to healthcare, including medicines, for its entire population without infringing or abandoning the TRIPS agreement. These issues are also the focus of our discussion in Chapter 7.

5.3 Pharmaceutical innovation

The object of this section is to assess the impact of TRIPS on the level of innovation in the Indian pharmaceutical industry. An empirical study by the National Institute of Science Technology and Development Studies (NISTADS) shows the impact of India's patent regimes on innovative activities (NISTADS 2005). The study uses two methods to measure the level of innovation; namely, the number of new drugs developed and the number of patents filed. An examination of the number of new drugs developed shows the extent of innovation in the pharmaceutical industry under both the pre-1970 (strong) and post-1970 (weak) patent regimes. The examination of the patent applications relates to the period between 1990 and 2002 divided into three sub-periods: 1990-94, 1995-98, and 1999-2002. The significance of these sub-periods is that they relate to the before and after periods when India signed the WTO agreements, with the final sub-period being closer to the deadline for implementation of the TRIPS agreement. A comparison between the sub-periods suggests that the level of innovation increased significantly after India signed the WTO agreements, and a further increase in the final sub-period.

These results appear to confirm Bashir's hypothesis about innovation. A renowned expert on intellectual property rights, Basheer (2008) hypothesised that most countries need to imitate first, before developing capabilities to innovate and that strong IP regimes stand in the way of permitting imitation on the way to subsequent innovation (cited in Kumar 2008). India's stringent pre-1970 patent regime did not help India's pharmaceutical industry to develop or to enhance its innovative skills. As noted in chapter 4, India's pharmaceutical industry developed under the weak patent regime of the post-1970.

Table 5.3 shows new drugs developed in India under both patent regimes - the pre-1970 regime and the post-1970 regime. The number of new drugs developed in India

may be small relative to drugs developed in the wealthy nations. It demonstrates, nevertheless, the capabilities of the Indian scientists. With the minimum resources that the research institutes had before the economic reforms of 1991, developing a number of new drugs was indeed a remarkable achievement.

Table 5.3: Select new drugs developed in India for human use (various years)

No.	Drug	Year	Use	Institution
1	Urea Stibamine	1921	Kala-azar	School of Tropical Medicine, Calcutta
2	Methaqualone	1956	Non-barbiturate hypnotic	RRL, Hyderabad, Lucknow University
3	Hamycin	1961	Anti-fungal	HAL, Pune
4	Centimizone	1972	Anti-thyroid	CDRI, Lucknow
5	Sintamil	1978	Anti-depressant	Ciba Giegy, Mumbai
6	Tinazolin	1978	Nasal decongestant	Ciba Giegy, Mumbai
7	Tromaril	1980	Anti-inflammatory	RRL, Hydearbad
8	Isaptent	1985	Cervical dilator	CDRI, Lucknow
9	Guglipid	1986	Hypolipidaemic	CDRI, Lucknow
10	Centbucridine	1987	Local anesthetic	CDRI, Lucknow
11	Centbutindole	1987	Neuroleptic	CDRI, Lucknow
12	Centchroman	1991	Nonsteroidal oral contraceptive	CDRI, Lucknow
13	Chandonium Iodide	1994	Neurmuscular blocking agent	CDRI, Lucknow, Punjab University
14	Centpropazine	1996	Anti-depressant	CDRI, Lucknow
15	Arteether	1997	Anti-malarial	CDRI, Lucknow, CIMAP, Lucknow
16	Standardised Brahmi extract	1997	Herbal remedy for memory improvement	CDRI, Lucknow
17	Bulaquin	n.a	Antimalaria	CDRI, Lucknow
18	Picroliv	n.a	Liver, Kidney	CDRI, Lucknow
19	CDRI-99/373	n.a	Antiosteoporosis	CDRI, Lucknow

Source: Based on Chaturvedi (2005) and Central Drug Research Institute (2008).

The new drugs developed in India suggest that even under the weak patent regime of post-1970 period, the innovative activities, including development of new drugs remained in progress. The development of new drugs was not undertaken only by the domestic industry. The large MNCs also contributed. For example, two new drugs were developed by Ciba Geigy (now part of Novartis) in 1978, after India had abolished product patents. However, most of new drugs were developed at the Central Drugs Research Institute (CDRI). The involvement of private enterprises in drug development remained limited during the period of weak patents. Following the economic reforms in 1991, particularly since India's accession to the WTO, innovative activities in the private sector have increased. Leading Indian firms have in recent years embarked on discovering new molecules in the pursuit of developing new drugs (see Table 5.4).

The signing of the WTO and TRIPS agreements has provided further impetus to research in the pharmaceuticals industry. By disallowing the 'reverse engineering' model, the new regime has caused the industry to shift from being the imitator to becoming the innovator. Leading Indian firms have significantly increased their R&D expenditure and embarked upon drug discovery. The R&D spending of the top five Indian pharmaceutical companies crossed US$500 million in 2006 (Mazumdar-Shaw 2007). The total sales revenue of the top five companies for the year was less than $5 billion taking their R&D spending to over 10 per cent of sales. This is a significant increase from less than 2 per cent hitherto the Industry spent on R&D. By comparison, leading MNCs spend around 14-15 per cent of sales on R&D. The Australian pharmaceutical industry's expenditure on R&D remains around 3 per cent of sales (Sweeny 2002). Since 2005, the R&D expenditure in the Indian industry in general and in the pharmaceutical sector in particular has increased significantly. The Department of Scientific and Industrial Research (DSIR) in India annually publishes a list of firms with in-house R&D capabilities and their R&D expenditure. According to the 2007-08 annual report of the DSIR, over 40 pharmaceutical companies spent more than Rs.50 million each (Government of India 2008a).

Table 5.4: Development of drugs by select Indian firms (2006-07)

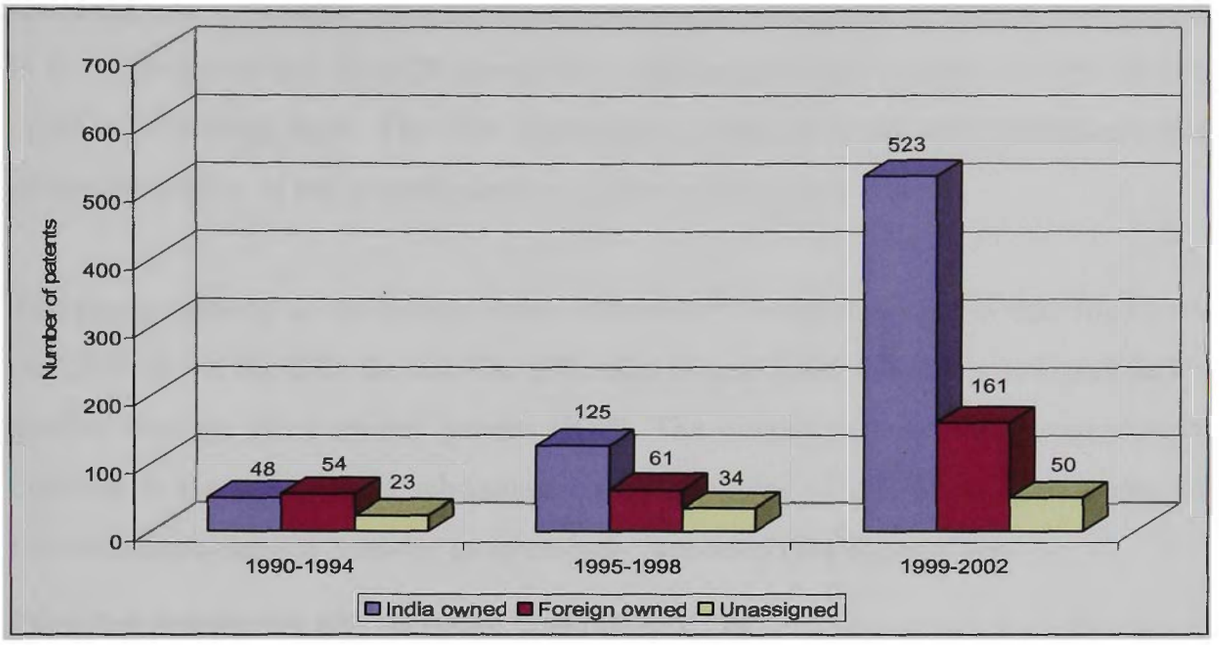
Company	No. of molecules in pipeline	Phase I	Phase II	Phase III
DRL	9	2	3	1
Ranbaxy	10		2	
Glenmark	6	2	2	
Nicholas Piramal	6		3	
Wockhardt	5	2	1	
Zydus Cadila	4	2	1	

Source: Based on various company websites.

According to the NISTADS (2005), India's innovative activities measured by the patent filings in India and in the US have significantly increased in recent years, particularly in the chemical and pharmaceutical sectors. The NISTADS study divided India's patent applications into the following categories: 1) India Owned Patents (IOP) such as domestic firms, institutions, universities; 2) Foreign Owned Patents (FOP) refer to patent filings by Indian subsidiaries of foreign companies; and 3) Unassigned referring to non-institutional Indian individuals. Figure 5.3 shows the patent applications filed with the United States Patent and Trademark Office

(USPTO). A significant increase in the IOP contribution can be observed in the 1995-1998 period with a further increase in the subsequent period.

Figure 5.3: Indian patents filed with the USPTO



Source: NISTADS (2005, pp. 52-3).

Based on the applications filed with the USPTO during the entire study period, the IOP category was the largest contributor, followed by FOP and the Unassigned categories (see Table 5.5). The figures in Table 5.5 show the sector-wise number of patent filings between the periods 1990-94 (pre-WTO), 1995-98 (post-WTO), and 1999-2002 (referred to as the current period). The IOP activity in pharmaceuticals progressively increased and the largest increase was in the 1999-02 period. The FOP activity in pharmaceuticals declined in the post-WTO period before rising back in the third sub-period.

Table 5.5: Sector-wise Indian patents activity at the USPTO (1990-2002)

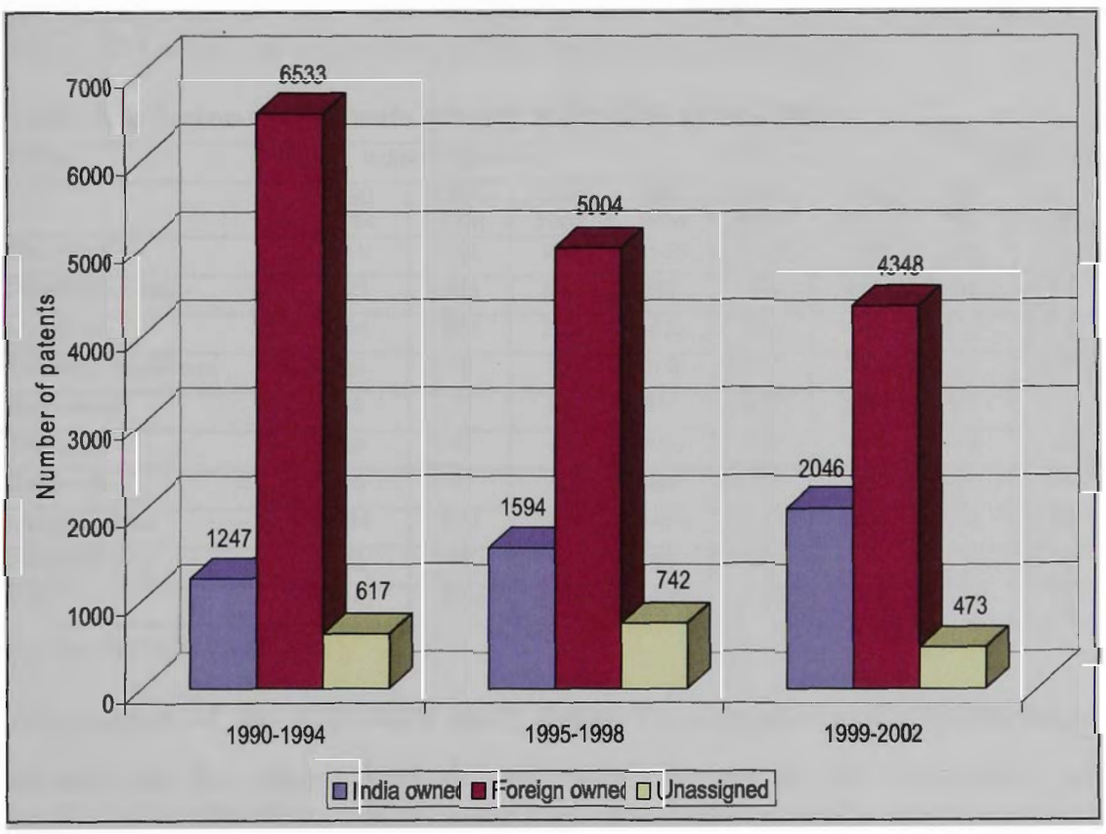
Sector	Indian Institutions			Foreigners			Indian Individuals		
	1990-1994	1995-1998	1999-2002	1990-1994	1995-1998	1999-2002	1990-1994	1995-1998	1999-2002
Chemical	24	42	166	10	6	22	4	3	7
Pharmaceuticals	9	48	227	29	14	30	1	7	9
Machinery	7	6	15	4	3	2	2	5	7
Electrical Equipment	0	0	1	1	3	9	1	2	3
Instruments	0	5	13	1	4	10	5	4	5
Transport	0	0	6	0	0	0	4	0	7
Electronics	0	2	7	3	5	23	2	0	1
Miscellaneous	8	15	42	4	21	59	3	9	9
Biotechnology	0	7	46	2	5	6	1	4	2
Total	48	125	523	54	61	161	23	34	50

Source: NISTADS (2005, p. 57).

In the first sub-period, the IOP did not file any patents in biotechnology in the US. The number of biotech patents remained modest in the second sub-period, but increased significantly in the final sub-period. The FOP activity in biotechnology remained low in the first and second sub-periods and declined in the final sub-period. In the first sub-period, the FOP dominated in pharmaceuticals as well as in the overall number of patents filed. The IOP dominated in the chemical and pharmaceuticals sectors as well as in the overall number in the remaining sub-periods.

The patent activity at the Indian Patent Office (IPO) was different to that filed with the USPTO. At the IPO, the number of foreign owned patents (FOP) was significantly greater than the India owned patents (IOP). The overall FOP activity progressively declined in the sub-periods subsequent to India signing of the WTO agreements. At the same time, the IOP activity progressively increased (see Figure 5.4).

Figure 5.4: Patents filed with the Indian Patent Office (IPO)



Source: NISTADS (2005, p. 63).

In terms of the number of patents filed at the Indian Patent Office, the FOP dominated throughout the entire study period. The number of FOP filings progressively declined compared with the first sub-period. This decline is ironic, however. After India signed the TRIPS agreement in 1994, India was obliged to strengthen its patent regime. Yet,

the number of FOP filings in India declined after 1995. The FOP filings declined further in the final sub-period. The IOP filings show a progressive increase suggestive of the industry anticipation of the then upcoming regime change. The IOP increase could also be, in part, attributed to the industrial and economic reforms introduced in 1991. The Unassigned category increased its share in the second sub-period but significantly reduced it in the final sub-period.

A sector-wise composition of the patents filed at the IPO suggests that the decline in the FOP activity is more significant in chemicals, machinery and miscellaneous sectors than other sectors (see Table 5.6). The decline in FOP applications needs to be understood in the right context however. Foreign MNCs account for over 80 per cent of the estimated 12,000 applications for product patents in the mail box (NISTADS 2005; Ram 2006) including the FOP activity. The patent applications for pharmaceutical products filed before 2005 were lodged into the *Mail Box*. Thus, those applications would not be shown as FOP filings, because they only became active after 2005 when the processing of the applications first began.

Table 5.6: Sector-wise patents activity at the IPO (1990-2002)

Sector	Indian Institutions			Foreigners			Indian Individuals		
	1990-1994	1995-1998	1999-2002	1990-1994	1995-1998	1999-2002	1990-1994	1995-1998	1999-2002
Chemical	419	492	668	1588	1178	1025	64	80	47
Pharmaceuticals	221	305	547	397	314	413	24	35	70
Machinery	201	267	223	1630	1282	1005	189	242	103
Electrical Equipment	39	30	30	289	221	148	35	36	15
Instruments	48	71	81	411	343	296	61	67	63
Transport	38	41	43	375	236	194	43	61	35
Electronics	15	17	42	299	345	296	28	15	15
Miscellaneous	234	333	352	1489	1048	934	172	201	121
Biotechnology	32	38	60	54	37	37	1	5	4
Total	1247	1594	2046	6533	5004	4348	617	742	473

Source: NISTADS (2005, p. 91).

An analysis of the NISTADS study shows the strengths and weaknesses in India's research in the pharmaceuticals and chemical sectors. The innovative activity in pharmaceuticals is highly concentrated in the CSIR, which alone accounted for most of India's patent activity (see Table 5.7). This is because, with 84 of nation's premier research institutes under its ambit, the Council of Scientific and Industrial Research (CSIR) has the largest network of research institutes in the country. During the entire study period, only 8 institutes, including the CSIR filed more than 10 patent applications, collectively accounting for 80 per cent of the IOP activity at the USPTO.

The concentration of innovative activity indicates that apart from the CSIR, only a handful of industry players are engaged in research that is globally competitive. The table also shows that companies such as Dabur and Panacea have more patent applications in the US than in India suggesting the focus of their research is on the US market rather than India.

Table 5.7: Overall leading patent applicant institutions: IPO and USPTO (1990-2002)

Organisation / Industry	USPTO	IPO	Total
Council of Scientific & Industrial Research (CSIR)	378	1660	2038
Hindustan Lever Limited (HLL)	0	565	565
Indian Institute of Technology	0	80	80
Ranbaxy Laboratories Limited	39	36	75
Dr. Reddy's Research Foundation	35	36	71
Indian Oil Corporation Limited (IOCL)	18	43	61
Defence Research & Development Organization (DRDO)	6	51	57
Hoechst India Ltd	0	48	48
National Research Development Corporation (NRDC)	7	41	48
Indian Petrochemicals Corporation Limited (IPCL)	9	37	46
Sree Chitra Tirunal Institute for Medical Sciences & Technology	1	41	42
Bharat Heavy Electricals Limited (BHEL)	0	41	41
Lupin Laboratories Limited	11	30	41
Steel Authority of India Ltd (SAIL)	0	38	39
J. B. Chemicals & Pharmaceuticals Ltd	0	31	34
India Jute Industry Research Association	0	30	30
Indian Space Research Organization (ISRO)	1	28	29
National Council for Cement & Building Material	0	30	30
Project & Development (India) Ltd.	0	29	29
Panacea Biotech Limited	13	9	22
South India Textile Research Association (SITRA)	0	21	21
National Institute of Immunology (NII)	13	6	19
Dabur Research Foundation	15	1	16

Source: NISTADS (2005, pp. 95-6).

Based on the above discussion, it can be concluded that the number of India-based patent filings in the US and in India increased substantially after India's signing of the WTO agreements in 1994. The patent filings at both agencies further increased in more recent years. The indigenous institutions are more focused on developing innovations for the US market than the India-based foreign enterprises. It is also clear that the primary focus of India's research is on serving the lucrative markets of the rich nations rather than meeting the needs of developing countries.

India's leading players in pharmaceuticals are investing significantly into basic research changing their business model from reverse-engineers to innovators. With the gradual rise in the level of patent literacy, more domestic firms are likely to join the basic research that would enhance India's global competitiveness. While it is too

early to reach definitive conclusions on how much of this increase in the level of innovation directly resulted from implementing the TRIPS agreement, these activities are likely to continue increasing further the level of innovation in the coming years.

5.3.1 The role of government in innovation

The Indian government offers various support measures to encourage the industry to undertake R&D. For example, drugs developed indigenously are free from any price control. The incentives also include 150 per cent weighted tax deductions on in-house R&D expenditure in the pharmaceutical industry, including expenses on clinical trials. The government also provides limited funding under the Pharmaceutical Research and Development Support Fund (PRDSF) to boost research on diseases like malaria, and tuberculosis, although total budget for the PRDSF, which consists of interest generated on the deposit of Rs.1500 million (~US$36 million), is miniscule by global standards (Government of India 2005a, p. 36). The Indian Council of Medical Research (ICMR) has also set up Medical Innovation Fund with cash rewards for innovative ideas (Alexander 2007). Small in monetary terms (by comparison, Pfizer alone has a R&D budget of $7 billion), these rewards are a symbolic gesture to acknowledge the origin of innovation.

The government is considering introducing the India Innovation Act and Innovation Zones to boost innovative activities. Similar to the Special Economic Zones, the concept of Innovation zones is aimed at bringing together different stakeholders in the innovation chain and offer significant incentives for investors. The India Innovation Act is likely to be modelled along the lines of the 'America Competes Act', which focuses on the following three key areas to maintain and improve innovation in the US in the 21st century: increasing research investment; strengthening education opportunities in science, technology, engineering, and mathematics from elementary through graduate school; and developing an innovation infrastructure (FICCI 2007).

It is widely acknowledged that currently around 90 per cent of the world's investment on R&D in pharmaceuticals is directed to serve 10 per cent of the world's population living in the developed countries, and only 10 per cent of the investment goes into developing cures for the diseases afflicting the world's 90 per cent poor population.

The high rates of economic growth and the development of its pharmaceutical industry now place India in a strong position to take a lead to address this 10/90 gap. India needs to introduce programs with significant incentives to attract investment and establish mechanisms such as the public-private-partnerships (PPP) to develop drugs for diseases specific to the developing countries.

5.4 Conclusions

This chapter set out with the objectives of examining the recent amendments to India's patent regime. Under India's international obligations, these amendments were necessary to make the regime TRIPS compliant by 1 January 2005. Of particular interest in this examination was the impact of this regime change on the development of India's pharmaceutical industry and its innovative activities.

Under the Indian Patents and Designs Act 1911, product patents were granted for pharmaceuticals. The Patent Act 1970 repealed the product patents and granted patents for a single process that was actually used in manufacturing the drug. This change allowed the use of the reverse-engineering model that played a central role in the development of domestic pharmaceutical industry. Around the same time, the government also introduced a range of protectionist measures that underpinned the growth of indigenous pharmaceutical industry.

As a member of the WTO, India was obliged to implement the TRIPS agreement, and has introduced the necessary amendments to make its patent regime TRIPS compliant. Ambiguities remain in the Patent Act regarding patentable subject matter, plants organisms, and data protection. In the overall scheme of things, these ambiguities could be considered as an integral part of the evolutionary process. However, these ambiguities are not unique to India. There is a clear division of interpretation of the terms used in TRIPS among the developing and developed member states. The developed countries, the major beneficiaries of stringent patents, tend to represent the originator industry. Developing countries, including India, along with health activists and other stake holders, are concerned with public health and access to medicines. India's final position on the issue of data exclusivity remains unclear. An Inter-Ministerial Consultative Committee was established to address the issue. If the

recommendations of the committee were implemented, India would grant data exclusivity for five years under specific conditions.

The provisions defining the patentable subject matter under Section 3(d) of the Patent Act are designed to prevent ever-greening of patents. India regards claims, such as new uses or new forms of existing substance, as frivolous and does not grant patents for such claims. Large MNCs have alleged that this Section contravenes the TRIPS agreement. Novartis has challenged the validity of this contentious Section in the Indian Courts. A large number of studies support India's position. Hundreds of thousands of people across the world have signed petitions against the Novartis challenge. Norway and the European Commission have appealed to Novartis to drop the case. The Supreme Court is yet to hear the case. A Novartis win would severely restrict access to low cost medicines.

India has made extensive use of the flexibilities provided under the TRIPS agreement to build adequate safeguards for compulsory licensing. The safeguards are conducive to the low cost drug supply by the domestic pharmaceutical industry. The insertion of the words *any person interested* to apply for compulsory licence enables NGOs and other stake holders to play an active role in providing access to low cost medicines. So far, no compulsory licence has been granted, however.

Since 2005, India has begun to process the product patent applications submitted to the official Mail Box. A number of applications have been opposed via the provisions for pre-grant opposition. Product patents on a number of drugs have been granted, most of which have been opposed via the provisions for post-grant opposition. The opposition to the patents has been primarily based on Section 3(d) citing the ineligibility to grant.

Imitations of a number of patented products have been launched by domestic companies. The courts have so far refused to grant injunctions to stop the domestic manufacturers. This was primarily because the price difference between the originator product and the copy has been too great to ignore. India should consider introducing provisions to discourage patent applications with frivolous claims in order to keep drug prices low and minimise patent litigations.

In compliance with the Waiver Decision of the WTO, India provides for exports of generic versions of on-patent drugs to countries with no or insufficient manufacturing capacity. The process of issuing a compulsory licence under these provisions is so complex that it is unlikely to be used frequently in the foreseeable future.

The Indian industry is increasingly investing into drug discovery and development. The innovative activities in India have increased substantially over the last decade and India is increasingly becoming a significant player in filing patent applications in the US. However, apart from the public institutes under the ambit of the Council of Scientific and Industrial Research (CSIR), only a small number of pharmaceutical companies are engaged in patent filings in the US. This suggests that innovative activities of a limited number of Indian firms are globally competitive. The data on patent filings also suggest that the Indian innovative activities are more focused on serving the rich markets of the developed world than providing low cost medicines for the poor in the developing countries. A number of government programmes, such as tax holiday and free-pricing on locally developed drugs, are designed to encourage innovative activities in India. The government needs to consider providing significant incentives to attract investments into disease specific R&D to fill the current gap more relevant to the poor countries.

Chapter 6

Price Controls, Health Insurance and Drug Affordability in India: Policy Options

6.1 Introduction

Two factors combine to determine affordability of drugs; drug prices, and health insurance. The aim of this chapter is to examine the current situation with respect to both of these factors, so as to assess the seriousness of the affordability component of *access to medicines*. Price controls are designed to maintain drug prices at affordable level. India's system of drug price controls is discussed in section 2, where overseas experiences are also considered. An investigation into the market behaviour demonstrates the problems for the Indian pharmaceuticals market, particularly for the consumers. Section 3 discusses the situation with health insurance in India, together with the health insurance situation in other countries. Section 4 provides conclusions.

The discussions in this chapter shows that India's policy of price controls has not been effective in providing essential[27] medicines at affordable prices to all sections of the community. In search for solutions, pricing models in Canada, New Zealand, UK, and Germany are considered, with a more detailed examination of the Australian pricing model. Data on publicly and privately insured population in selected countries is compared to assess India's situation, which indicates the level of contribution of third party payers in India. The level of out-of-pocket private health expenditure is determined by examining India's public health expenditure at both the state and the central government levels. We further argue that in considering new models for drug price controls and for health insurance India can benefit from the experiences of some of the other countries, including Australia.

[27] Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford (WHO website). http://www.who.int/topics/essential_medicines/en/, viewed 2 June 2008.

6.2 Drug price controls

Price controls are a method of regulating prices of medicines for achieving health policy goals (Gray & Matsebula 2003). Drug price controls are an important policy instrument, because health systems cannot rely entirely on market mechanisms for healthcare delivery. In a perfectly competitive market, the level of competition in supply and demand, and not the conscious policy making would, effectively decide the health outcomes (Goddard et al. 2006). But, medicines are no ordinary goods and cannot be left to the market forces to determine the price, for several reasons. First, the user (the patient) has no say in the selection of the product because the doctor prescribes it. Second, the decisions of the third party payers (public reimbursement list, private insurers) also play an important role in the selection of the product. Third, the patient's ability to pay (co-payments, brand premiums, fully payable) determines the sale and consumption of the product. Finally, drug prices to a large extent are managed by their manufacturers, rather than the market (Gray & Matsebula 2003).

The pressures for cost containment and increased demand for healthcare have intensified in recent years. There are two fundamental factors driving the healthcare costs. First, the populations are ageing, which means that the number of people reaching old age has increased significantly particularly in the developed world. Second, the people today are living longer and the old age group accounts for a substantial part of nation's healthcare costs. Drug price controls are an important instrument to contain healthcare costs.

All developed countries, and most of the developing countries, have some degree of control over drug prices (Ballance, Pogány & Forstner 1992). The governments use interventions from the supply side by controlling drug prices and/or from the demand side by restricting reimbursements and by raising patient co-payments (Cai & Salmon 2005). From the manufacturers' perspective, price controls restrict free market activity, limit profits and restrict return on investment. While the policy-makers try to strike a balance between rewarding innovative activities to maximise scientific progress and maintaining an affordable healthcare, the price controls are deemed necessary to ensure drug affordability and containment of healthcare costs. Table 6.1 shows a large number of industrialised as well as developing countries with

substantial price controls, and a significant number of countries with limited price controls and seven developing countries with no drug price controls.

It should be noted from the outset that the TRIPS agreement, the implementation of which the primary focus of this thesis, is not concerned with price controls. In other words, drug price controls do not constitute a contravention of the agreement. The TRIPS agreement is concerned with the protection of intellectual property rights, and not with full range of market regulations.

Table 6.1: Drug price controls in selected countries

Level of price control	Industrialised countries	Developing countries
Substantial	Austria, Belgium, Finland, France, Greece, Hungary, Israel, Italy, Norway, Portugal, Spain, and Sweden	Algeria, China, Colombia, Costa Rica, Egypt, Ghana, India, Iran, Jordan, Mexico, Morocco, Nigeria, Pakistan, Korea, Sudan, Syria, Thailand, and Tanzania
Limited	Australia, Canada. Denmark, Germany, Ireland, Japan. Netherlands, New Zealand, Switzerland, United Kingdom, and United States	Argentina, Bangladesh, Bolivia, Brazil, Indonesia, Uruguay, and Venezuela
None		Chile, Hong Kong, Kenya, Malaysia, Philippines*, Sri Lanka and Taiwan

Note: *Officially no, in practice yes.

Source: Balance, Pogány and Forstner (1992, pp. 142-4).

6.2.1 Drug price controls in India

India's price controls are examined in terms of variations to the number of drugs under price control at different periods and the changes to the criteria used to select drugs for price control. But what is the actual impact of these controls on drugs prices in the market? Two different examinations of the market behaviour are undertaken to make a considered assessment of the impact of price controls.

While health care is primarily a state matter under India's federal constitution, responsibility for regulation and finance is shared between the states and the Union Government. The Central Drugs Standard Control Organization (CDSCO), which is under the Ministry of Health and Family Welfare, grants market approvals for drugs. The licences to manufacture the approved drugs are issued by the state/territory drug authorities. The National Pharmaceutical Pricing Authority (NPPA), which is under the Ministry of Chemicals and Fertilizers, is responsible for price controls. The Department of Industrial Policy and Promotion under the Ministry of Commerce and Industry looks after the TRIPS and WTO related obligations.

India applies price controls to a limited number of drugs that are selected on the basis of criteria published under its policy. The Indian formulations market uses around 600[28] drugs, of which 74 or around 12 per cent are currently under price control. The selection criteria to place drugs under price control have changed significantly since their introduction more than forty years ago. There has been a number of Drug Price Control Orders (DPCO) issued with variable scope and the level, which have been substantially watered down over the last thirty years. The DPCO that is currently in force was pronounced in 1995.

DPCO – 1995

In 1991, under its liberalisation program, India introduced significant reforms to relax its industrial policy. The number of drugs under price control was reduced from 142 to 74 under the DPCO – 1995. The changes, to the selection criteria of drugs for price control, introduced under the DPCO – 1995 were the most significant. Under the new rules, the drugs listed on the Schedule[29] were based on 1990 market value of the drug, the sales revenue and the market share of manufacturers, and the number of manufacturers in that segment of the submarket (see Box 6.1).

Box 6.1: Considerations for price controlling bulk drugs

Determining factors for scheduled bulk drugs
Bulk drugs placed on the scheduled list of the DPCO 1995 are considered to have met one of the following criteria. For a bulk drug with a turnover of Rs 40 million or over: • the number of producers of such drug must be less than five; • the number of formulation manufacturers who use this drug must be less than ten; and • the leader of such formulations' retail market has a share of 40 per cent or over. For a bulk drug with a turnover of less than Rs 40 million: • the bulk drug turnover must be over Rs 10 million; and • the leader of such formulations' retail market has a share of at least 90 per cent.

Source: Based on Government of India, (1995, Section 7).

The market environment replaced essentiality as the basis for price control. The changes to the selection criteria made under DPCO – 1995 have grave consequences for India's provision of affordable healthcare. First, the qualification criteria for inclusion or exclusion of a drug lack transparency and appear irrational. It is because the criteria, on which the drugs qualified for price control, were based on the market

[28] Author calculations based on *CIMS* (2007).
[29] List of drugs under price control

data of 1990, which are secondary and unchanging. In contrast, the sales and the market data are changing constantly. A basis as dynamic as market environment would require continuous monitoring of market data and accordingly amend the list of drugs under price control. However, such is not the case under the current DPCO. Consequently, some truly life-saving and essential drugs being have been left outside the DPCO while some dubious drugs have fallen under price control (Narrain 2004). The implications of these inconsistencies would be that the manufacturer could charge high prices for essential drugs and these prices could vary significantly between companies as the following studies demonstrates.

An expert study observed significant price variations between different brand products for the same drug. The highest price difference noted was 881 per cent (Rs.4.81 vs. Rs.0.49) for Amlodipine 5mg (Das, Mandal & Mandal 2007). Amlodipine is an anti-hypertensive drug, which is also used to treat angina. Amlodipine is included in India's Essential Drug List 1996 as well as in the National List of Essential Medicines (NLEM) 2003, but is not under price control. If the drug was under price control, there would be a price ceiling in place, and the price differences noted above would be minimum.

Second, there is no provision for updating, adding new drugs to or deleting old ones from the list. There have been over 300 new drugs discovered since the implementation of the DPCO – 1995 and no new drugs have been added to the list. The WHO Model List of Essential Drugs is updated every two years. If the list of scheduled drugs were to be based on market share, and sales revenue, the list should have been updated annually to correspond to the changing market trends.

Third, India's healthcare needs are constantly changing. Until recently, India's disease burden primarily consisted of the tropical diseases. However, the recent spread of HIV/AIDS and the emergence of life style diseases such as cancer and cardiovascular have significantly added to India's disease burden. The current price control framework ignores these ground realities.

6.2.2 The evolution of price controls

India introduced drug price controls in the 1960s because India, at the time, had one of the highest drug prices in the world (Lall 1974). The vast majority of the Indian population was living below the poverty line and the affordability of medicines was a significant issue. Following the 1962 border conflict [war] with China, amid fears that the war could trigger[30] steep price increases, the government froze drug prices to maintain status quo. As a part of India's overall industrial policy that was primarily based on import substitution and making the country self dependent in drug supply, the price control regime was strengthened significantly in 1970. The control regime in 1979 introduced essentiality as the qualification criteria for bringing drugs under the ambit of price control. Consequently, the scope of price control was reduced, which was further reduced in 1986 and again in 1995. While India has progressively relaxed drug price controls since 1979, its plans to further liberalise control over drug prices under the Pharmaceutical Policy – 2002 have been hampered by legal challenges filed by citizen groups as noted later in this chapter. Table 6.2 shows the evolution of price controls in India.

Table 6.2: Drug Price Controls in India at a glance

Year	Framework	Level of control	Approx. market share (%)
Pre -1970	1963: Defence of India Act. 1966: Essential Commodities Act.	Formulations only: 1963: Drug prices frozen; 1966: Drug Prices (Display and Control) Order.	Not known.
DPCO 1970	Essential Commodities Act.	Almost all Bulk drugs and their formulations.	Indirectly, the entire market.
DPCO 1979	Drug Policy – 1977	347 Bulk drugs and their formulations.	80%
DPCO 1987	Drug Policy – 1986	142 Bulk drugs and their formulations.	60%
DPCO 1995	Drug Policy – 1994	74 Bulk drugs and their formulations.	> 40% at the time of implementation, but now accounts for around 25%.
DPCO 2004*	Pharmaceutical Policy – 2002	38 Bulk drugs and their formulations.	> 20%

Source: Based on Drug Policy – 1977; Drug Policy – 1986; Drug Policy – 1994; Pharmaceutical Policy – 2002; and other documents from Government of India.

Pre-1970 Price Controls

Under the Defence of India Rules, prices for all formulation were frozen in 1963 until the next phase of price controls. This prevented the industry from raising drug prices in case of excessive rise in demand following the war with China. In 1966, the government issued the first Drug Prices (Display and Control) Order under the

[30] It was feared that extra demand resulting from war could create shortage of pharmaceuticals leading to sharp price rises.

Essential Commodities Act[31] 1955. Under this order, manufacturers had to obtain government approval before prices could be increased on formulations with mark-ups of up to 150 per cent over ex-factory costs. Foreign MNCs generally had a mark-up higher than 150 per cent and remained mostly unaffected by the price control measures. From the applications filed for price increase under these rules, the MNCs accounted for just 6 per cent and, yet had around 68 per cent market share (Chaudhuri 2005).

The pre-1970 form of price controls had limited effect. It is argued that the price freeze in 1963 was better than the price control of 1966 for the consumer and for the domestic producers, because it applied to all formulations without any qualification. Under the 1966 policy, the products with mark-ups of more than 150 per cent out stayed outside the price control. Large MNCs benefited from this provision at the expense of small domestic producers, who had priced their products to supply the low end of the market. Neither of the pre-1970 price control measures considered the drugs on essentiality.

DPCO – 1970

The Drug Price Control Order (DPCO or the Order) – 1970 formed a part of India's policy shift towards increased controls and protectionism. Under this Order, almost all bulk drugs were also brought under the Essential Commodities Act, which gave the government the power to fix a ceiling price for essential[32] bulk drugs. Return on capital was the consideration for fixing the ceiling prices for bulk drugs, while cost-based pricing determined the retail prices of formulations. The controls were also applied to mark-ups and overall profits. A ceiling of 75 per cent and 150 per cent mark-up on scheduled and non scheduled drugs respectively was imposed. If the overall pre-tax profits exceeded 15 per cent of sales revenue, the surplus was to be deposited with the government, spent on R&D or offset against future losses (DPCO – 1970).

[31] Under Section (2) of the Essential Commodities Act, medicines are considered essential commodities.
[32] As listed in Schedule – I appended to the DPCO – 1970.

It is argued that the cost-based approach used for formulations, introduced under the DPCO – 1970, which to a large extent remained unchanged to date, had a number of flaws. Determining the actual costs as opposed to the claimed costs remained a major issue. It was because authorities could not independently ascertain the costs of new drugs, except for the costs submitted by manufacturers. This method of calculation left open the manufacturers to evade the prescribed limit on overall profitability.

The cost-based approach indirectly encouraged imports over locally manufactured products. For the imported products, the landed cost was used as the basis for calculating the market price, which left loopholes open for transfer pricing.[33] For the MNCs:

> ... it was far more profitable ... to import the bulk drugs and drug intermediates from their parent companies, often at monopoly prices that had no relation to the ruling international prices, and formulate them into finished dosage packs sold under popular brand names. (Bhagat 1982, p. 58)

For example, Pfizer charged US$9,000 per Kg for a material available from Italy at US$125 per kg; Sandoz imported at US$60,000 an item available from Germany at US$23,000 (Lanjouw, J 1998, p. 12). The practice of transfer pricing was not confined to a country or a company a specific period. MNCs including Glaxo, Parke Davis, Merck Sharp & Dohme, and Wyeth frequently engaged in transfer pricing, Recently, an out of court settlement with the US authorities of a litigation involving transfer pricing cost the UK based pharma giant GlaxoSmithKline (GSK) over US$4 billion in 2006 (mX 2006). The implications for consumers were unnecessary high drug prices through inflated costs claimed.

DPCO – 1979

Following the protectionist policies introduced in India in the early 1970s, the government constituted a high level committee to find ways to make India self sufficient in manufacturing drugs and formulations. The Hathi Committee Report (HCR) submitted in 1975, considered to be the most comprehensive study on India's pharma industry, recommended wholesale nationalisation of the drug industry. Other recommendations included formulating a list of essential drugs, controlling the prices

[33] Transfer pricing refers to companies charging their subsidiary significantly higher price for a product than otherwise available.

of drugs based on essentiality, and establishing a National Drug Authority. The committee also recommended mandatory use of generic names for all new single-ingredient products, which the industry opposed.

With its conceptual foundation for a domestic industry and technological capacity building measures, the HCR became the basis for the Drug Policy – 1977. Under this policy, a change in the price control strategy adopted a selective approach. The drugs under the DPCO – 1979, were selected on the basis of essentiality and the number of drugs under price control was reduced to 347.

India had close relations with the erstwhile Soviet Union in the 1970s, and India's general policy shift towards closed economy was noticeable, yet the high level of influence of the pharmaceutical industry in New Delhi ensured that most of the recommendations of the HCR remained unimplemented. Nevertheless, the Drug Policy – 1977 and the Patent Act 1970 (discussed in previous chapter) laid the foundation stone for India's domestic pharma industry, which eventually brought down the drug prices, and made the country self sufficient in pharmaceuticals.

DPCO – 1987

In the mid 1980s, India began introducing selective measures towards industrial liberalisation. The introduction of Drug Policy – 1986 titled 'Measures for Rationalization, Quality Control and Growth of Drugs and Pharmaceuticals Industry in India' was particularly relevant to the pharma industry. This policy was the first clear indication of India's strategic shift from protectionist regulatory framework to adopting a more liberal approach. The relaxation of the regulatory controls was deemed necessary to accelerate growth of the domestic pharma industry. Under the DPCO – 1987, the number of drugs under price control was reduced from 347 in 1979 to 142 in 1987. In relative terms, the 59 per cent drop in the number of drugs reduced the collective share of drugs under price control from 80 per cent to 60 per cent of the Indian market. From the equation, it would be safe to assume that the 205 drugs taken off the list were low priced, or had low sales or both.

While India achieved low drug prices relative to other countries, the share of drugs relative to other healthcare factors is 4-6 times higher in India than in the developed world. India's high level of drugs costs, as a proportion of the total healthcare costs, does not reflect the low pricing that is widely claimed in the literature. In order to bring the share of drug costs to the level of the developed countries, the prices in India would need to reduce to around 20 per cent of the current pricing level, which is highly unlikely to occur.

As noted in earlier chapters, India is almost self sufficient in the production of formulations and around 70-80 per cent of the bulk drugs, and not dependent upon expensive imports, so the drug prices could easily be lowered. It could be argued that prices in the domestic market are influenced by the impact of India's rising exports. India's leading pharma companies such as Ranbaxy and Dr. Reddy's draw more than 50 per cent of their annual revenues from oversees markets. This rapid increase in exports is draining the resources away from the domestic supply to serve the lucrative oversees markets.

This situation presents a challenge for the policy makers. India's low drug prices are not low enough to extend affordability to two thirds of India's population, which remains without access to medicine. India's experience shows that by controlling the drug prices alone, the provision of affordable healthcare is not achieved. What India needs, is a new policy that would subsidise the healthcare costs, and provide an income based system of out-of-pocket patient co-payments.

While the drug price controls played an important role in achieving the low prices, the enforceability and the effect of stand-alone price controls remained questionable. There was no dedicated agency to practically oversee the market activity and enforce price controls. The monitoring of the prices was left to the State drug Controllers, for whom, this was not among their primary tasks. The enforcement and prosecution required a body at the central level.

In 1999, the National Pharmaceutical Pricing Authority (NPPA) was established. The express functions of the NPPA include the implementation and enforcement 'of the provisions of the Drugs (Prices Control) Order in accordance with the powers

delegated to it' (Government of India 2003a). Here 'in accordance with the powers delegated to it' becomes important for two reasons. First, with just 75-staff, the NPPA is significantly understaffed for effective policing (The Sen Committee 2005). It mainly relies on State Drug Controllers and other sections of the government. Second, if a case of over-pricing of a drug is brought to the NPPA's attention, it can only serve the offending company notices to deposit the over-charged amount. The companies usually ignore the notice or go to court and obtain a stay order. The NPPA on average recovers annually Rs 15 crores[34] of the overcharged amount from drug companies, of which, most of the amount is in litigation and there is uncertainty about its quantum and final recovery (Government of India 2005b, p. 39). With the inadequate powers and the lack of sufficient staff, currently delegated to the authority, the NPPA is far from being effective.

DPCO – 2004 (proposed but not yet enacted)

Under the Pharmaceutical Policy – 2002, the DPCO – 2004 was planned, which would have reduced the number of drugs under price control from the current number of 74 to 38. However, as a result of legal action by citizen groups, drugs earmarked under the Pharmaceutical Policy – 2002 for price-decontrol from 2004, could not be set free and the status quo remains (Government of India 2005a). Responding to a petition jointly filed by the citizen groups,[35] the Supreme Court of India (India's apex court) made an order on March 10, 2003, directing the Union Government to ensure that essential and life-saving drugs do not fall out of price control and to review the drugs, which are essential and life saving in nature (Narrain 2004).

Different sections of the Indian Government have different views on the scope of drug price control. The Ministry of Health and Family Welfare, and the Ministry of Chemicals and Petro-Chemicals prefer to bring all 354 drugs under price control. The Prime Minister's Office, and the Planning Commission, would rather seek alternatives to the expansion of price control. The industry opposes any expansion of price controls. The industry suggests that price controls should be abolished altogether and replaced with a less restrictive price monitoring system. According to Minister

[34] The number one crore is equal to ten million.
[35] The All India Drug Action Network (AIDAN), the Medico Friends Circle (MFC), the Low Cost Standard Therapeutics (LOCOST) and the Jan Swasthya Sahyog

Paswan, the Minister responsible for the pharmaceutical industry, the drugs under the current price control account for around 22 per cent of the market by value and placing the 354 drugs on the NLEM under control would amount to around a third of the market. The industry argues that placing the entire [NLEM] list under the DPCO would extend control to around 60 per cent of the market.

6.2.3 The continuing search for alternatives

Several committees have been constituted to investigate drug prices in India. While all such committees, including the National Manufacturing Competitiveness Council (NMCC), the National Commission on Macroeconomics and Health, and the Standing Committee on Chemicals and Fertilizers have made valuable contributions to the debate, the work of the following committees are considered particularly relevant for the issues pertaining to drug price controls.

First, a committee constituted by the Director General Health Services reviewed the National Essential Drugs List (NEDL) in 1996 and compiled the National List of Essential Medicines (NLEM) in 2003. The committee chaired by Dr. S.D. Seth (The Seth Committee) identified essential medicines as 'those that satisfy the priority healthcare needs of the population' (The Seth Committee 2004, p. iii). The committee followed the general principles of the World Health Organization (WHO) on essential drugs. Other terms of reference included India's current disease burden; safety and efficacy; comparative cost effectiveness and the infrastructure available at the delivery level. The NEDL 1996 contained 286 drugs compared with 354 in the NLEM 2003. This number is in stark contrast with just 74 drugs under price control since 1995. From the 354 drugs contained in the NLEM 2003, only 15 or less than 5 per cent are under the purview of the price control currently in place, which demonstrates that the parameters of the control mechanism not keeping pace with the dynamics of public health in India.

Second, in August 2004, Ram Vilas Paswan, the Minister of Chemicals and Fertilisers, constituted a committee under the Chairmanship of G.S. Sandhu. The terms of reference given to the Sandhu Committee were to review the span of price control in light of Supreme Court orders. Other tasks included an examination of trade

margins on the sale of drugs. The Sandhu Committee used a consultative process, in which various stakeholders including the industry and field experts were consulted.

The Sandhu Committee formed the view that the NLEM 2003 as comprehensive and adequate to form a basket of medicines under price management. The Sandhu Committee found the current system of price monitoring to be 'not very effective' and recommended monitoring to be specified into two different types; namely, intensive monitoring and normal monitoring (cited in The Sen Committee 2005, p. 80). The drugs under intensive monitoring would cover all drugs in the NLEM 2003 basket that are currently not price-controlled. The Sandhu Committee recommended that the intensive monitored drugs be rigorously watched and a ceiling of 10-15 per cent annual increase applied. Any increase beyond that would be deemed as over-charging and the extra amount would be recovered from the company. Normal monitoring would imply the continuation of the current practices of the watchdog and would apply to drugs outside the NLEM basket.

For the consumers, the net benefits of the Sandhu Committee's recommendations remain doubtful. First, to place 339[36] drugs under intensive monitoring would not be possible with the current staff levels and the limited powers, which the National Pharmaceutical Pricing Authority (NPPA) has. Second, price monitoring is not the same as price controls. Price monitoring would amount to gathering market intelligence, in contrast, price controlling would establish a price ceiling. Third, if the annual increase of 10-15 per cent were permitted, it would more than double the price of the medicine every few years[37] (in five years at 15 per cent and in eight years at 10 per cent). This provision would be detrimental to consumer interests and drug affordability. In comparison, France caps drug price rises at annual consumer price index (CPI) level, which would be significantly lower than 10-15 per cent. In New Zealand, drug prices are negotiated every five years, and remain fixed for the term.

The Sandhu Committee reviewed the trade margins and found that at present, there are no limits on trade margins on non-scheduled drugs. The 'government was

[36] The 354 drugs on the NLEM list minus the 15 drugs currently under price control.
[37] At 15 per cent (yr1) 115, (yr 2) 132, (yr 3) 152, (yr 4) 174.9, (yr 5) 201; at 10 per cent: (yr 1) 110, (yr 2) 121, (yr 3) 133, (yr 4) 146, (yr 5) 161, (yr 6) 177, (yr 7) 187, (yr 8) 205.

concerned over the exploitation of consumers by retailers and pharmaceutical companies that were charging up to 1000 to 2000 times margin from the customers', Ram Vilas Paswan, Minister for Chemicals and Fertilizers (cited in The Tribune 2004). The average margins are around 500 per cent on the generics; however, anecdotal evidence points to margins over 200,000 per cent in certain cases (Government of India 2005g). The Sandhu Committee recommended that the trade margins for all categories be capped (see Table 6.3 below):

Table 6.3: The trade margins as recommended by the Sandhu Committee (2004)

Drugs	Price controlled	Wholesaler	Retailer
All	Scheduled	8 %	16 %
Brand medicine	Non scheduled	10 %	20 %
Non-brand (generics)	Non-scheduled	15 %	35 %

Source: Based on The Sen Committee (2005, Appendix).

Other recommendations of the Sandhu Committee included mandatory price negotiations at launch of patented drugs, greater coverage of health insurance, special programs for people living the below the poverty line, and reducing of taxes and levies on drugs on the NLEM. For government procurement of drugs, the Sandhu Committee recommended replicating the open-tender approach already adopted by Rajasthan Model of Medicare Societies that saves patients over 50 per cent on the market prices.

The third committee (The Sen Committee) was constituted by the Prime Minister's Office 'to explore options other than price control for achieving the objectives of making life-saving drugs reasonable prices'. The Committee under the Chairmanship of Proneb Sen, Principal Advisor, Planning Commission used the consultative process to arrive at its conclusions. It met with all stakeholders including the industry, international agencies, health professionals, NGOs, and academics. While the industry suggested that 'price regulations are not necessary for drugs and that competition should be able to provide the necessary discipline', the Sen Committee opined that 'the pharmaceutical industry by its very nature is non-competitive, and requires active public intervention to ensure competitive outcomes' (The Sen Committee 2005, p. 19). In its report submitted in September 2005, the Sen Committee re-emphasised that price controls are an essential instrument to curb the market behaviour. The Sen Committee made the following principal recommendations:

Price controls should:

- apply only to formulations and not to bulk drugs or any upstream products;
- not be based on the turnover, but on essentiality of the drug;
- take into considerations the effect of control on the entire therapeutic class; and
- be replaced with price ceilings, within which the companies would be free to position themselves. The price ceilings to rise in accordance with the Wholesale Price Index (WPI) for manufactured goods.

The Sen Committee found the cost-based approach intrusive and open to manipulation. It was suggested that the ceiling prices be based on readily monitorable market-based benchmarks (reference pricing) and not on the cost. The reference pricing should be applied as follows: for existing essential drugs, the price quoted in the bulk procurement by government or other agencies should become the reference price. For new drugs, it would be based on the average price of the top three selling products by value in the therapeutic category, and if less than three brands in the market, the average of all existing medicines would be taken. If no reference in the domestic market, then the lowest price anywhere in the overseas markets would become the reference price. The companies would be free to approach the *Price Negotiations Committee* to review the ceiling price on the basis of superior therapeutic cost effectiveness. All patented drugs and their formulations would be subject to mandatory price negotiations before the market approval would be granted, suggests the Sen Committee.

Contrary to the recommendations of the Sandhu Committee, the Sen Committee does not prefer any ceilings on wholesale and retail margins for generics. The Sen Committee argues that limiting margins on low end products would provide disincentives to retailers to sell generics. Another study suggests that capping the margins on generics would reduce company profits and may result in large companies like Ranbaxy and Cipla abandoning the generics altogether (Institute of Intellectual Property Development 2007). It is argued that in the event of margins being capped, these firms are likely to use different marketing strategies to boost sales rather than abandon the products. The generics remain the core business of India pharma. For example, Ranbaxy's annual report indicates that the generics business grew at 20 per

cent in 2007 and the company has strengthened its generics R&D and expanded its generics operations (Ranbaxy 2008). Cipla is well known for being pro-generics. Both of these companies derive a substantial part of their sales revenue from generics and hence, unlikely to discontinue the generics segment.

It is interesting to note that both the Sandhu Committee and the Sen Committee used the consultative process to obtain views of the industry as well as field experts and other stakeholders including NGOs. Yet, these committees arrived at totally opposing conclusions with regards to the trade margins.

Following the submission of the reports of the various committees, the Department of Chemicals and Petro-Chemicals put out a draft of the Pharmaceutical Policy – 2006 (Part A), which would become a blue print for future directions. Part B that is the new price control framework would be released after finalisation of Part A. The policy draft (Part A) contained a number of significant changes including mandatory price negotiations of patented medicines before marketing approval would be granted.
This clause would have the following implications. If the price is significantly high, the government may not grant marketing approval, and if granted, the high price would render the drug beyond the reach of common Indians. If the price is low, which the government would prefer, then the medicine may not be launched in India, and the patients would miss out on the latest drugs.

6.2.4 Trade margins

The policy draft also included capping of trade margins in accordance with the Sandhu Committee recommendations. Capping trade margins would keep the prices of generics at a reasonable level, which would increase the number of people with access to medicine in India. Fixing or capping the trade margins on medicines is also a form of price control that limits the mark-up by the wholesaler and the retailer, and thereby keeps the prices down. Trade margins are lower for the wholesalers and higher for the retailers, and a number of countries place limits on these margins (see Table 6.4). The Table shows that wholesaler and retailer margins are low in the US at around 2 per cent and around 15 per cent respectively. The trade margins in Spain are

fixed at a level higher relative to the US and Egypt, Switzerland has variable margins, which transcend the Spanish limits.

Table 6.4: Trade margin in select countries (percentage of the drug price)

Country	Wholesaler	Retailer
Egypt	7%	20%
Spain	12.4%	43.7%
Switzerland	11.1% - 17%	26% - 70%
US	Around 2%	Around 15%

Source: Based on Sakthivel (2005).

6.2.5 Trade margins in Australia

Australia applies a formula to workout the trade margins for retailers of medicines. The retailer margins are dependent on the dispensed price (price to consumer) of the medicine and are worked out using the formula shown in Table 6.5 (see also Table 6.6). This formula is negotiated within the context of the 5 yearly Community Pharmacy Agreements between the Commonwealth Government and the Pharmacy Guild. The wholesaler margin was set at 10 per cent of the price-to-pharmacist (PTP), which has since 2006 been reduced to 7 percent of the PTP. This equates to a PTP of $100 being shared at $93 and $7 between the manufacturer and the wholesaler.

Table 6.5: Formula for calculating dispensed price in Australia

Price to pharmacist (PTP)	Dispensed price
From January 1991 to June 2000	
up to $180.00	PTP + 10% margin + dispensing fee
between $180.01 and $360.00	PTP + $18.00 + dispensing fee
$360.01 and higher	PTP + 5% margin + dispensing fee
From July 2000 to June 2006	
up to $180.00	PTP + 10% margin + dispensing fee
between $180.01 and $450.00	PTP + $18.00 + dispensing fee
$450.01 and higher	PTP + 4% margin + dispensing fee
From July 2006	
up to $180.00	PTP + 10% margin + dispensing fee
between $180.01 and $450.00	PTP + $18.00 + dispensing fee
between $450.01 and $1,000.00	PTP + 4% margin + dispensing fee
$1,000.01 and higher	PTP + $40.00 + dispensing fee

Source: Based on Sweeny (2008, p. 61).

Currently, the dispensing fee in Australia is set at $5.44 for ready[38] medicines. For opiates such as morphine, a "Dangerous Drug" fee is added to this for certain items. A higher dispensing fee is specified for medicines that require the pharmacist to mix them with a solvent, or if the pharmacist has to break a pack and provide a separate container (Sweeny 2008). To keep it manageable, the discussion is confined to ready medicines. So, under the current scenario, retailer margins for ready medicines can be calculated as follows.

[38] Dispensed as received, i.e. without breaking the packs, or taking out small quantities from bottles etc.

Table 6.6: Retailer margins in Australia (2008)

	Retailer's margin (absolute)	Retailer's margin (relative)
up to $180.00, say $100	$10+$5.44 = $15.44 ($100)	15.44% ($100)
between $180.01 and $450.00	$18+$5.44 = $23.44	13.02% to 5.21%
between $450.01 and $1,000.00, say $800	$32+ $5.44 = $37.44 ($800)	4.68% ($800)
$1,000.01 and higher	$40.00 + $5.44 = $45.44	4.54%

Source: Author calculations based on Table 6.5.

Table 6.6 demonstrates that the level of retailer margins for the ready medicines listed on the Pharmaceutical Benefits Scheme (PBS) depend on the price of the medicine. The high priced medicines have low retailer margins (4.54 per cent for $1,000.01 and over) and low priced items have higher margins (15.44 per cent for $100). The table also shows that the margin varies with the price for items up to $180 and also from $450.01 to $1,000. The margin is fixed for items between $180.01 to $450 and $1,000.01 and above. For the Australian consumer, this system has the following the implications. In the price bracket of up to $180 as well as in the price range of $450.01 to $1,000, the retailer has an incentive to dispense a more expensive item, because the retailer benefits more from a higher price. In the other categories, where the retailer margin is confined to a fixed amount, there is no incentive for the retailer to dispense an expensive item, which benefits the consumer.

Under the current price control arrangements in India, the consumer does not necessarily pay a low price for generics. The significantly high margins, common on generics as noted above, means that the dispensing retailer is the highest beneficiary in India, and not the consumer. The exorbitant margins of thousand per cent and more make even the generics unaffordable for the poor masses of India. With the level of poverty prevalent in India, the Sandhu Committee recommendations for trade margins are more in line with what India needs.

6.2.6 Market behaviour

Two different examinations are applied to assess the market behaviour for drug price controls. First, during recent negotiations with the government regarding the scope of price controls, 11 domestic pharma companies voluntarily agreed to reduce prices on a collective total of 886 formulations. We examine the claimed prices of these drugs against the actual prices in the market. Second, we examine the changes in prices of 406 drugs in the 2005-08 period that demonstrates the post-TRIPS price movement.

Price reductions under the voluntary agreement

As a part of the agreement reached between pharmaceutical companies and the government, 11 companies agreed to reduce the prices of 886 formulations (see Table 6.7). The agreed prices of these 886 items were checked against the prices published in 2007-08 editions of CIMS, Drug Today, IDR Pharmacy Compendium. The revised (low) prices were supposed to take effect from 1 October 2006. In reality however, the companies did not reduce the prices on a significant share of the agreed formulations. The government's own assessment indicated that as at 14 May 2007, only 295 or only a third of the agreed items had their prices reduced (Government of India 2007a).

Table 6.7: Summary of price reduced formulations (2006)

S. No.	Name of the Manufacturer	No. of Formulations	Range of Reduction (in %)
1	Alembic Ltd.	109	3.06% to 36.67%
2	Cadila Healthcare	391	2.07% to 74.53%
3	Wockhardt Ltd.	101	8.33% to 40.00%
4	Emcure Pharmaceuticals Ltd.	10	26.81% to 65.67%
5	Unichem Laboratories Ltd.	16	17.24% to 54.29%
6	Ranbaxy Laboratories Ltd.	72	0.26% to 42.00%
7	Lupin Ltd.	68	6.67% to 71.45%
8	Nicholas Piramal	18	2.78% to 20.00%
9	Cipla Ltd.	49	10.00% to 50.00%
10	Alkem Laboratories Ltd.	22	8.51% to 45.34%
11	Medley Pharmaceuticals Ltd.	30	11.11% to 40.00%
	Total	886	0.26% to 74.53%

Source: Government of India (2006i).

An item by item examination of the list by the author revealed the following. The 886 items included a pregnancy test card, 7 Ayurvedic medicines, at least 31 forms of iron, vitamins or other nutritional supplements. Notwithstanding the positive role the foregoing items play in healthcare, it is argued that these items could not be viewed as [allopathic] formulations. It was found that from the 886 items, only 134 or 15.1 per cent were listed in CIMS[39] (July-Oct 2007), Drug Today (Oct-Dec 2007), or IDR (Nov 07- Jan 08). Table 6.8 below shows that out of the 134 items listed, 103 items had a price higher than the agreed price while 16 items had a lower price. The Table also shows that the prices on 9 items were lower than or equal to the agreed price in at least one reference book but higher in the other(s). Only 6 items were found to have the correct prices in all three reference books.

[39] CIMS, Drug Today and IDR are the reference books used by medical practitioners to prescribe medicines.

So, what are the implications for the consumer? The significance of items listed in the reference books would be that these items would be available in a substantial part of India, while the unlisted items may be targeted at a niche market in certain region(s) or area(s) with low sales. A recent study concluded that from the medicines listed in CIMS, less than a third of the formulations were available in the urban areas and even less in the rural (Das, Mandal & Mandal 2007). This study was confined to West Bengal, which is considered to be one of the more progressive states. If less than a third of medicine listed in CIMS were available in West Bengal, it can be safely assumed that in the less developed states such as Bihar, Orissa and Uttar Pardesh,[40] the number of medicines available would be even less than West Bengal. The 752 items that are not listed in any of the reference books would have insignificant sales, which would render the voluntary agreement trivial. It is highly unlikely for the doctors anywhere to prescribe medicines that are not listed in these reference books. Consequently, this price reduction agreement would have minimum impact on the sales revenue of the companies involved. The implications for the consumer are that despite the widely publicized price reductions, most of these drugs continue to be sold at higher prices. The benefits of these claimed price reductions to the consumer would be limited.

Table 6.8: Summary examination of claimed price reductions (2008)

S. no	Manufacturer	No. of items priced				No. of Items	Claimed no. of items with	%age of items
		High	Low	Mixed	Equal	Referenced	Prices reduced	Referenced
1	Alembic	12			1	13	109	11.93%
2	Alkem Laboratories	9		6		15	22	68.18%
3	Cadila Healthcare	17	4	3		24	391	6.14%
4	Cipla	37			1	38	49	77.55%
5	Emcure Pharmaceuticals	8				8	10	80.00%
6	Lupin	7			4	11	68	16.18%
7	Medley Pharmaceuticals	3	5			8	30	26.67%
8	Nicholas Piramal	2				2	18	11.11%
9	Ranbaxy Laboratories		4			4	72	5.56%
10	Unichem Laboratories					0	16	0.00%
11	Wockhardt	8	3			11	101	10.89%
	Total	103	16	9	6	134	886	15.12%

Source: Author.

[40] Uttar Pardesh is the most populous state in India.

Examining changes to drug prices (2005-08)

This examination studies the drug prices for 406 formulations for the period 2005-2008. This study was initially based on the research of prices of 152 formulations for the period 1994-2004 by Sakthivel (2005). The significance of this period is that India signed the TRIPS agreement in 1994 and the Sakthivel study was considered to reflect the market behaviour in the lead up to the implementation of the agreement in 2005. While the contribution of foregoing study is gratefully acknowledged, the Sakthivel[41] study considered the brands, but did not consider strengths, forms, quantity or packs of the formulations. The omission of these parameters does not make any allowance for a follow up study. To illustrate the point, Sakthivel listed price changes on two amoxicillin formulations; namely, Novaclox and Novamox. Yet, we found and considered 13 different versions (7 for Novaclox, and 6 for Novamox) packed in different forms, strengths, and quantities. This lack of specificity by Sakthivel (2005) made it difficult to compare the price changes of the formulations in the pre and post TRIPS period.

Our study for the period of 2005-2008 involved comparing prices of formulations listed in Drug Today (Jan-Mar 2005) with CIMS (July-Oct 2007), Drug Today (Oct-Dec 2007), and IDR (Nov 2007-Jan 2008). The 406 items were categorised in 10 therapeutic groups. Table 6.9 provides an overview of the main findings of the two studies.

Table 6.9: Price changes during two study periods

Sakthivel study						
Period	Studied items	Price unchanged	Price reduced	Price increased	Lowest increase	Highest increase
1994-2004	152	19 (12.5%)	26 (17.1%)	107 (70.4%)	0.18% on Crotorax-HC	18.19% on Urografin
Our study						
2005-08	406	214 (52.71%)	64 (15.76%)	128 (31.28%)	0.08% on Zimalgin	107.4% Fluracil

Source: Author estimates.

The Table above shows that over 70 per cent items during 1994-2004 and over 31 per cent during 2005-08 had a price increase. The difference is in the level of increase is significant. During the first study period, 11 items (7.24 per cent of 152) or 10.3 per cent of 107 items had more than 10 per cent increase. During the second period of study of 83 items (20.44 per cent of 406) or 64.84 per cent of 128 had a double-digit

[41] Emails to Sakthivel were not replied. (on record with the author).

increase, of which 57 items (14.03 per cent of 406) or 44.53 per cent of 128 drugs registered a price increase of 20-70 per cent. Notwithstanding the lesser number of items, the first study did not find increases of more than 18.19 per cent over a ten-year period. The post-2005 increases are substantial considering the shortness of the study period. All therapeutic groups, except the HIV/AIDS group had price increases over the study period. In the HIV/AIDS group, prices either reduced or remained unchanged (see Appendix B for full details).

Of the 406 formulations studied, 149 were under the current price control (Drug Price Control Order – 1995) and 231 were on the National List of Essential Medicines (NLEM 2003). From the formulations that had prices increased from 2005 to 2008, 71 were listed in the NLEM and 25 were under the DPCO – 1995. While the increases on most items, which are under price control were found to be minimal, the price increases for items outside price control, were significant including those on the essential medicines list. Had essentiality been a criterion under the current price control mechanism, all formulations listed on the NLEM would have been considered for price control. The net result in the market would have been minimum price increases for all items listed on the NLEM.

While the NIPER's (2006) report on the *'Impact of TRIPS on pharmaceutical prices (with specific focus on generics in India)* suggests that TRIPS is unlikely to have an effect on drug prices in the times to come, our analysis clearly demonstrates that prices are indeed affected in the upward direction. From the foregoing discussion, the following conclusions can be drawn. The current price control framework does not deliver affordable medicines, which the government-appointed experts consider essential. The shift away from essentiality as a criterion for price control had adverse impact on the affordability of essential drugs. In the lead up to the implementation of the TRIPS agreement in 2005, there were apprehensions among citizen groups and other stakeholders, that after 2005, drug prices would rise substantially in India, which would further erode the drug affordability. Our analysis of post-2005 price changes confirms those fears.

The various committees appointed by different departments reached different conclusion on the level of control, i.e. price control/price monitoring or

formulations/bulk drugs. Nevertheless, the committees unanimously agreed that essentiality should be the primary basis for drug selection criteria. The implicit conclusion reached is that the changes to the selection criteria introduced under the DCPO – 1995 was a mistake that has resulted in unnecessarily high prices on essential drugs.

The enforcement agency; namely the National Pharmaceutical Pricing Authority (NPPA) does not have adequate manpower to effectively undertake the tasks the NPPA is assigned to perform. The current rules do not provide the NPPA adequate powers for effective enforcement. The authorities have had limited success in recovering from the companies the over-charged amounts. The recovery process is cumbersome and when taken into account the recovery time and costs, the net gains to the society would be questionable.

It is ironic that India, a major producer and exporter of low-cost generics, as noted in earlier chapters, has such high drug expenditure as a proportion of the total healthcare expenditure. Over the last 30 years, the price control framework, in conjunction with other regulatory measures, ultimately lowered the drug prices in India. However, India's drug prices are low relative to drug prices in other countries in absolute terms, but not low in relative terms. A low level of drug expenditure in India, similar to most of the OECD countries, as a share of total health expenditure, would require a significant drop in drug prices in India in absolute terms.

Against the backdrop of the above discussions, India needs to explore other options. Until now, the Indian approach to healthcare has been patchy and incomplete. The past policies provided a framework that underpinned the growth of the domestic pharma industry and brought down the drug prices. Yet, around two third of India's population remain without access to medicine, which is in stark contrast with India's recent economic growth. Under the Indian Constitution, the State is charged with the responsibility to 'regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties' (Article 47). With India's future policy directions in disarray, its policy makers need to consider healthcare options that are equitable, affordable and implementable. India

could learn from other countries' experiences and see how these countries make the essential drugs affordable to the poor as well as keep the industry growing.

6.2.7 Price control models

Most developed markets have fully integrated programmes in place that employ drug price controls on the one hand and deliver equitable healthcare on the other. Under these programmes, the products listed on the formulary are subsidised by the government, and this listing is considered the key to success in these markets. The out-of-pocket patient co-payments account for a small percentage of the drug sales. The process for listing is rigorous and involves both manufacturers and the authorities agreeing to specific pricing conditions. In France for example, where over 90 per cent of the total drug sales are subsidised, the government uses its monopsonistic power to negotiate low drug prices. This helps the government to keep the drug prices under control and to rein in the rising healthcare costs. The price control framework has two components; namely, negotiating/determining the drug price (supply side), and controlling the demand to influence the quantity sold. Table 6.10 shows a range of instruments employed in connection with achieving these objectives in different countries, from which the main instruments are considered hereunder.

The introduction of a drug into these markets is usually a two-stage process; namely, seeking the marketing approval and the listing on the formulary for reimbursement. The focus of this discussion is on the latter part of the process. Generally, when submitting an application for listing of a new drug on the formulary, the manufacturer is required to supply the data on safety, efficacy, and in many cases also on the cost-effectiveness of the drug relative to comparator. This data enables the government evaluate the drug and assess its price. One of the most commonly used methods for the drug assessment is reference pricing.

Reference pricing and pharmacoeconomic analysis are used to establish the true value of the benefits of a new drug (Harvey, K et al. 2004). Reference pricing allows price comparisons against existing drugs within the same molecular/ therapeutic group or against a basket of countries where the [proposed] drug is already marketed. Under the molecular comparison, the proposed drug is compared for costs against existing

drugs and/or therapies to treat the same condition. Reference pricing is commonly used for follow up generics, which must not be more expensive than the innovator drugs in the market. Reference pricing helps minimise the pharmaceutical costs because the lowest priced brand becomes the benchmark for others within the same therapeutic group (Sweeny 2008). Reference pricing is not suitable for more effective drugs relative to the existing ones.

Table 6.10: Instruments of drug price control in selected countries

	Supply	UK	GER	FR	SP	AUS	NZ	Can
Price	Cost plus pricing				■			
	Pharmacoeconomics criteria	■	■	■		■	■	
	Molecule/class reference pricing		■	■	■	■	■	■
	Cross-country reference pricing			■	■			■
	Mandatory rebates		■	■				
	Price cuts/price freezes	■	■	■	■			
Volume	Marketing spend limits			■	■			
	Product volume caps			■				
Spending	Profit controls	■						
	Revenue controls				■			
	Demand	■	■	■	■	■	■	■
Price	Co-payments/co-insurance	■	■	■	■	■	■	■
	Generic substitution incentives				■	■	■	■
Volume	Prescribing guidelines	■	■	■		■	■	
	Positive/negative lists	■	■	■	■	■	■	
	Formularies						■	■
	Parallel import dispensing targets/ incentives	■	■					
Spending	Physician Rx budgets	■	■					
	Physician healthcare budgets	■		■				

Source: Based on BCG, (2004).

Reference pricing highlights the price interdependency, which results from the use of third country prices for the calculation of permissible domestic prices (WHO/WTO 2001). The draw back of reference pricing is that pricing level in the reference country could affect the price acceptability in the domestic negotiations. With the increased use of prices as a reference in other countries, the market separability is disappearing and the countries are merging into larger markets with similar price levels.

In 1993, Australia pioneered the pharmacoeconomics (cost-effectiveness analysis) criterion for the drug price assessment. The pharmacoeconomics criterion measures 'value for money' on the basis of the evidence of a new drug's likely cost and clinical

effectiveness relative to the existing treatment alternatives. The cost-effectiveness analysis (CEA) seeks to maximize health gains within the budget constraints (Goddard et al. 2006). The CEA has gained wider acceptance in the process of price determination in a number of countries including UK, Germany, and New Zealand. Some other models for price control are as follows.

The United Kingdom model is based on controlling the overall profits and return on capital but does not fix the drug prices. The pricing of branded prescription medicines is indirectly controlled through the Pharmaceutical Price Regulation Scheme (PPRS), under which prices are negotiated every 5-6 years between the government and the pharma industry. The last PPRS was negotiated in 2005. The PPRS determines the prices of all brand medicines primarily sold to the National Health Service (NHS), and the hospitals. Under the measures introduced in 2000 and in 2005, certain [branded and unbranded] generics sold to community pharmacies and dispensing doctors under the 'Maximum Price Scheme' place a ceiling on the prices of these generics (Department of Health 2005). In the UK, all prescription medicines are reimbursed except those on the negative list. India has, in the past, tried to control drug prices by limiting the profits. This approach has a limited applicability, because, under this policy, the manufacturers would exploit the flexibility and raise the drug prices to the highest level possible without exceeding the overall profitability.

In New Zealand, the Pharmac determines the drug price and the level of subsidy for reimbursement and lists the drugs on the Pharmaceutical Schedule. Under certain conditions, the manufacturer cannot set the price higher than the subsidy. The Pharmaceutical Schedule includes certain over-the-counter, patented and off-patent products. The Pharmac calls for tenders for the exclusive supply of a sole brand in a chemical listed for a fixed period. The manufacturer has exclusive and guaranteed product sales in exchange for an agreed price. The agency also negotiates the listing of a drug in exchange for lowering the price and subsidy of another (Braee 2001).

The tendering process is already used in a number of Indian states such as Karnataka, Maharashtra, Tamil Nadu (Tamil Nadu Drug Corporation) and Rajasthan for purchase of medicines. This approach could provide significant advantages for India if the tendering process was centralised to purchase the medicines at the national level

rather than by individual states, because the central government would have much larger negotiating power. While the New Zealand approach helps the state negotiate low prices on a particular brand, it effectively locks out all other competitors from the market for the duration of the contract, which reduces choice for prescribers and consumers.

In Canada, the Patented Medicine Prices Review Board (PMPRB) sets the 'factory gate' prices, at which the manufacturers sell the patented medicine to wholesalers, hospitals and pharmacies. The Board has no jurisdiction over the wholesaler, or retail prices. The prices for generics as well as over-the-counter (OTC) drugs are also outside the control of the PMPRB. While each province and territory has its own drug insurance plans that vary in cost-sharing arrangements and drugs reimbursed, all plans encourage the use of generics (Sketris, Bowles & Manuel 2003). The price of a new [patented] drug is governed by existing drugs within the same therapeutic group available in Canada. For innovative drugs, the median price in France, Germany, Italy, Sweden, Switzerland, UK and the US is used to determine the maximum price for the proposed drug (Government of Canada 2008).

The Canadian system seems to be working reasonably well for patented medicine, and these cost significantly less in Canada than in the US. It is evident from the US patients' purchase of their prescription medicine across the border. As Canada does not exercise any control over the price of the generics, these are generally higher priced than the US. The overall Canadian approach would not suit India's situation, where the generics account for over 90 per cent of the market. Besides, the state-by-state healthcare approach would increase the gap that already exists in health outcomes between states in India.

In 2004, Germany established the Institute for Quality and Efficiency (IQWiG) to provide the benefits evaluation and cost-benefits assessment for pricing, and level of reimbursement for innovative drugs (Graf von der Schulenburg 2007). The healthcare reforms introduced in 2007 allow the apex body of health insurance funds to stipulate the maximum reimbursement price for patented drugs based on the cost-benefit assessment (Verband der Forschender Arzeneimittelhersteller 2007). Germany also calls for mandatory prescription of the most cost-effective drug within the therapeutic

group. Introduced in Germany since 1993, the physician drug budgets also reinforced the cost-effective analysis approach. Under this policy, individual physicians could still prescribe drugs of their choice subject to not exceeding their drug budgets (Schreyoegg & Busse 2005). The mandatory prescription of most cost-effective drugs would help India reduce the use of less effective drugs and increase the use of low-cost generics. An approach such as the IQWiG would help analyse a new drug for efficiency and its 'value for money'.

In Australia, before applying to the Department of Health and Ageing for a listing on the Pharmaceutical Benefits Scheme (PBS), the product must be approved for marketing by the Therapeutic Goods Administration (TGA) and registered on the Australian Register of Therapeutic Goods (ARTG). The process for marketing approval for drugs that takes on average 526 days, compared with the average of 308 and 371 days in the UK and the US respectively (Rawson 2000). As at 17 June 2008, there were around 11,364 medicines on the Australian Register of Therapeutic Goods (ARTG) (TGA, 2008, pers. comm.[42] 17 June).

The listing of a product on the Pharmaceutical Benefits Scheme (PBS) is a rigorous process that evaluates safety and efficacy, assesses the proposed drug for value, considers cost of proposed drug against the products already listed, and/or compares the price in other countries. There are two main bodies involved in the process; namely, the Pharmaceutical Benefits Advisory Committee (PBAC) and the Pharmaceutical Benefits Pricing Authority (PBPA). In order to help the manufacturers with submissions, the Australian Government has made available online the two principal documents used in the process. *Policies, Procedures and Methods used in the Pricing of Pharmaceutical Products,* which is updated regularly (last one December 2006) and *Guidelines for Preparing Submissions to the Pharmaceutical Benefits Advisory Committee* (last one December 2007). The manufacturer can argue on a cost-effectiveness basis that their medicine is superior to the comparator justifying a price premium (higher price), or on a cost-minimisation basis, which means that the proposed medicine is equivalent to the comparator but priced lower (Sweeny 2008).

[42] Email from the TGA on record with the author.

The Pharmaceutical Benefits Advisory Committee (PBAC) considers the effectiveness and cost of a proposed benefit compared to alternative therapies, and provides advice to the Pharmaceutical Benefits Pricing Authority (PBPA) regarding the findings of alternatives on their cost effectiveness. The PBPA uses a number of criterion including PBAC comments on clinical and cost effectiveness, and reference pricing in the same therapeutic group an/or the price of the drug in other countries. The final process includes negotiations between the government and the manufacturer to agree a mutually acceptable price, and 'this is where the government uses its monopsonistic purchasing strength to achieve lower prices relative to those paid in international markets' (Duckett 2004, p. 60).

The Minister for Health and Ageing may approve the listing of drug if the expected annual cost to the PBS is less than A$5 million, while costs between A$5 million and A$10 million have to be approved by the Department of Finance and Administration. In case of more expensive drugs, they have to be cleared by the Cabinet before these can be placed on the PBS (Sweeny 2008). These increased drug costs, with the listing of more expensive drugs, could be justified in a wider economic context. Because the listing process involves cost-effectiveness, the additional expenditure may be offset in reduced time off work and increased productivity, argues Ducket (2004).

These price control models offer an overview of instruments that have been successfully used in different countries. Some of the committees appointed by the Indian Government have considered some of these instruments. For example, the recommendations of the Sen Committee included reference pricing, and cost effectiveness analysis. India could consider these models to develop its own price control framework that would be more effective, than the current system, in providing essential drugs at affordable prices.

6.3 Health insurance

The object of this section is to assess the current role of health insurance, if any, in India's provision of healthcare, including the consideration of access to medicines and how India's situation compares with other countries. Health insurance is defined as 'any mechanism which covers the risks of payment for health care at the time of its requirement' (Ellis, Alam & Gupta 2000, p. 207). Most of the industrialised nations,

except the US, and a small number of developing countries, have some form of universal health insurance programs that cover a vast majority of their populations for a substantial share of their health expenditure including pharmaceuticals. In the US, in 2006, the public health insurance (Medicaid, Medicare and Military) covered only 27 per cent of the population (DeNavas-Walt, Proctor & Smith 2007). The debate for universal healthcare and increased price controls in the US has gained momentum in recent years. Senator Hillary Clinton, one of the presidential candidates for the Democrats, favoured the universal health insurance that would cover the entire US population. Other experts oppose the introduction of drug price controls in the US and argue that such a move would result in much higher costs than benefits to the society (Santerre & Vernon 2006).

In Australia, the public expenditure accounted for 85 per cent of the costs of drugs listed under the PBS programme (Duckett 2004). The Medicare programme covers the entire population for medical costs such as visits to the doctors and hospitalisation at public institutions. The down side of relying purely on universal health insurance is that public hospitals in Australia have waiting periods of several months or years for non-emergency procedures. People, who have private health insurance, can access private or public healthcare facilities without waiting.

6.3.1 The Indian approach to health insurance

In contrast to the developed world, most developing countries including India do not have universal health insurance programmes. Until recently, the lack of appropriate framework in India barred private investors from participating in the insurance sector, which remains under developed. The life insurance industry was nationalised in 1956 and 176 companies were merged to for the Life Insurance Corporation of India. The nationalisation of the entire general insurance business followed in 1972. The General Insurance Business (Nationalisation) Act, 1972 (GIBNA) was enacted to nationalise and take over the shares of 55 Indian insurance companies and the undertakings of 52 insurers carrying on general insurance business (General Insurance Corporation of India 2008). Lack of competition meant that there was no pressure on the state owned enterprises to promote insurance. The sector became so inefficient that he overall insurance penetration remained at just 6 per cent (Nagendranath & Chari 2002). In

recent years, in the Annual Reports of the all four state-owned insurers; namely, National Insurance, New India Assurance, Oriental Insurance, and United Insurance, which account for most of the Indian insurance sector, health insurance did not get a mention. The life insurance plays a dominant role in India, in which, the Life Insurance Corporation (LIC), another state owned enterprise is the largest insurer.

The absence of universal health insurance in India created a vacuum, which different groups tried to fill. The approach has been fragmented with employment based private groups, public sector employees, and community-based insurance groups providing the health cover for specific segments of the Indian population. In 1948, the Employees State Insurance Corporation (ESIC) launched the Employees State Insurance Scheme (ESIS), which provided medical benefits. This scheme was started as a compulsory social security benefit scheme for workers in the formal sector (Ellis, Alam & Gupta 2000). The scheme covered non-seasonal factories using power with 10 or more employees or non-power using non-seasonal firms employing 20 or more (Gupta, I & Trivedi 2005). A major difficulty of this scheme is that small firms, which employ fewer workers than the stipulated minimum limit, cannot be covered under the ESIS. According to IAMR (2003), in 2003, the ESIS covered 8 million or just 2 per cent of India's 411.5 million strong workforce (cited in Gupta, I & Trivedi 2005). The scheme is based on premiums through payroll tax of 4.75 per cent on the employer and 1.75 per cent on the employee, and substantially funded by the respective state governments. The scheme provides healthcare through dedicated dispensaries and hospitals.

The Central Government Health Scheme (CGHS) was started in 1954. The CGHS is designed to provide healthcare to the current and former Central Government employees and their families. Similar to the ESIS, the CGHS also has dedicated dispensaries, most of which are allopathic. The CGHS is criticised because 'the large central bureaucracy in India definitely belongs to the middle-income and high-income categories, they are likely to make above-average use of health services' (Ellis, Alam & Gupta 2000, p. 210). The CGHS has long waiting lists and requires significant out-of-pocket costs for treatment. Despite mostly being fund the Central Government, the out-of-pocket upfront costs discourage low-paid employees from using the CGHS

scheme. The ESIS and CGHS collectively cover around 3 per cent of the population including employees and their families (Garg 2000).

Other schemes for the employees of various Ministries and Departments also provide health cover. Railways Health Services, Defence Medical Services, and Ex-Servicemen Contributory Health Scheme collectively provide health benefits to around 15 million Indians. Ministry of Textiles offers health cover for workers in the textile sector. The Health package for handloom weavers is non-contributory but restricted to treating TB, Asthma and inflammation of alimentary system and the maximum annual benefit is Rs. 1,500 (US$38) per weaver. This scheme covers around 4 per cent of the 6.5 million weavers. Health package insurance for handicraft artisans, in collaboration with United India Insurance provides reimbursements of up to Rs. 15,000 for hospitalisation. While the state owned health schemes such as the ESIS, and CGHS have been widely criticised for their performance, the Railways Health Services have become a benchmark of their own. The railways provision of high quality healthcare is ensured through 'high degree of accountability, mainly because of very alert labour unions, and well-informed and aware employee population' (Gupta, I & Trivedi 2005, p. 4135). The public health insurance schemes and government sponsored programmes, such as for the handloom weavers, amount to around 85 million or less than 10 per cent of India's population (ibid). No equity based programme provided health cover for those, who worked in the unorganised sector or were out of work.

In addition, some community based health insurance schemes as well as NGOs run schemes operate in some parts of India, which cover only small amount of people. Rag-picker's scheme in Pune (Maharashtra) recognises the importance of the role these poor people play in cleaning up the city. In conjunction with the New India Assurance, the Municipal Corporation provides reimbursements of up to Rs. 5,000 for hospitalisation. The State of Karnatka, in conjunction with Karuna Trust, which is an NGO, and National Insurance, provides health cover for the BPL families. A premium of Rs. 30 for BPL and Rs. 60 for non-BPL families is payable. Students Health Home in West Bengal cover around 1.6 million students, for which, the state government provides an grants-in-aid on direct medical expenses of up to 50 per cent (Acharya & Ranson 2005).

Health insurance for the poor has gained momentum in India in recent years (Ahuja & Narang 2005). The Vajpayee government, in 2003, launched a Universal Health Insurance (UHI), specifically designed for the poor in India, which did not bring the desired results. Under the programme, the government agencies, such as the United India Insurance company, and the New India Assurance Company, would implement the policy. The insurance premium considered nominal is shown in Table 6.11. For the families living below the poverty line (BPL), the government would contribute Rs. 100 to the annual premium. Under the policy, New India would reimburse expenses of hospitalisation up to Rs. 30,000 (~US$750) and a limit of Rs. 15,000 (~US$375) would apply to a single disease.

Table 6.11: Premium for the universal health insurance

Premium	Daily	Yearly
For an individual	Rs. 1.00	Rs. 365.00
For a family up to 5 (including the first 3 children)	Rs. 1.00	Rs. 548.00
For a family up to 7 (including the first 3 children and dependent parents)	Rs. 2.00	Rs. 730.00

Source: The New India Assurance Company (2008).

The UHI programme remained a non-starter and the up take of the policy remained negligible. The lack of awareness of the programme among the target population was considered to be the main reason. Some other factors also contributed to the failure of the programme. First, under the programme, the benefits were confined to the hospitalisation and that only at specified public hospitals, when the private healthcare sector, such as local doctors account for 82 of healthcare delivery (Acharya & Ranson 2005). Second, the programme provided for reimbursement of expenses, which meant that the poor would have to pay for treatment first and then seek reimbursement. For practical reasons, it would not be possible for the poor, the BPL families in particular, to raise funds for treatment. Third, against the high costs of treating diseases such as cancer or cardiovascular, the extent of total benefit and the limit on a single illness were set significant low. A monthly supply of Imatinib mesylate for chronic myeloid leukaemia is marketed by Novartis as Glivec costs Rs. 120,000. Even the generic versions cost between Rs. 10,000 and 12,000 a month.

The Singh government recently launched its own health insurance programme for the poor below the poverty line (BPL). The new policy known as the Rashtriya Swasthya Bima Yojana (RSBY) facilitates direct billing the authorities (i.e. no paying first and

seeking reimbursement later), and the premium in full for the BPL families would be paid by the government.[43] The RSBY was supposed to become operational on 1 April 2008 in Delhi and Haryana, and the programme was expected to be introduced in the other states over the coming years. According to Mr. P Chidambaram, the Finance Minister, 'There would be no paucity of funds for the scheme, which would benefit over 30 million people' (OneIndia 2007). The beneficiaries will be issued Smart Cards, which will facilitate cashless transaction up to Rs 30,000 so that the poor would not have to pay anything for medical treatment.

Under the RSBY programme, pre-existing illnesses would be covered and the transportation costs up to Rs 1,000 would also be covered. The only cost, the poor would have to pay, would be Rs. 25, the one-off cost of the Smart Card. However, the details of the policy do not indicate if the new programme caters for visits to private doctors or if it covers the treatment by Ayurvedic, Yoga, Unani, Siddha, and Homeopathic (AYUSH) practitioners that are dominant in rural India. The RSBY is specially designed for BPL families and it is too early to comment on the impact of the RSBY on the health of the poor or how the BPL segment may response to the latest call of the government to enrol into this programme.

6.3.2 Private health insurance in India

In contrast to employment based compulsory health insurance or universal healthcare, private health insurance is voluntary and purely based on affordability. The more comprehensive benefits are sought; the higher the premium has to be paid. The private health insurance uptake in the developed world is significantly higher relative to developing countries. Recent studies concluded that 69 per cent Canadians had private insurance for partial or full coverage of prescription medicine, 19 per cent were publicly insured. Around 12 per cent of Canadians, who were likely to have the least education and lowest incomes, had no insurance for prescription drugs (Harten & Ballantyne 2004). In the US, in 2006, the employment based or directly purchased private health cover accounted for 67 per cent of the population, while 47 million or almost 16 per cent of the population did not have any health insurance (DeNavas-Walt, Proctor & Smith 2007). Around 45 per cent of Australians have additional

[43] The Union Government contributes 75 per cent and the states 25 per cent.

private health insurance that provides for immediate treatment. The Australian government encourages the uptake of private health insurance by providing a 30 per cent tax rebate on the cost of the insurance.

The significance of third party payers such as private health insurers increases substantially in developing countries, most of which do not have universal health insurance programmes such as the PBS that covers the drug costs in Australia. In the absence of such programmes, all the medical costs, including drugs have to be met by out-of-pocket expenditure. For example, Malaysia does not have a universal health insurance programme or drug price controls. A recent study found that around 15 per cent of the Malaysian population had private health insurance and that the drug prices were too high relative to the average income (Ibrahim & Bahri 2003). This study suggests that Malaysian consumers would benefit from lower the drug prices if price controls were introduced.

In India, the concept of private health insurance is a recent phenomenon. Under the reforms initiated in the insurance sector since 1999, foreign equity of up to 26 per cent is permitted. Among the 24 private companies that have been granted licences under the new policy, there are 9 general insurers including a standalone health insurance company (Insurance Regulatory and Development Authority 2008). The entrance of domestic conglomerates such as the Birla group and the Ambani group (Reliance Health), demonstrates the emerging economic significance of the health insurance. Despite the private health insurance registering a growth of 30 per cent in 2005-06 in India, it still amounted to less than one per cent of the population having private health insurance (Insurance Regulatory and Development Authority 2007). In the wake of the low health insurance incidence, the drug prices, which form the bulk of the healthcare costs in India, become more significant.

The General Insurance Corporation (GIC), through the major four state owned enterprises (noted earlier in the chapter), launched the Mediclaim health insurance scheme back in 1987. Mediclaim provided only hospital cover and domiciliary expenses for groups and individuals. The number of people covered under Mediclaim increased to around 1.3 million in 1993-94 (Ellis, Alam & Gupta 2000), which was a fraction of India's large population. The reasons for low penetration were lack of

promotion, high premiums, and no cover for the out-patient (non-hospitalised) care, which accounts for most of India's healthcare delivery. The absence of competition made the Indian insurance sector inefficient.

Table 6.12 below shows the level of inefficiency of the Indian health insurance system. Relative to the US and Chile, the current India health insurance programmes are significantly less efficient in the public sector. In the private sector, India is less efficient than Chile and the US, when the cost range is taken at the lower end. The US is less efficient than India when the cost range is taken at the higher end in the private sector. The introduction of competition in the insurance sector, which was absent under public sector monopoly prior to the regulatory changes, may increase efficiency in the health insurance sector.

The inefficient insurance sector had the following implications for Indian consumers. This means that the costs to provide health insurance in India were higher than in the US and Chile. Consequently, these high costs were passed on to the consumers. With the increasing number of new entrants in the insurance sector in recent years, the competition is expected to intensify, which is likely to raise the efficiency level and lower the costs.

Table 6.12: Administrative costs of health insurance programmes (percentage of expenditures)

Country	Private	Public
Chile	18.5	1.8
India	20.0-32.0	5.0-14.6
US	5.5-40.0	2.1 (Medicare)

Source: Based on Mahal (1999, p. 73).

While opening-up of the insurance sector to foreign investors is widely viewed as a positive step, the increase in the private insurance may have hidden costs to the poor. The poor may suffer longer delays at public institutions because resources are likely to be diverted to privately insured patients (Garg 2000). Experts suggest a number of steps to safeguards the interests of the poor (Ferreiro 2000). The privately insured should not be subsidised at a public facility. 'Those who prove to have the payment capacity to buy a private health insurance should pay the full rate (real cost of delivery, including investment provisions) of the health care given by a public provider' (ibid, p. 81). It could also be argued that the privately insured are more likely to seek treatment at private facilities, which would free more resources for the

poor at the public institutions. This would mean that a rise in private health insurers would indirectly contribute to improved access to healthcare including access to medicines for the poor.

Most of the public and private health insurance programmes, except the Defence Medical Services, and Ex-Servicemen Contributory Health Scheme, which provide cashless healthcare, are based on reimbursement of the expenses occurred. This feature alone makes the provision of healthcare cumbersome and inefficient. Wether it is ESIS, CGHS or Mediclaim, the requirement to reimburse rather than paying the provider directly, causes unnecessary financial hardships to the poor, and discourages the sick from seeking treatment.

6.3.3. Patient co-payments

Generally, the healthcare programs in most of the countries in the OECD[44] including Australia are funded by the government through some form of universal healthcare. The government subsidy accounts for the bulk of the drug costs, and patient/insurance co-payments cover the remainder. On the one hand, the co-payments are considered necessary to prevent and/or minimize the abuse and wastage of medicine. On the other hand, these payments place a substantial burden on the society and deny access to medicine to the poorer sections. A study of the Canadian market concluded that while shifting costs to patients reduced public expenditure [and discouraged wastage], it also decreased patients' use of essential and discretionary medications resulting in poor health outcomes (Harten & Ballantyne 2004).

High patient co-payments also deny access to medicines. In Australia, around 23 per cent of prescriptions for general patients are not filled, because of the high patient co-payments (Blendon et al. 2002). Among the concession-card holders, this share is only 2 per cent. The Blendon et al. study demonstrates that the general patient co-payments in Australia is set too high, because the co-payments does not consider the range of income levels within the general patients category. It is a 'one size fits all' approach. A more comprehensive framework that considers progressive co-payments for different income levels similar to the Income Tax payments would be more

[44] Organisation for Economic Co-operation and Development

appropriate for Australia. We argue that the co-payments gap between concession card holders and the general patients is so large (see details below), that it discourages families at the lower end of the general patient category, from purchasing the prescribed medicines. Another category set closer to the concession co-payments, say at 150 per cent of the concession co-payments, i.e. A$7.95 at the current level, could encourage this patients group to buy the medicines. The increase in PBS costs would be offset by gains in rise in living standard, reduction in time off-work and increased productivity.

The Pharmaceutical Benefits Scheme (PBS) has been operating successfully since 1948. Initially, all medication on the PBS were provided free of cost. In 1960, for general patients, a co-payment of A$0.50 was introduced that increased over time reaching A$32.90 in 2009. For concession card holders,[45] a co-payment of A$2.50 was introduced in 1990, which has since increased to A$5.30 (2009). The amount of co-payment is annually adjusted in accordance with the consumer price index (CPI).

Where there are two or more brands of the same drug listed on the PBS, the government subsidy is limited to the cost of the lowest priced medicine in the same therapeutic group. If the patient opts for the more expensive brand, the difference (brand premium) is paid by the patient in addition to the co-payment. The payment of brand premium does not count towards the Safety Net threshold. The Safety Net threshold is designed to help families or individuals with chronic illnesses that need a lot of medicine. Once the total of patient co-payments has reached the threshold limit in a calendar year, the medicines become less expensive for the remainder of the year (see Table 6.13).

Table 6.13: PBS Safety Net thresholds from 1 January 2009

Category	PBS Safety Net threshold	Patient contribution
General patients	$1264	$5.30
Concession card holders	$318.00	Free

Source: Government of Australia (2009).

[45] Denotes holders of a Pensioner Concession Card; Australian Seniors Health Card; Health Care Card; or DVA White, Gold, or Orange Card (http://www.pbs.gov.au/html/consumer/pbs/about). These cards are means tested, which means that people with assets above the government threshold would be ineligible.

The PBS programme in Australia has been successfully covering the entire population for most of the drugs over half a century. Over this period of time, Australia has developed a system to determine what drugs should be approved and at what price. The online availability of the information increases transparency of the process that helps the manufacturers, healthcare providers as well as consumers.

Under Australia's fully integrated provision of healthcare, the Medicare levy is an indirect payment for healthcare, and the out-of-pocket patient co-payments directly contribute towards medicine costs. While Medicare provides access to basic healthcare needs such as visits to the local doctor, the PBS subsidises the medicines and keeps the out-of-pocket payments at a reasonable level.

By comparison, India's attempts have been directed to control drug prices, and thereby extend healthcare affordability. The drug prices in India have not been low relative to other factors in the healthcare delivery. The drug share of total healthcare costs is five to six time higher in India than in the OECD countries. The out-of-pocket private health expenditure, when compared with the patient co-payments in Australia, is also many times higher in India. The public health programmes served only specific employee groups or certain regions, and the share of private health insurance in India is insignificant.

There exists a large gap between India's provision of healthcare and those who need to access it. No attempts were made to develop a fully integrated programme that co-ordinates and meets the entire healthcare needs of the Indian community. A healthcare programme similar to that of Australia could fill the gap that currently exists in India's provision of healthcare for all. Development of such a programme would need to consider a number of other factors as outlined below.

6.3.4 Other significant factors

There is a significant part of the Indian community that contributes to the economic activity such as rickshaw-pullers but hardly get a mention in the literature. This group of people is too rich to belong to the BPL families and too poor to belong to the middle class Indians. The 300 million strong middle class (M-class) Indians are the

primary target for marketers and often acknowledged in the global media. The around 350 million poor, who live below the poverty line of $1-a-day (BPL1), have drawn worldwide attention because of their significant size and India's economic success in recent years. In between the M-class and the BPL1, there are around 450 million Indians, who live on around US$2-a-day (BPL2). The population in the BPL2 group and lower end of middle class group mostly get into irrecoverable debts in health crisis. India's healthcare would be incomplete without addressing the needs of all three segments of the community.

A significant factor for the long term planning in healthcare is that Indians are now living substantially longer than a century ago (details in Chapter 7) and the population has slowly begun to age. The ageing factor plays a vital role in healthcare planning because the aged people are the major recipients of healthcare delivery. In 2004, people aged 65 and over accounted for 13 per cent of the Australian population (Australian Bureau of Statistics 2006) and yet, pensioners and other concession cardholders accounted for almost 80 of the drug expenditure (Duckett 2004). In India, the share of the aged has increased by 0.9 per cent between 1981 and 2001 (see Table 6.14). Similar to the rest of the community, about 75 per cent of the aged lived in the rural and 25 per cent in the urban areas (Government of India 2006k). The current share of the aged is estimated to be around 8 per cent that is expected to grow to 9 per cent by 2016 (Government of India 2006b).

Table 6.14: Share of the aged population in India

Year	1981	1991	2001	2016 (est.)
Percentage	6.5	6.8	7.4	9
Total number (million)	43.5	61.4	76.6	114.2

Source: Based on Government of India (2006b, T. 8; 2006f).

It is ironic that while the population has begun to age in India, the public health expenditure has been reduced. As a share of the aggregate expenditure on social services, medical and public health expenditure averaged 16.0 per cent during the 1990-95 period but declined to 11.9 per cent in the 2001-06 years (Reserve Bank of India 2007). Table 6.15 shows that at just 0.22 per cent, India's public health expenditure as a share of the gross domestic product (GDP) was significantly low in 1950-51. The public health expenditure in 1955-56 more than doubled the level of 195051, and further increased to 1.05 per cent as a share of the GDP in 1985-86. Since around mid 1990s, the public health expenditure has been below or around 0.9

per cent of the GDP. In absolute terms, the public health expenditure per capita increased substantially from less than a rupee in 1950-51 to Rs. 2.48 in 1960-61 to or 4.06 times of the amount spent a decade earlier. The 1970-71 recorded the lowest increase relative to the health expenditure a decade ago. The Table also shows that in 2001-02, the per capita public health expenditure reduced in absolute terms over the previous year.

Table 6.15: India's public health expenditure (PHE) as a share of GDP (1950-2004)

Year/Category	Public Health Expenditure as % of GDP			Per Capita PHE	% change in per capita PHE over previous decade
Year	Revenue	Capital	Total	(Rs)	NA
1950-51	0.22	NA	0.22	0.61	
1955-56	0.49	NA	0.49	1.36	
1960-61	0.63	NA	0.63	2.48	4.06
1965-66	0.61	NA	0.61	3.47	
1970-71	0.74	NA	0.74	6.22	2.50
1975-76	0.73	0.08	0.81	11.15	
1980-81	0.83	0.09	0.91	19.37	3.11
1985-86	0.96	0.09	1.05	38.63	
1990-91	0.89	0.06	0.96	64.83	3.34
1995-96	0.82	0.06	0.88	112.21	
2000-01	0.86	0.04	0.90	184.56	2.84
2001-02	0.79	0.04	0.83	183.56	
2002-03	0.82	0.04	0.86	202.22	
2003-04	0.86	0.06	0.91	214.62	

Source: Government of India (2006g, Table 4.2.2).

In India, the states account for approximately two thirds of the total public health expenditure and the Union Government contributes around one third (Economic Research Foundation 2006). Together both levels of government spend on health around 0.9 (0.3 + 0.6) per cent of the GDP, which is lower even by developing country standards as noted earlier (see Table 6.1). The public health expenditure in most of the OECD countries has an average of around 5 per cent (WHO 2006). A breakdown of India's public health expenditure provides an insight into the expenditure on health by two levels of government. While the Union Government increased its expenditure on health and family welfare in 1999-2000 in absolute terms and in relative terms over the previous year, as a share of the GDP, the Union Government expenditure has remained at 0.3 per cent since 1999-2000 (see Table 6.16).

The decline in the states health expenditure over the last 25 years has contributed to the increase in the private health spending. Table 6.17 shows that the Union Government significantly increased the health spending as a share of total public expenditure from 0.22 per cent in 1981 to 0.83 per cent in 2005. The decline in the state governments' expenditure on health nullified the increase in the Union Government's spending on health. Because the states share on health expenditure is around twice that of the Union Government, there has been a net loss to consumers.

Table 6.16: Central Government Expenditure on Health & Family Welfare

Year	%age of	Expenditure (Rs. Crore)	
	GDP	Total exp	H & FW
1997-98	0.2	232053	3174
1998-99	0.2	279340	3993
1999-00	0.3	298053	5012
2000-01	0.3	325592	5291
2001-02	0.3	362310	5977
2002-03	0.3	413248	6521
2003-04	0.3	471203	7195
2004-05	0.3	498252	8191
2005-06	0.3	506123	9911
2006-07	0.3	581637	10744
2007-08	0.3	680521	14384

Source: Based on ICRIER (2007).

The table below shows that in all states, except Jammu and Kashmir, the health expenditure as a share of total expenditure decreased and in 2005 remained below the level of 1981. The states in the table collectively represent almost 90 of India's population. The table shows that the public health expenditure in all states was highest in 1987. The public spending decreased in 13 out of the 18 states by more that 20 per cent from the 1981 level to 2005. Over the entire study period, the largest decrease in health spending was over 85 per cent in West Bengal and the lowest in Uttar Pradesh at 4.26 per cent.

Many observers, including the world-renowned economist Jeffery Sachs, have suggested that India should increase its public health spending as a share of GDP, Sachs suggesting that it should be increased to 4-5 per cent of the GDP. While coming to power in 2004, in its Common Minimum Programme, the current UPA (United Progressive Alliance) government and the National Rural Health Mission (2006) committed to increase the public health expenditure to *at least* 2-3 per cent of the

GDP. Notwithstanding the new healthcare initiatives introduced, in all the budgets presented by the UPA government including the most recent 2008-09, no significant increase in public health spending as a share of GDP was reported.

Table 6.17: Public health expenditure as a percentage of the total expenditure (selected states)

	Year								Percentage change
State	1981	1987	1991	1996	1998	2001	2003	2005	1981-2005
Andhra Pradesh	5.8	7.88	5.53	4.65	5.44	4.74	3.96	3.53	-39.14
Assam	3.96	10.21	NA	5.84	5.87	4.66	3.69	3.06	-22.73
Bihar	3.78	8.49	5.1	5.79	5.24	4.01	3.17	3.24	-14.29
Goa, Daman & Diu	7.19	13.45	8.7	5.39	4.89	3.9	4.02	3.27	-54.52
Gujarat	4.38	9.58	5.03	4.7	4.57	3.38	3.21	3.05	-30.37
Haryana	4.33	8.25	4.11	2.95	3.27	3.26	2.88	2.59	-40.18
Himachal Pradesh	6.63	13.5	3.32	6.16	7.04	5.64	4.5	5.08	-23.38
Jammu & Kashmir	3.79	12.5	5.56	5.5	4.97	4.89	5.3	4.78	26.12
Karnataka	3.79	8.23	5.4	5.28	5.85	5.11	4.17	3.49	-7.92
Kerala	6.56	9.85	7.21	6.53	5.68	5.25	4.74	4.71	-28.20
Madhya Pradesh	4.94	10.11	5.16	4.81	4.57	5.09	4.11	3.39	-31.38
Maharashtra	4.85	9.38	5.13	4.56	4.29	3.87	3.71	3.51	-27.63
Orissa	5.17	8.5	5.13	5.16	4.82	4.15	3.75	3.9	-24.56
Punjab	3.67	10.52	6.73	4.62	4.93	4.54	3.54	3.1	-15.53
Rajasthan	4.85	14.48	6.5	5.7	7.97	5.16	4.24	3.94	-18.76
Tamil Nadu	6.18	10.04	6.91	6.29	6.28	4.86	4.1	4.2	-32.04
Uttar Pradesh	4.69	9.08	6.31	6.03	1.74	3.98	3.75	4.49	-4.26
West Bengal	6.3	9.73	8.37	6.43	NA	5.63	4.95	0.93	-85.24
Union Government	0.22	0.29	0.56	0.46	0.52	0.76	0.77	0.83	277.27

Source: Based on Raymus (2007, Table 3.3).

Table 6.18 below shows the high share of out-of-pocket household spending on health. The all India average of household spending on health was 73.5 per cent in 2004-05. The household expenditure on health as share of total health expenditure was between 70-80 per cent and 80-90 per cent in 9 states each, while in Bihar and Nagaland, this share increased to over 90 per cent. In all, the household share on health spending was more than 70 per cent in 20 out of 27 states. The lowest share of household health expenditure was in Mizoram, which, with less than one million people, accounts for less than 0.1 per cent of India's population.

Table 6.18: Healthcare spending in India (2004-05)

	Per capita	Percentage share		
State	Expenditure (Rs.)	Household	Public	Other
Andhra Pradesh	1118	73.4	19.4	7.2
Arunachal Pradesh	4365	86.5	13.5	0
Assam	1347	80.8	17.8	1.4
Bihar	1497	90.2	8.3	1.5
Delhi	1177	56.4	40.5	3.1
Goa	4564	79.2	17.5	3.3
Gujarat	1187	77.5	15.8	6.7
Haryana	1786	85	10.6	4.4
Himachal Pradesh	3927	86	12.4	1.6
Jammu & Kashmir	2082	77.3	20.7	2
Karnataka	997	70.4	23.2	6.4
Kerala	2952	86.3	10.8	2.9
Madhya Pradesh	1200	83.4	13.6	3
Maharashtra	1576	73.3	22.1	4.6
Manipur	2068	81.2	17.2	1.6
Meghalaya	664	36.5	58.4	5.2
Mizoram	1027	39.4	60.6	0
Nagaland	5338	91.7	7.6	0.7
Orissa	995	79.1	18	2.9
Punjab	1813	76.1	18	5.9
Rajasthan	808	70	24.5	5.5
Sikkim	2240	56.9	43.1	0
Tamil Nadu	933	60.7	26.6	12.7
Tripura	1101	69	27.4	3.6
Uttar Pradesh	1152	84.3	13	2.7
West Bengal	1188	78.4	17.3	4.3
Union Territories	598	85.1	8.8	6.1
All India	1377	73.5	22	4.5

Source: Government of India (2005f).

6.4 Conclusions

This chapter set out to investigate the effectiveness of drug price controls in India in making medicines more affordable. Since their introduction in the 1960s, price controls have been progressively amended. Price controls were most rigid in the 1970s, but have been gradually relaxed since the 1980s, reducing, in turn, the number of drugs under price control. The price controls have had limited success in lowering the drug prices, which are admittedly low relative to many other countries, but not sufficiently low relative to household incomes and other relevant factors affecting affordability of healthcare. Only one-in-three Indians is considered to be able to afford to buy medicines in India.

India's public expenditure on health is significantly low even by the standards of the developing countries. Correspondingly, the share of private health expenditure is very high, as most of the healthcare costs are met by out-of-pocket household expenditure and the coverage of health insurance is almost nonexistent. Without a comprehensive programme to pay for these medicines through additional public health expenditure, India's policy on controlling drug prices will remain incapable of providing affordable healthcare.

It can be concluded that in terms of India's provision of healthcare, implications of both, low public spending on health and high share of drugs relative to the total health care costs, have contributed to significantly high private health expenditure. Both these issues would need to be addressed together. India's past experience showed that controlling drug prices alone was not sufficient to provide an affordable healthcare to all. Indian policy makers could learn from other countries and consider the options discussed earlier to develop a strategy or set of strategies to negotiate and maintain low drug prices. There is a need to streamline the hierarchical nature of the regulatory structure, recognise drug pricing and affordability as inseparable and interdependent in providing healthcare. This recognition would need to form the basis of the new policy.

Chapter 7

Broadening the Access to Medicines and Healthcare in India

7.1 Introduction

Our discussion in the previous chapter shows that drug prices have risen significantly since the implementation of TRIPS and the rise was more marked for those drugs that were outside the price controls. Controlling prices of all drugs would be counterproductive for future investment in the industry and it would do virtually nothing to benefit the poor. It is common knowledge that patented drugs have high prices under monopoly rights. Under the pre-1970 product patent regime, India was dominated by the multinational corporations (MNCs) and was among the highest drug priced countries. Notwithstanding the role of India's domestic pharmaceutical industry in bringing about the current level of low prices, the situation is likely to change significantly in the coming years. With the increasing number of patent protected drugs to be introduced in India mostly by the foreign MNCs, the market domination of domestic pharma is likely to diminish and prices are likely to rise. The poor in India, who currently do not have access to medicine, are not going to be able to afford drugs at any prices, let alone at the expected high prices. Learning from other countries' experiences, what India needs now is not just low drug prices, but an integrated model to provide an equitable access to healthcare and subsidised medicines to all sections of the population.

Against this background, the aim of this chapter is to propose an equity-based, integrated healthcare programme for a broader access to medicines and healthcare to India's entire population. While the number of people living below the poverty line (BPL) in India has declined from 54.88 per cent of total population in 1973-74 to 26.1 per cent in 2001 (Government of India 2003), the vast majority of India's population remain without access to medicine. A WHO report on the World Medicine Situation estimates that between 649 million and 811 million Indians were without access to medicine (WHO 2004b, p. 62) and the principal reason for this is the lack of affordability under the current system of healthcare.

The policies of the successive Indian governments have focused, as noted in earlier chapters, on developing domestic pharmaceutical industry, but little attention has been paid to increasing the access to medicine. These policies were primarily aimed at making the country self sufficient in drugs and medical equipment (Government of India 1952, Chapter 32). While price controls and other policy measures indirectly increased the share of population with access to medicine from 15-20 per cent in 1980 (Bhagat 1982) to around 35 per percent in more recent years (Nanda 2006; WHO 2004b), access to medicine as such has never been the explicit focus of the government policies.

India's Second Five-Year Plan proclaimed that, in conjunction with the Constitution of India and the Directive Principles of State Policy, the Parliament had accepted a socialist pattern of society as the guiding objective of the Plan (Government of India 1957) (Chapter 19, Clause 13). In subsequent years, the socialist principles were applied to the development policies of industries including the drugs and pharmaceutical industry. In the 1980s, India began the process of economic reforms that became more pronounced in 1991. These reforms progressively liberalised the economy with pro-industry measures, such as de-licensing and relaxed controls, but did little to increase access to medicine to the poor.

Similar to India's past policies, the National Pharmaceutical Policy – 2006, which is currently under discussion, also contemplates different methods of price controls or price monitoring attempts to keep drug prices low. In the wake of the implementation of the TRIPS agreement since 2005, a recent report of the Planning Commission notes that 'provisions of compulsory licensing and parallel imports under the patent regime will keep prices of patented medicines within the common man's reach' (Government of India 2007e) (p. 13). These provisions could make drugs available in India but would not place them within common man's reach.

In the wake of India's recent status as a rising economic power, introduction of social policies for lifting the health status of the poor would be timely and essential for the long term economic development. This would be necessary because several studies have reported a direct correlation between the health of its people and economic growth of a nation (Abegunde & Stanciole 2006; Misra, Chatterjee & Rao 2003).

Even India's First Five Year Plan acknowledged that 'in terms of resources for economic development, nothing can be considered of higher importance than the health of the people' (Government of India 1952, Chapter 32, Clause 1). According to the World Development Report (2006), when the traditional model of relying on the public hospitals works badly, especially for the poor and excluded groups, an equity-based health system should be considered (World Bank 2006).

The rest of the chapter is set out as follows. Section 7.2 presents a model – referred to as the IndiaHealth model below – for equitable access to medicines and healthcare. The IndiaHealth model is based on the Australian experience, but has been modified to incorporate the India's specific features, such as demographics, income levels and affordability issues. The proposed IndiaHealth model recognises that as India's population increases to reach 2 billion by 2050, the proportion of the high users of healthcare, i.e. the population of over 65 years of age, is estimated to increase significantly from the current level. This demographic change would require substantial additional resources devoted to healthcare. The IndiaHealth model also recognises the very high incidence of poverty in India noted in the introduction. Recognition is also given to the pressing healthcare needs of people with disabilities. Based on the total numbers of people in the various income groups and age groups, different levels of out-of-pocket co-payments are proposed. The total costs of implementing the proposed model are calculated, including separate estimates for the public sector and for out-of-pocket private costs. The costs of the proposed IndiaHealth model are also checked against the commitment of India's current government to increase public expenditure on healthcare. Section 7.3 summarises the main conclusions.

7.2 Providing access to medicines in India

The proposed model is based on the principle of government-patients sharing the burden of healthcare, with the government accounting for a larger share. The patient co-payment on medicines would be income-tested to ensure affordability. Two particular groups of the population, namely those with mental and psychological disabilities and those living below the poverty line (of $1 per day), would be required to make no contribution toward the cost of medicines. The rest of the population

would make co-payments to share the burden with government. The total impact of this proposal on the public budget would be around 1.6 per cent of the GDP for 2010. This level of public spending on healthcare is consistent with the commitments made by the current government under the Common Minimum Programme.

Under the proposed model IndiaHealth cards would be issued as a device to identify different population groups and their entitlements. Sensitivity tests show that it would be possible to adjust the government-patient balance of the financial cost, if necessary. It should be noted from the outset that the proposed model does not call for the discontinuation of free distribution of drugs through public pharmacies, community pharmacies or drug banks. However, under the proposed model, patient copayments would apply to outpatient prescriptions. A thorough and careful consideration of the operational dimensions and complexities associated with the proposed model would be a pre-requisite to the success of the model.

It is also important to note at this point that although the model presented below is about healthcare financing only, this does not imply that fixing the financing of drugs alone will fix the problem of access to medicines in India. There are other aspects of healthcare delivery system, which will also need to be improved. These aspects include: the treatment of outpatients in rural areas by rural medical practitioners (RMPs) who are not always formally qualified and act more as local drug vendors; and the difficulties in identifying the poor so that benefits of the new model are not wrongly appropriated by those who are not really poor. These aspects of healthcare would also need to be addressed in complementary reforms to service delivery system to make effective and sustainable improvements in the access to medicines to India's entire population.

7.2.1 Methodology

The following methodology was applied to developing the proposed IndiaHealth model. Healthcare models adopted by Australia, New Zealand, Canada, Germany and the United Kingdom were considered. The basic design of the proposed model is based on the Australian healthcare model. In Australia, the Medicare programme

provides access to healthcare providers, while the Pharmaceutical Benefits Scheme (PBS) subsidises medicines listed on the formulary (PBS list).

Under the Australian model, the process for drug pricing is initiated by the manufacturers, who wish to list their drugs on the formulary. However, before the process can be commenced, approval must be sought from the Therapeutic Goods Administration (TGA) to market the proposed drug. In Australia, there are two main bodies involved in the pricing process; namely, the Pharmaceutical Benefits Advisory Committee (PBAC) and the Pharmaceutical Benefits Pricing Authority (PBPA). The PBAC compares the effectiveness and cost of the proposed drug with those of alternative therapies, and advises the PBPA accordingly. In addition to the PBAC comments, the PBPA uses a number of criteria in the price assessment, such as clinical and cost effectiveness, and reference pricing. Firms can argue their case on a cost-effectiveness basis that their medicine is superior to the comparator justifying a price premium (higher price), or on a cost-minimisation basis, which means that the proposed medicine is equivalent to the comparator but lower priced (Sweeny 2008). The final process constitutes negotiations between the government and the manufacturer to agree on a mutually acceptable price. This is where the government is able to use its monopsonistic purchasing power to achieve lower prices relative to those paid in international markets (Duckett 2004, p. 60). With a significantly large market such as India's, the government often has enough clout to influence the outcome of these negotiations to maximise the benefits to potential users.

The relevance of the New Zealand model of pharmaceutical pricing was also considered, but was found to be less attractive for India's case. In New Zealand, the government puts out the tenders, to which the manufacturers respond. Under this model, all firms other than the successful bidder are effectively locked out of the market. Unsuccessful bidders could market their products but without listing for reimbursement, their product sales would be negligible. If such a model were used in India, a single supplier to the entire Indian market could possibly achieve economies of scale and undercut the price significantly. But it would also create a monopoly for the duration of the contract, which may not be particularly helpful to the domestic pharma industry. India has over 8,000 small domestic manufacturers, who do not have the capacity to serve the entire market. Under the proposed model, survival of firms

would predominantly depend on listing their products on the formulary. Excluding the small manufacturers could effectively send them out of business.

The Australian model would be more appropriate for India with a significant number of firms to meet its healthcare needs. The Australian model provides opportunities for the small manufacturers to list their products, especially in the off-patent generics category. The small manufacturers generally price their products significantly lower than the big brand names creating a competitive environment. Thus, the small manufacturers would use the cost-minimisation approach noted under the Australian model. A successful listing of a small manufacturer's product would force other firms to lower their prices reducing the overall healthcare costs.

7.2.2 The proposed model

Under the model proposed in this study, a new organisation called MedicineIndia would be responsible for sourcing adequate supply of the required medicines at the appropriate prices. MedicineIndia would be guided by the principles contained in *Equitable access to essential medicines: a framework for collective action* (WHO 2004a). Other WHO documents that form the basis for the rationale for the proposed model include:

- *Effective medicines regulation: ensuring safety, efficacy and quality* (2003a);
- *How to develop and implement a national drug policy* (2003b);
- *Promoting rational use of medicines: core components* (2002a); and
- *The selection of essential medicines* (2002b).

The structure of MedicineIndia would have three subordinate authorities; namely, the National Pharmaceutical Pricing Authority (NPPA), the National Pharmaceutical Evaluation Authority (NPEA), and the National Drug Authority (NDA). Each of the authorities would perform specific tasks to achieve the overall objectives of MedicineIndia.

The primary responsibility of the NPPA would be to assess and negotiate the drug price based on the data submitted by the manufacturer. The drug evaluation process

would be based on the principles of pharmacoeconomics,[46] which compares the net benefits to the net costs at a given price (Henry, Lopert & Lang 2001). In other words, the NPPA assessment would measure the cost-effectiveness of the proposed drug. The current office of the NPPA is responsible for determining and revising the prices for drugs listed under price control. Thus, it would be easy for the current NPPA to take up the new responsibilities under MedicineIndia.

The NPEA would be a new establishment consisting of experts with technical knowledge and experience in drugs. The role of the NPEA would be to provide an independent advice on pharmaceutical evaluations based on technical assessment of the proposed drug. The independence of this body would remove any bias in the drug evaluation process. In the long run, the NPEA would set up an institute similar to the IQWiG (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) in Germany providing information on effectiveness, quality, and efficiency of drugs, non-drug interventions, and raising public awareness on health (INHATA 2008).

If the price determined by the NPPA was considered too low and/or evidence could be provided to prove superior therapeutic effectiveness to warrant a higher price, the manufacturers could approach the *Price Negotiations Committee,* which would function similar to an appellate body. In accordance with the suggestions of the Sen Committee (2005), a price negotiating committee would be established comprising the Chairman of MedicineIndia and outside experts drawn from other government departments, the Indian Council of Medical Research (ICMR), health professionals, pharmacologists and civil society organisations (The Sen Committee 2005).

The National Drug Authority (NDA) would be the sole body responsible for establishing and maintaining quality standards and granting market approvals. Currently, the Drug Controller General of India (DCGI) is responsible for the approval of licences of specific categories of drugs, such as blood and blood products, while the Central Drug Standards Control Organisation (CDCSO) grants approvals for the rest of the drugs. Both offices carry out similar functions and this causes confusion and makes the system inefficient. The central body would integrate both

[46] The expression used in drug evaluation literature.

offices into a single authority increasing efficiency. The office of the DCGI and the CDCSO would be merged to form the NDA. The idea of an authority similar to the US Food and Drug Administration (USFDA) was first conceived by the Hathi Committee 30 years ago and reiterated in the Drug Policy 1986 and again by the Mashlekar Committee (2003), Government of India (2005a) and by the Sen Committee (2005).

7.2.3 Implementing the IndiaHealth model

This sub-section outlines the practical details associated with the implementation of the proposed model for delivery of healthcare and access to medicines. In the Sixth Five-Year Plan (1980-85), India adopted the policy of 'Health for all by 2000 AD' enunciated in the Alma Ata Declaration in 1977 (Government of India 1980, Chapter 22, paragraph 16),). This has been the objective for a long time. The proposal here is designed to make its achievement more likely.

IndiaHealth cards

IndiaHealth cards would be issued to all Indians regardless of their social and economic status or place of residence. All IndiaHealth cardholders would be entitled to seek treatment at the public hospitals as well as from authorised allopathic doctors and practitioners of traditional Indian systems of medicine. The authorised Rural Medical Practitioners (RMPs), practitioners of all systems of medicine, except yoga,[47] would be issued with a prescriber number printed on the prescription together with the prescriber's name and address.

The prescription would be presentable at authorised pharmacies and dispensing doctors/practitioners. The patients would be responsible for co-payments where applicable and the government would contribute towards the rest of the medicine costs. The retailers would be issued with a dispenser number, which would be used to request reimbursements. The correct verification of the prescriber details on the

[47] The yoga practitioners would be excluded for two reasons. First, under yogic therapies, no medicine is dispensed. The main focus is on physical exercises and body postures. Two, there is no infrastructure in place for validation of the claims or for qualifications.

prescription would be the basis for authorisation for reimbursement to the dispensing agency. The validation of the qualifications would be the key to authorising doctors, RMPs, practitioners of traditional medicines, and pharmacists. The Indian Government recently initiated pilot programmes to formally train and validate qualifications of practitioners of traditional medicines in order to bring them into mainstream healthcare providers (Government of India 2008b). This process is just a beginning of the long term strategy required to recognise the significance of the services provided by the RMPs, and practitioners of traditional medicines in India's overall provision of healthcare.

The IndiaHealth cardholder entitlements would be income tested and the patient co-payments would vary accordingly. For estimation of the patient co-payments, the Australian healthcare experience provides a good guide. Australia has a two tier system of co-payments. In 2009, the patient co-payments were fixed at $5.30 for the concession[48] card holders (e.g. pensioners, low-income earners) and up to $32.90 for general patients. Some critics argue that the general patient co-payments in Australia are set too high. For example, a recent study of Australian healthcare has suggested that around 23 per cent of prescriptions are not filled, because of the high patient co-payments (Blendon et al. 2002).

In respect of income, the Indian population may be divided into the following broad categories:

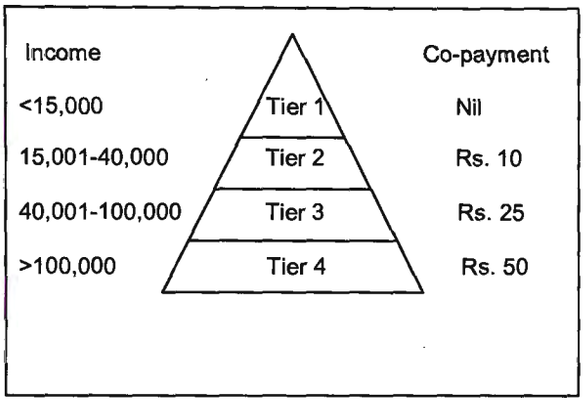
11. the poor living below the poverty line of $1-a-day (BPL1);
12. the population with an income of around $2-a-day (BPL2);
13. the lower middle class (M1); and
14. the upper middle class (M2).

Based on these population groups, the proposed model would adopt a four tier co-payment programme (see Box 7.1). Learning from the Australian experience, the level of co-payment has been set sufficiently low to encourage people to use the prescribed

[48] Includes the Department of Veterans Affairs issued Pensioner Concession Cards and Commonwealth Seniors Health Cards. The Department of Human Services through Centrelink also issues a range of Health Care Cards and other types of concession cards, such as Disability Support Pension Card.

medicines. The poor living below the poverty line (BPL1) would make no co-payments at all, while the population in the next income level (BPL2) would contribute Rs.10 per prescription. The co-payment for the people in the lower and upper middle class would be set at Rs. 25 and Rs. 50 respectively. In Australia, patient co-payments are CPI[49] indexed annually. The co-payments in India would remain fixed for the first three years, and would be WPI[50] indexed annually thereafter.

Box 7.1: Different levels of patient co-payments



Source: Author

These four income groups have been further divided into the following eight categories. This division was considered necessary to accommodate the significant diversity in income levels that exists among the Indian population. Each category would be issued with clearly identifiable colour-coded IndiaHealth cards. Card holders would have entitlements specific to each population group (see Table 7.1).

As reliable data are not available for the accurate number of people in each category and their true financial status, the 1999-2000 income tax brackets are used as a guide for the above segmentation of the population. It should be understood from the outset that the income brackets represent different levels of income that exist in India. Those brackets are not necessarily the true reflection of the number of people in the income range. The segmentation identifies each population group, its income range, the type of IndiaHealth card and the number of estimated cards. Because the proposed model considers different income levels and different age groups separately, we needed to make certain assumptions about the population of the aged[51] within different income groups. Thus, we have made the following assumptions across all income groups.

[49] Consumer Price Index.
[50] Wholesale Price Index used in India.
[51] Over the age of 65 years.

First, the aged population is a constant share at around 5 per cent. This assumption is consistent with the United Nations (2005b) study on population for 2005. The number of cards in the aged group is based on the assumption that each card in this group would list two adults over the age of 65 years.

Table 7.1: Entitlements of IndiaHealth cards at a glance

S. No	Income p.a. (Rs.)	Category	Colour	Co-payment per prescription (Rs.)	SafetyNet Threshold (Rs.)	Co-payment per prescription (post SafetyNet) (Rs.)
1	None	S-Card	Brown	Nil	n.a.	Nil
2	<15,000	B1-Card	Red	Nil	n.a.	Nil
3	15,001-40,000	B2-Card	Yellow	10	500	Nil
4	15,001-40,000	A1-Card	White/Yellow	10	500	Nil
5	40,001-100,000	A2-Card	White/Purple	25	1,125	10
6	40,001-100,000	M1-Card	Purple	25	1,125	10
7	>100,000	A3-Card	White/Green	50	2,000	25
8	>100,000	M2-Card	Green	50	2,000	25

Source: Author.

Second, the average Indian family consists of five members across all income groups. This is consistent with the recent Government of India (2006k) study. The population, except the population group over the age of 65 years, in each group is divided by five to obtain the number of cards for that group. The number of cards for the aged group assumes two adult members per card.

Third, the Indian middle class is estimated at 300 million. This population size is consistent with a study by Knowledge@Wharton (2008), of which, the aged group (at 5 per cent) would account for 15 million or 7.5 million families of aged couples. From these 7.5 million middle class aged families, 2.5 million families would possibly qualify for each of the A1-Card, A2-Card and A3-Cards. Different types of IndiaHealth cards, each population group and its entitlements would be as follows.

S-Card

The S-Card would be issued to persons with special physical or psychological needs such as handicapped. No income test would be required for this population group. This group makes no co-payments on prescriptions. The total number of people in this

category is estimated to be 40 million[52]. The number of S-Cards would correspond to the population in the category, because only the individual card holder would be listed for entitlements.

B1-Card

The B1-Card would be issued to the people (BPL1 category) with an annual income of less than Rs. 15,000 (~$375). This population group is considered to be living below the poverty line of $1-a-day (BPL1). No tax returns were recorded for this category for 1999-2000. An estimated 350 million Indians belong to this category. At 5 per cent of 350 million, 17.5 million elderly population would be issued with 8.75 million B1-Cards (Aged). At 5 members per family, 66.5 million B1-Cards would be issued to the remaining 332.5 million population in this income group. Thus, the total number of B1-Cards would be 86.5 million (8.75+66.5+11.25 from B2-Card (Aged)). Holders of B1-Cards would make no co-payments toward prescriptions.

B2-Card

The B2-Card would be issued to the people (BPL2 category) with an annual income of Rs. 15,001(~$375) - Rs. 40,000 (~$1,000). This group is considered to be living below $2-a-day (BPL2). In 1999-2000, this group accounted for 12.98 per cent of the total number of individual tax returns filed (Government of India 2003c, pp. 176-7), However, the tax returns indicate only the number of people at the higher end of the income range in this group. No tax returns would be recorded for people close to the lower end of the scale. The total size of this group is estimated to be 450 million. At 5 per cent of 450 million, 22.5 million elderly population would be issued with 11.25 million B1-Cards (Aged). This is because the Aged in this group are considered to have income level closer to that of BPL1. Thus, the total number of B2-Cards would be 85.5 million (remainder of (450-22.5)/5). Holders of B2-Cards would make a co-payment of Rs. 10 per prescription.

[52] Adjusted up 1991 figures of 38.8 million for the disabled in Government of India (2003b, p. 98).

A1-Card

The A1-Cards would be issued to middle class retirees with an annual income of between Rs. 15,001(~$375) - Rs. 40,000 (~$1,000). The number of cards in this group is estimated to be 2.5 million. Holders of A1-Cards would make a co-payment of Rs.10 per prescription.

A2-Card

The A2-Cards would be issued to middle class retirees with an annual income of between Rs. 40,001(~$1,000) - Rs. 100,000 (~$2,500). The number of cards in this group is estimated to be 2.5 million. Holders of A1-Cards would make a co-payment of Rs. 25 per prescription.

M1-Card

The population in the lower middle class with an annual income of Rs. 40,001(~$1,000) - Rs. 100,000 (~$2,500). would be entitled to M1-Card. This group of people accounted for around two thirds of the total number of individual tax returns in 1999-2000. From the 285 million middle class population (300 million-15 million aged), two-thirds or 190 million is estimated to belong to M1 category. Allowing 5 members per family, the total number of cards would be 38 million (190 million/5). Holders of M1-Cards would make a co-payment of Rs. 25 per prescription.

M2-Card

The M2-Cards would be issued to the higher middle class people with annual income of over Rs. 100,000 (~$2,500). This group constituted over 20 per cent of the overall number of tax returns. The total size of this group is estimated at 95 million (285 million-190 million in preceding category). At 5 members per family, 19 million M2-Cards would be issued. Holders of M2-Cards would make a co-payment of Rs. 50 per prescription.

A3-Card

The A3-Cards would be issued to middle class retirees with an annual income of above Rs. 100,000 (~$2,500). The number of cards in this group is estimated to be 2.5 million. Holders of A1-Cards would make a co-payment of Rs.10 per prescription.

The distinction between different types of cards is important for estimating the total contribution of patient co-payments. This is because the non-contributory (the B1-Cards and S-Cards) would make no co-payments and the number of people covered under specific cards would also vary. For example, the S-Card would list a single individual with special needs. The A-Cards for the aged category would entitle the listed individuals or couples to IndiaHealth services. All other cards, except S-Card and A-Cards, list the entire family i.e. the parents and their dependent/unmarried children.

Safety Net Threshold

The Safety Net threshold is a safeguard to keep medicines affordable by limiting out-of-pocket co-payments for card holders who need a large number of medicines. Under the Safety Net, after a card holder reaches the prescribed Safety Net threshold, all subsequent medicines on the formulary are provided at a concession for the remainder of the year.[53] In 2009, under the Australian model, the Safety Net threshold is reached after co-payments of $318 (60 prescriptions @ $5.30 each) in a calendar year for the concession card holders and $1,264.90 (38.4 prescriptions @ $32.90 each) for general patients (Government of Australia 2009). If a more expensive brand medicine is purchased or prescribed than the medicine listed on the formulary, the additional premium would not count toward the Safety Net threshold. The high number of prescriptions for Safety Net for the elderly and other concession card holders alludes to the fact that the population in the aged group need more medicines than the younger people.

[53] Under the proposal, the year would mean Indian accounting year (April–March) because it would be easier for budgetary planning and accounting purposes.

The Safety Net in Australia has a *20-day Rule*. Under this Rule, repeats of specific medicines listed[54] under the rule must not be dispensed within 20 days of the previous supply, except when explicitly authorised by the prescribing doctor. The cost of a medicine repeated within 20 days may not count towards the safety net threshold (Government of Australia 2007a). If the Safety Net is already reached, a repeat supply of the same medicine within 20-days may incur pre-Safety Net co-payment. This rule is designed to prevent any abuse of the system, such stocking up of medicine at a concession. India could consider a similar rule with the same objectives.

The proposed model considers different income levels in India and proposes a three-tier Safety Net threshold. Under the proposed model, the Safety Net threshold would be reached after 50 prescriptions in a 12-month period for B2-Cards and A1-Cards. Holders of these cards would get all subsequent medicines free of cost for the remainder of the year, which means that the most these families would spend on medicines would Rs. 500 in a12-month period.

After 45 prescriptions, holders of M1-Cards and A2-Cards would pay Rs. 10 for all subsequent medicines for the rest of the year. After 40 prescriptions, holders of M2-Cards and A3-Cards would pay Rs. 25 for all subsequent medicines for the rest of the year. Holders of B1-Cards or S-Cards holders are exempt from any co-payments; thus, the Safety Net would not apply.

In India's case, the Safety Net is expected to maximise the poor's access to medicines, who carry the largest disease burden. In addition, sufferers of chronic diseases and serious illnesses such as cancer, for which the cost of medicines is significantly high, would benefit from lower co-payments after reaching the Safety Net threshold. Patient co-payments for all those on the IndiaHealth card count toward the Safety Net threshold. Larger families would also benefit from the Safety Net. They would benefit because the more family members on the card, the more likelihood of them getting sick and faster the family would reach the Safety Net threshold.

[54] Medicines specifically listed under the 20-day Rule (e.g. for chronic diseases such as HIV/AIDS).

While married children may be living in the same household, they would need to apply for their own IndiaHealth card. The separate cards would prevent exploitation of the system and reaching the Safety Net prematurely. It is because all persons listed on each card would be counted as one family and the total amount of co-payments made for each card would be counted towards Safety Net threshold. While the S-Card holders would have the same entitlements as the BPL1 group, people with special needs would not be issued with B1-Cards. This is because the S-Card would apply to a single individual, as opposed to the B1-Cards being for the entire family.

7.2.4 Comparing out-of-pocket expenditure

This subsection intends to examine the out-of-pocket (OOP) expenditure under the proposed model. First, the OOP expenditure under the current model is established. Then these data is used vis-a-vis the proposed model. Under the current model, the total out-of-pocket household expenditure is estimated as follows. According to a health survey conducted in 2005-06, the monthly per capita household health expenditure was Rs. 44 in rural and Rs. 71 in urban area, of which 64 per cent (Rs. 28.16) and 56 per cent (Rs. 39.76) respectively accounted for medicines (Government of India 2007c). Based on these data and the rural-urban (70:30) composition of India's 1,140[55] million population, the Indian average of household expenditure on medicines was derived (see Table 7.2). In 2005-06, a family of five spent Rs. 3,126 on health, of which Rs. 1,898.4 was spent on medicine.

Using the data from Table 7.2, expenditure on medicines, the out-of-pocket private expenditure, and government expenditure is calculated for the same year under the proposed model. In order to compare the out-of-pocket expenditure under the current model and under the proposed model, expenditure after reaching Safety Net has to be estimated. The Australian experience provides a useful guide for estimates on post-Safety Net medicine expenditure. Sweeny (2008) suggests that concessional and general patients constitute 25 per cent and 75 per cent of the Australian population respectively. He notes that for the year 2006-07, the post-Safety Net accounted for 11.66 per cent of the total expenditure on PBS (Pharmaceutical Benefits Scheme) medicines for general patients and over 21 per cent for concession card holders.

[55] Based on Government of India (2007f).

Table 7.2: Calculating health and medicine expenditure (Rs.) in 2005-06

Category	Population (million)	Monthly health expenditure		Monthly medicine expenditure	
		Per capita (Rs.)	Total Rs. (million)	Per capita (Rs.)	Total Rs. (million
Rural	798	44	35112	28.16	22471.68
Urban	342	71	24282	39.76	13597.92
Total (India)	1140		59394		36069.6
Based on the above data		Yearly health expenditure		Yearly medicine expenditure	
Rural			421344		269660.16
Urban			291384		163175.04
Total (India)			712728		432835.2
Per person		625.2		379.68	
Per family of five		3126		1898.4	

Source: Government of India (2007c).

The IndiaHealth model is based on the premise that those who can afford should pay more, and those who can not should pay less. Population groups at the lower end of the income scale (B1-Cards) as well as holders of S-Cards do not make any co-payments at all toward the cost of the medicines. The provisions of the Safety Net would not apply to these two categories. For holders B2-Cards or A1-Cards, the maximum out-of-pocket contribution would be limited to reaching the Safety Net. All subsequent medicines would be supplied free of cost for the rest of the year to these two categories. Holders of cards in the remaining 4 categories (A2, M1, A3 and M2) upon reaching the Safety Net would be entitled to medicines at a concessional rate thereafter. For these 4 categories, another 10 per cent was added to the total in order to estimate the post-Safety Net out-of-pocket expenditure. For most of the Indian population, the out-of-pocket expenditure declines significantly under the proposed model (see Table 7.3).

All categories, except A3-cards and M2-cards, would be better off under the proposed model. The holders the B1-cards as well as holders of S1-Cards would be best off. Population groups in B2 and A1 categories would be significantly better off and save annually Rs. 1,398 (1,898-500) per family. For holders of A2-cards and M1-cards, the out-of-pocket annual expenditure on medicines would also fall to around two thirds from the current level. Holders of A3-cards and M2-cards or around 9 per cent of the total population would pay 15.8 per cent more than the current level. At a high income level, an increase in the expenditure on medicine is considered justifiable.

Table 7.3: Annual expenditure on medicines under current and proposed models

S. No.	Category	Estimated population (million)	Estimated no. of cards (million)	Total drug expenditure, India (Rs. million)	Total out-of-pocket co-payments (Rs. million)	Government contribution (Rs. million)	Average out-of-pocket co-payments per family (Rs.)	Average out-of-pocket drug expenditure per family (Rs.)
				(current)	(proposed)	(proposed)	(proposed)	(current)
1	2	3	4	5	6	7=(5-6)	8	9
1	S-Card	40	40.00	15187.2	0	15187.2	0	1898.4
2	B1-Card	350	86.50*	132888	0	132888	0	1898.4
3	B2-Card	450	85.50**	170856	42750	128106	500	1898.4
4	A1-Card	5	2.50	1898.4	1250	648.4	500	1898.4
5	A2-Card	5	2.50	1898.4	3093.75	0	1238	1898.4
6	M1-Card	190	38.00	72139.2	47025	25114.2	1238	1898.4
7	A3-Card	5	2.50	1898.4	5500	0	2200	1898.4
8	M2-Card	95	19.00	36069.6	41800	0	2200	1898.4
	Total	1,100	236.50	432,835	141,419	291,416	598	1898.4
				100%	32.67	67.33		

Note: *Includes 8.75 million aged with B1-Cards and 11.25 million aged with B2-Cards.

*Excludes 11.25 Aged from this group.

Source: Author calculations based on Government of India (2007c).

In absolute terms, the national average household (of five members) expenditure on drugs would decrease from the current level of Rs. 1,898 to Rs. 598. After deducting the number of non-contributory cards (B1-Cards and S1-Cards), the average annual drug expenditure of a contributory household would be around Rs. 943. [56]This would still amount to substantial savings on the current level. The contribution of third parties, such as private insurance, charities, and NGOs, is not considered for reasons discussed later in this chapter.

Table 7.3 also shows the composition of total out-of-pocket co-payments and government contributions toward the drug expenditure under the proposed model. Based on Government of India (2007c), the total out-of-pocket expenditure on medicines for 2005-06 is estimated to be Rs. 432,835 million. Currently, this expenditure is met entirely by out-of-pocket household expenses. The Table shows that under the proposed model, the annual household expenditure on medicines would decline to Rs. 141,419 million or around a third of the current level. The share of the government would account for around 67 per cent of the total expenditure on medicines.

[56] Rs. 141,419/150 (sum of all cards except S1 and B1).

While the share of patient co-payments would decline to around 33 per cent of the India's total drug expenditure, this share would still be twice the share of that of the Australian population toward the cost of medicines. For the financial year July 2005 – June 2006, Australians filled out 168,322,615 prescriptions at a cost of over A$6.5 billion, from which the government spending accounted for $5.4 billion. The patient contribution of $1.1 billion constituted less than 17 per cent of Australia's total expenditure on medicines for the year (Government of Australia 2006). However, the proposed model significantly reduces the household share of the expenditure on medicines from the current level. Public contribution as a share of India's total expenditure on medicines would increase significantly to offset the reduction in household expenditure.

The proposed model provides a complete healthcare package, which would be a significant departure from the past policies. The past policies focused on controlling prices of allopathic medicines rather than providing healthcare. The past policies contributed to the development of India pharma but lacked a cohesive vision for the entire healthcare industry. The traditional systems of medicine were not given due recognition for their part in the provision of healthcare. In contrast, the proposed model focuses on providing an equitable healthcare, including access to traditional medicines. On the patient side, the proposed model requires out-of-pocket co-payments based on different income levels of the population. On the government side, the following subsection considers the size of the financial commitment required to fund the IndiaHealth programme.

7.2.5 Benefits of the proposed model

The proposed healthcare model would provide significant benefits over the existing model for the patients, the industry and the government. The current Indian healthcare model is limited to controlling the prices of drugs listed on the Schedule of the Drug Price Control Order (DPCO), and the number of drugs under price control is significantly small. The current model focuses on keeping the prices low on drugs the DPCO considers necessary. There are no other provisions to ensure accessibility to medicines. Consequently, even at the controlled prices, drugs are unaffordable to the

vast majority of the poor. The proposed model would ensure access to allopathic drugs as well as traditional medicines.

The current model provides limited access to public health institutions. There is no provision for facilitating access to private doctors or practitioners of traditional Indian healthcare systems. The proposed model would include access to public institutions, authorised doctors and practitioners of traditional medicines.

The current practice restricts profits and discourages investment into R&D and supply of controlled drugs. Manufacturers avoid using the controlled drugs and where possible, substitute them with non-controlled drugs to keep the profits up. The proposed model would increase transparency enhancing certainty for investors and consumers. The guaranteed subsidy and the drug price under the proposed model would significantly enhance sales forecasts for the listed drugs. The sales would be boosted, because all Indians would have access to medicine. No social groups would be excluded from seeking healthcare due to affordability. The sales would significantly increase the size of the Indian pharmaceutical market as well as disease specific sub-markets. These sub-markets are likely to attract new investments into research and development of drugs for tropical diseases that are more common in developing countries. Until now, sufferers of these diseases lacked the purchasing power and investors neglected these diseases, because the potential for high returns was unlikely.

The proposed model would provide several economic advantages to India. First, the increased access to medicine would improve health of India's labour force. This would effectively translate into increased productivity and higher economic growth, because good health is a significant contributor to the economy of a nation. Health assumes even greater significance in a poor country like India, where the only asset most people have is their bodies (Misra, Chatterjee & Rao 2003). Abegunde and Stanciole (2006) also suggest that diseases reduce life expectancy and economic productivity depleting quality and quantity of the nation's labour force. Thus, broadening access to medicines would accelerate the Indian economy.

Second, in India's provision of healthcare, it would free resources currently occupied by segmented group insurances (employment and/or community based) and bring them all under one umbrella. For example, the dedicated health institutions, such as Railways Health Services, ESIS[57] or CGHS[58] hospitals and dispensaries currently serve specific population groups. These are public institutions, yet general public can not access them. Only certain employee groups and their families have access to these institutions. Under the proposed model, all public institutions such as these would be streamlined and accessible to all Indians.

Finally, the consolidation of all the resources would provide a clear and complete picture to the planners and policy makers regarding the challenges ahead and the resources available.

7.2.6 Costing the IndiaHealth programme

In order to estimate the costs of the programme, thorough understanding of India's demographics is required. Currently, India is estimated to have 1.14 billion population (Government of India 2007f). India has a young population relative to other countries. According to the latest census (2001), more than 55 per cent of Indians were younger than 24 in 2001 (Government of India 2006b) and the share of the population over 65 years of age would increase significantly from 5 per cent in 2005 to more than 17 per cent in 2050 as the population begins to mature (United Nations 2005b).

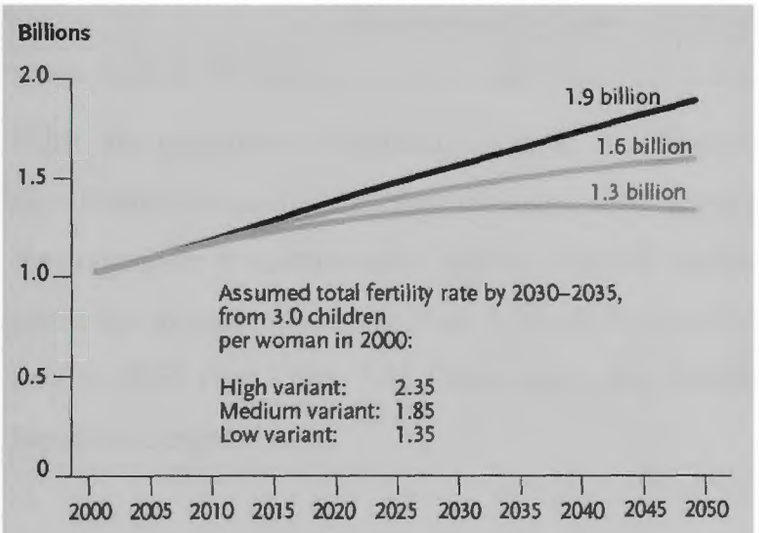
The relevance of the demographics is that the utilization of healthcare, including medicines increases significantly in the old age relative to lower age groups. Expert estimates show that in Australia, the population over 65 years of age uses 4 times more healthcare than the younger population. This ratio is 6-9 times higher for the population over 80 years of age. If the entire population over 65 years of age (including those over 80 years of age) is pooled into a single group, the healthcare expenditure is around 4 ½ times higher than the rest of the population (Australian Institute of Health and Welfare 2005). This is because the population over 80 years of age is significantly smaller than the 65-79 years age group. The same study suggests

[57] Employees' State Insurance Scheme (ESIS).
[58] Central Government Health Scheme (CGHS).

that children up to age of 4 years require significantly more healthcare than the children between 5 and 14 years of age. It is because children aged 0-4 years require health services, such as vaccination and nursing that the older children do not need. If the population between 5 and 64 is taken as one group, the healthcare expenditure of this group is only slightly higher than the expenditure level of the 0-4 age group. For costing of the proposed model, we consider that the population under 4 years and over 65 years of age would use 1.2 times and 4.5 times respectively more healthcare than the population in the 5-64 years age group.

Some projections suggest that India's population could reach 1.9 billion or even surpass 2 billion by 2050 (Haub & Sharma 2006). Other estimates put the size of the population at 1.3 billion by the same date, assuming India manages to control its fertility rate (see Figure 7.1). Based on the medium variant, India's population is estimated to reach 1.6 billion in 2050.

Figure 7.1: India' population projections (2000-2050)

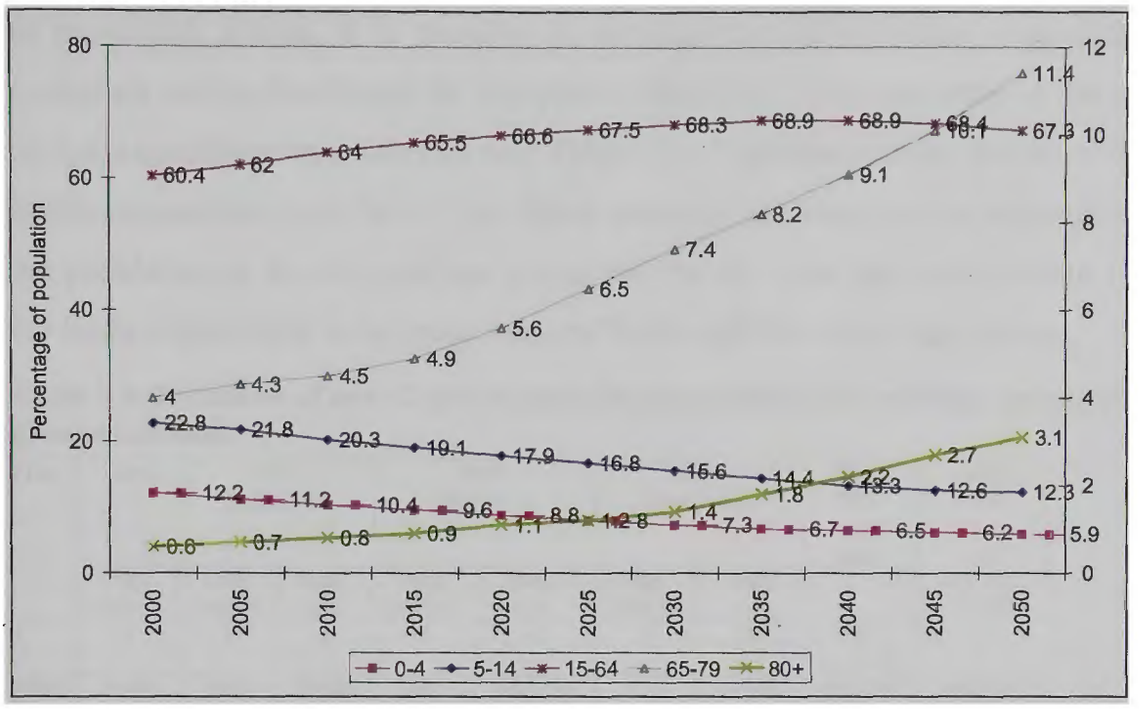


Source: United Nations (2005a).

Taking the extreme case scenario of India reaching 2 billion population in 2050, the population of the over 65 year olds could reach 290 million, including around 60 million those who would be over 80 years of age. If however India manages to restrict its population to 1.3 billion by the middle of the century, the number of those, who would be more than 65 years of age, is expected to be around 189 million, with an estimated population of 40 million of over 80 years of age. In either case, these projections foreshadow the need for significant additional resources to be spent on healthcare. When India's population begins to age, the share of children 0-4 years of

age is expected to decline to less than half in 50 years from 2000. The share of the 5-14 years age group is also expected to decline significantly, while the shares of other three population groups are estimated to increase (see Figure 7.2).

Figure 7.2: Projected population of India by age groups (2000-2050)



Source: Based on UN Population Division (United Nations 2005a, medium variant).

With the population beginning to age, the share of the aged is expected to rise significantly over the next few decades. The aggregate share of the two age groups that consume proportionately higher share of healthcare (the 0-4 years and the 65+ years age group) would rise from 16.6 per cent of total population in 2000 to 21.4 per cent in 2050 (see Table 7.4). Once again, this would require a significant increase in healthcare expenditure.

Table 7.4: Projected population of India by age groups (percentage of total)

Year	0-4	5-14	15-64	65-79	80+	Total
2000	12.2	22.8	60.4	4.0	0.6	100
2005	11.2	21.8	62.0	4.3	0.7	100
2010	10.4	20.3	64.0	4.5	0.8	100
2015	9.6	19.1	65.5	4.9	0.9	100
2020	8.8	17.9	66.6	5.6	1.1	100
2025	8.0	16.8	67.5	6.5	1.2	100
2030	7.3	15.6	68.3	7.4	1.4	100
2035	6.7	14.4	68.9	8.2	1.8	100
2040	6.5	13.3	68.9	9.1	2.2	100
2045	6.2	12.6	68.4	10.1	2.7	100
2050	5.9	12.3	67.3	11.4	3.1	100

Source: Based on UN Population Division (United Nations 2005a, medium variant).

The IndiaHealth programme is an integrated programme that facilitates access to healthcare and access to subsidised medicines. In order to accurately assess the overall costs of the IndiaHealth programme, it would be imperative to estimate both, the costs of healthcare as well as the costs of medicines. After projecting the change in population shares, it is possible to estimate the out-of-pocket expenditure on medicines and on healthcare for the period 2006-2015. First we estimate the out-of-pocket expenditure on medicines (see Table 7.5). Then we estimate the out-of-pocket health expenditure (see Table 7.6). These estimates are based on the assumption that the population in the 0-4 year age group and the 65+ year age group utilize 1.2 and 4.5 times respectively more medicines and healthcare than other age groups.

Table 7.5: Estimates of out-of-pocket *medicine* expenditure (Rs. million) and population groups (million)

Year	Total	0-4 (factor1.2)		5-64 (factor 1)		65+ (factor 4.5)		Total OOP med. exp.	Total OOP med. exp. Incl. 5% CAGR
	Pop-ulation	Pop-ulation	Med. exp.	Pop-ulation	Med. exp.	Pop-ulation	Med. exp.		
1	2	3	4	5	6	7	8	9 (4+6+8)	10
2006	1140	126.5	57635	956.5	363164	57.0	97388	518187	518187
2007	1160	127.6	58137	973.8	369732	58.6	100122	527991	554390
2008	1181	127.5	58091	993.2	377098	60.2	102855	538045	593194
2009	1201	127.3	58000	1011.2	383932	62.5	106785	548717	635209
2010	1220	126.9	57818	1028.5	390501	64.7	110544	558862	679301
2011	1237	126.2	57499	1044.0	396386	66.8	114132	568016	724949
2012	1254	125.4	57134	1059.6	402309	69.0	117891	577334	773683
2013	1271	124.6	56770	1075.3	408270	71.2	121649	586689	825531
2014	1287	124.8	56861	1088.8	413396	73.4	125408	595665	880068
2015	1303	125.1	56998	1102.3	418521	75.6	129167	604686	938066

Note: CAGR= Compound annual growth rate.

Source: Based on United Nations (2005a); and Government of India (2007c).

Table 7.6 provides estimates of household health expenditure, including medicines and other expenses such as doctors' fees, X-rays and ultrasound, etc. Again these estimates are based on the assumption that the use of healthcare by the 0-4 years of age population and the 65+ year age group would be higher than the other age groups as shown in the Table. In the final column of Tables 7.5 and 7.6, the expenditure considers inflation and rises by 5 per cent per annum.

Table 7.6: Estimates of total out-of-pocket *health* expenditure (Rs. million) and population groups (million)

Year	Total	0-4 (factor1.2)		5-64 (factor 1)		65+ (factor 4.5)		Total OOP health exp.	Total OOP health exp. incl. 5% CAGR
	Pop-ulation	Pop-ulation	H/care exp.	Pop-ulation	H/Care exp.	Pop-ulation	H/Care exp.		
1	2	3	4	5	6	7	8	9 (4+6+8)	10
2006	1140	126.5	94905	956.5	598004	57.0	160364	853273	853273
2007	1160	127.6	95731	973.8	608820	58.6	164865	869416	912886
2008	1181	127.5	95656	993.2	620949	60.2	169367	885971	976783
2009	1201	127.3	95506	1011.2	632202	62.5	175838	903545	1045967
2010	1220	126.9	95205	1028.5	643018	64.7	182027	920251	1118570
2011	1237	126.2	94680	1044.0	652709	66.8	187935	935324	1193737
2012	1254	125.4	94080	1059.6	662462	69.0	194125	950667	1273984
2013	1271	124.6	93480	1075.3	672278	71.2	200314	966072	1359360
2014	1287	124.8	93630	1088.8	680718	73.4	206504	980851	1449164
2015	1303	125.1	93855	1102.3	689158	75.6	212693	995706	1544667

Note: CAGR= Compound annual growth rate.

Source: Based on United Nations (2005a); and Government of India (2007c).

Based on the total out-of-pocket health expenditure in the Table above, India's total health expenditure can be estimated. According to Government of India (2005c), the total health expenditure in India comprises as follows:

Households (out-of-pocket)	72.0 per cent
Public expenditure on health (Central, state and local)	20.3 per cent
NGOs	0.1 per cent
Employment based	5.3 per cent
External support (e.g. donations to NGOs or governments)	2.3 per cent
Total	100 per cent

Taking the estimates of total out-of-pocket health expenditure as 72 per cent under the current situation, India's total health expenditure can be rebased as 100 per cent (see Table 7.7). Under the proposed model, the share of out-of-pocket health expenditure would decline from the current 72 per cent to around 33 per cent of total health expenditure. Correspondingly, public expenditure on healthcare would increase from around 20 per cent to around 67 per cent. The share of third party contributors, such as employers, and private health insurers is likely to fall significantly under the proposed model. This is based on the following assumptions. First, after the implementation of the IndiaHealth programme, the share of employers' contributions is likely to be limited to out-of-pocket co-payments towards the purchase of the

medicine rather than the total cost of healthcare. This would reduce the employer contribution as share of the total health expenditure to around 1.7 per cent (around a third of the current level).

Second, the uptake and the retention of private health insurance are likely to fall, because in the wake of IndiaHealth, the incentives to take up private health insurance would all but disappear. Third, the contribution of the NGOs is likely to be limited to national calamities and/or emergencies. Thus, the total contribution of the third parties is likely to be rendered negligible. Consequently, the public expenditure on health would also make up for the shortfall created by the reductions in contributions by the third parties. Should the share of the third parties not change as assumed, minor adjustments would need to be made to the share of public expenditure on health.

Table 7.7: Projected distribution of total health expenditure (Rs. million)

	Current situation		Proposed programme			
Year	Total OOP health exp. incl. 5% CAGR (72%)	Estimated total health exp. (THE) (100%)	Public exp on health. (PEH) at (67.33%)	Total OOP health exp. at (32.67%)	GDP estimates	PEH as % of GDP
2006	853273	1185101	797897	387204	39743850	2.01
2007	912886	1267898	853642	414256	45453590	1.88
2008	976783	1356643	913392	443251	50916870	1.79
2009	1045967	1452731	978085	474646	57361880	1.71
2010	1118570	1553570	1045977	507593	64612270	1.62
2011	1193737	1657968	1116266	541702	72713230	1.54
2012	1273984	1769422	1191305	578117	81814440	1.46
2013	1359360	1888000	1271140	616860	92075660	1.38
2014	1449164	2012728	1355116	657612	103585118	1.31
2015	1544667	2145371	1444421	700950	116533257	1.24

Note: CAGR= Compound annual growth rate.

Source: Based on Government of India (2005c, 2007c); and IMF (2008).

Table 7.7 shows that India would need to need to spend 1.62 per cent of the GDP to meet fully the share of public expenditure on health if the proposed model were implemented in 2010. These estimates consider the projected increase in India's population and take into account annual inflation of 5 per cent. The estimates suggest that the level of public spending on health as a share of the GDP would progressively decline. Under the proposal, the level of public expenditure on health is estimated to be less than 1.3 per cent from 2014-2015 onwards.

Sensitivities tests suggest that making changes to one variable in the model would affect the outcome for other variables. In case 1, co-payment for the lowest paying

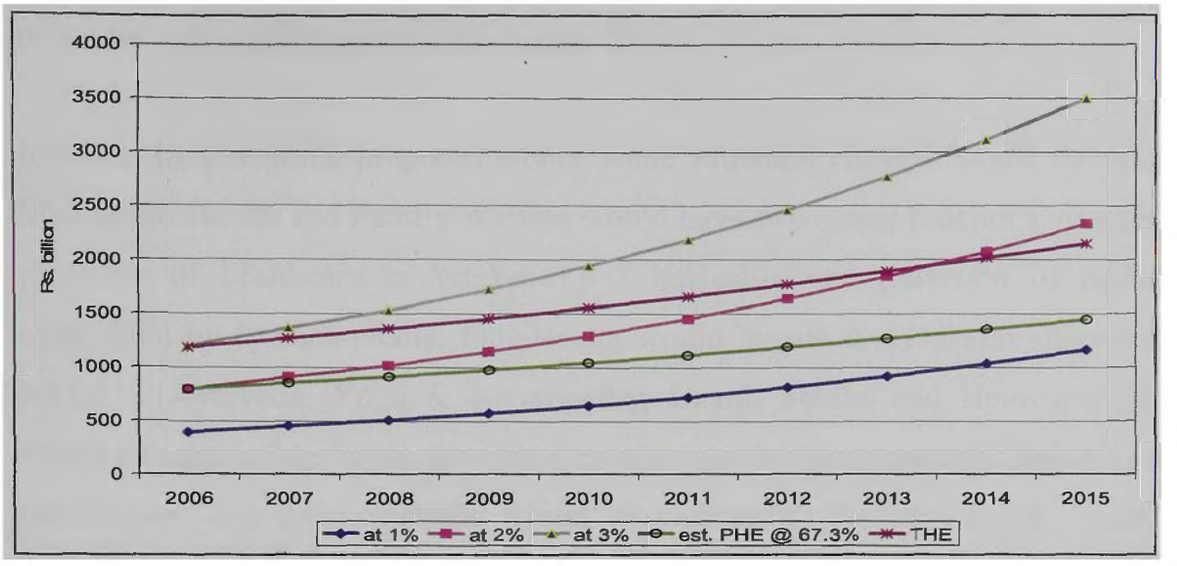
categories (B2 and A1) is raised from Rs. 10 to Rs. 15 per prescription. The Safety Net is also raised from Rs. 500 to Rs.750. The payment schedule for the other categories remains unchanged. The test shows that the public contribution on health for 2010 declines from 1.62 per cent (base case) to 1.50 per cent (see Appendix C for details).

In case 2, co-payment schedule for the lowest paying categories remains unchanged. For the A2 and M1categories, the co-payment is raised from Rs. 25 to Rs. 30 and the Safety Net is raised from Rs. 1,125 to Rs. 1,350. For the A3 and M2 categories, the co-payment is raised from Rs. 50 to Rs. 60 and the Safety Net is raised from Rs. 2,000 to Rs. 2,400. Consequently, the public contribution on health for 2010 declines from 1.62 per cent (base case) to 1.51 per cent (see Appendix D for details).

7.2.7 Funding the IndiaHealth Programme

Subsequent to estimating the costs of the IndiaHealth programme, this sub-section considers the sources for funding the programme. According to the National Health Policy – 2002, India's public spending on health has declined from 1.3 per cent of the GDP in 1990 to 0.9 per cent of the GDP in 1999 (Government of India 2002a) and the level of public health spending has remained at the latter rate ever since (Economic Research Foundation 2006; Mahal 2002; Raymus 2007). The Common Minimum Programme of the current United Progressive Alliance (UPA) government states that 'The UPA government will raise public spending on health to at least 2-3% of GDP over the next five years' (Government of India 2004, p. 7). If the government were to honour its commitment to raising the public spending on health, the entire IndiaHealth becomes easily affordable. This argument is based on the IMF estimates of India's current GDP and the forecasts for growth to 2013 (IMF 2008). The GDP forecasts for 2014 and 2015 have been based on the growth trends outlined by the IMF study. Figure 7.3 shows the public expenditure on health required under the proposed model as well as the level of expenditure on health committed by the government. The Figure also shows that India's total expenditure on health at around 3 per cent of the GDP in 2006 declining to below 2 per cent of the GDP from around 2014. The total expenditure on health includes the out-of-pocket private health expenditure as well as the public expenditure on health.

Figure 7.3: Variable levels of public expenditure on health relative to total health expenditure



Source: Based on IMF (2008); and Government of India (2004).

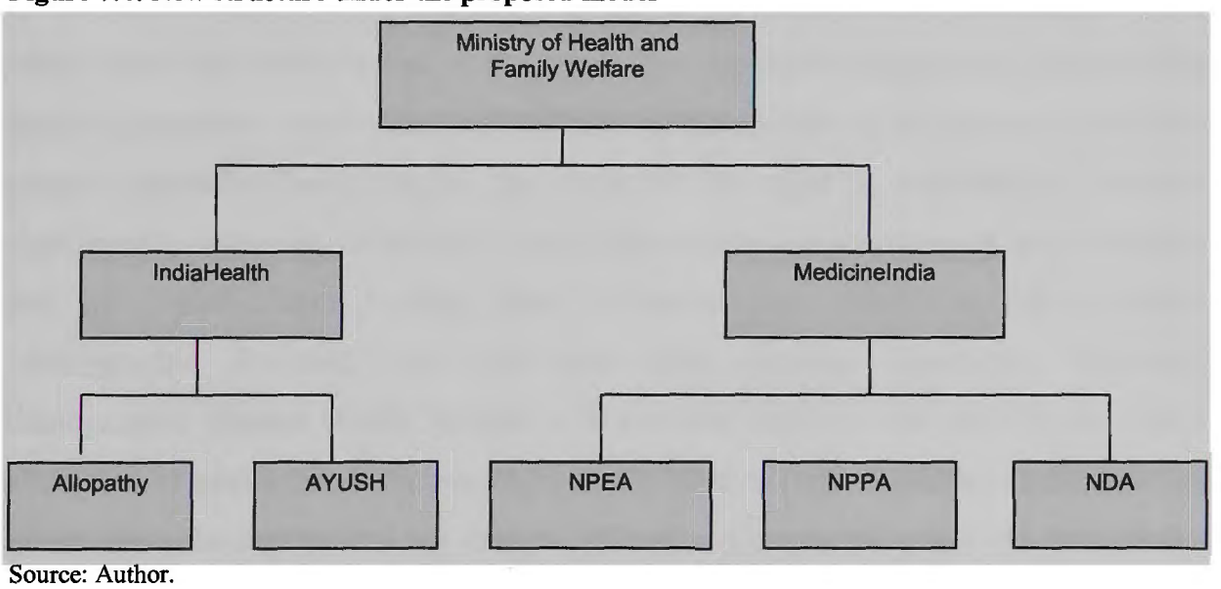
Figure 7.3 shows that by raising the public expenditure on health to 1.62 per cent of the GDP from 2010, the government could afford to fund the IndiaHealth programme. This level of public expenditure on health would not only be adequate to subsidise medicines, but also to fund other healthcare costs. It may be noted that this programme covers the entire population including those sections, which until now had no access to medicine. A subsequent rise in India's public expenditure on health to 3 per cent of the GDP over the next five years would provide additional resources for the programme. If the public expenditure on health as a share of the GDP was held constant over the coming years, the public health spending per capita would increase significantly. This is because the expected annual population increase is around 1.2 per cent compared with expected economic growth of 6-7 per cent in India. If the IndiaHealth programme were to be implemented in different stages, provision of subsidised medicines could form stage one of the programme.

The allocation of funds to finance the IndiaHealth programme would require re-prioritising of other government programmes meaning partial or complete withdrawal of funds to delay or cancel low priority programmes. Alternatively, IndiaHealth could be partially financed through budgetary deficits through issuing government bonds. The setting up of a programme of this magnitude would require significant additional infrastructure and human resources, who would be involved in issuing the IndiaHealth cards, awareness campaigns, validation, certification, and authorisation of doctors and pharmacists, and the preparation of formulary. Bearing in mind the difficulties

associated with implementing such a programme, it would be envisaged that the programme be implemented from 1 April 2010.

In accordance with the proposed model, some structural changes would be required. Ministry of Health and Family Welfare would have two major functions; namely, the provision of healthcare undertaken by IndiaHealth, and provision of medicines undertaken by MedicineIndia. IndiaHealth would be sub-divided into allopathy and AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy) that would be responsible for the development of access to their respective health systems (see Figure 7.4). MedicineIndia would be responsible for securing the supply of medicines to meet India's health needs, while IndiaHealth would be responsible for the distribution of the medicines. IndiaHealth would need to develop adequate infrastructure, and provide sufficient human resources to ensure the timely and equitable distribution of medicines to all sections of the population.

Figure 7.4: New structure under the proposed model



Source: Author.

The proposed model would provide access to healthcare and medicines with progressive patient co-payments based on various income levels. The level of household contribution would decline substantially while the share of public expenditure on health would increase significantly under the proposal. The share of third party contributors, such as employers and private health insurers, is likely to decline significantly. In the wake of the UPA government's commitment to raise the health expenditure to at least 2-3 per cent of the GDP, the proposed model would

become affordable if the public expenditure on health was raised from the current level of 0.9 per cent to less than 2 per cent of the GDP.

7.3.Conclusions

The two main objectives of this chapter were to explore the factors denying access to medicines to the majority of Indians and to develop a model that could provide access to healthcare including medicines to all in India. While the number of the poor in India living below the poverty line has declined over the last three decades, poverty remains the largest impediment to access to medicine in India. In the past, government policies have focused mainly on controlling drug prices rather than providing healthcare. There is no doubt that the share of India's population with access to medicines has increased since the 1980s. However, around two thirds of the population still remains without access to medicines.

At the current stage of economic development, India would need to introduce policies, which raise the health status of the poor. The population projections indicate that India's population could reach two billion by the middle of the century. With the people generally living longer, the share of the aged is expected to increase significantly, although India will enjoy a favourable age-structure of its population and will benefit from a rising share of working-age population (the so-called 'demographic dividend) over the next three decades. Eventually, however, demographic change would require a significant shift in the health policy and allocation of additional resources. India would need to raise its public expenditure on health from the current 0.9 per cent to 1.62 to implement the proposed IndiaHealth programme in 2010. The healthcare model presented in this chapter is financially affordable, implementable and practical. This model could also be used as a guide to consider other policy options.

The proposed model does not claim to be the end goal for India, but would be a small step in the right direction to help India achieve its objective of *health for all.* This model would provide access to both the allopathic and the traditional healthcare providers. The IndiaHealth programme would provide access to medicines requiring patient co-payments based on patients' ability to pay. Our costing presented above

suggests that the increase in the public expenditure on health required to fund the IndiaHealth programme is well within the level of commitment already given by the UPA government in its Common Minimum Programme. Our estimates indicate that by raising public expenditure on health care to 1.62 percent of GDP by 2010, India should be able to overcome the barriers to affordability of medicines. Going forward,, the ratio of public expenditure on health is expected to fall to 1.24 percent of GDP by 2015. The implementation of this model, or another variation of it, should relieve India's households of significant health expenditure and help the country to achieve better health outcomes.

Chapter 8

Is TRIPS Appropriate for Developing Countries?

8.1 Introduction

This chapter joins the global debate on the social and economic impact of raising the protection of intellectual property rights (IPRs) in developing countries under the TRIPS agreement. More specifically, the purpose of this chapter is to examine the appropriateness of applying the harmonised regime of intellectual property rights under the TRIPS agreement. The focus of this discussion is only on the protection of pharmaceutical product patents, because this form of patent protection has the greatest impact on access to medicines.

The controversy about the appropriateness of TRIPS arises out of the conflict between the interests of the developing countries on the one hand and of the developed countries on the other. Until recently, the developing countries could 'free ride' the intellectual property created in the developed world without sharing the cost of its development. The TRIPS compliant regime disallows 'free riding' and raises both the standard of protection and the cost of medicines in the developing countries.

The large MNCs maintain that stringent IPRs are necessary to encourage innovation, industry development and technology transfer. For example, Pfizer (2005) suggests that without stringent patent protection, large investments required to develop new drugs would not be possible. Similarly, Sharer, the Chairman of the Pharmaceutical Research and Manufacturers of America (PhRMA) argues that 'a robust IP system is crucial to our success in developing innovative new medicines. Without it, our industry wouldn't exist and neither would our products' (cited in PhRMA 2007, p. 5).

The Indian experience, summarised in the earlier chapters, shows that a weak patent regime has been beneficial for the development of Indian pharmaceutical industry, and increased the level of innovation in the country. While innovative activity was predominantly confined to reverse engineering, some new drugs were also developed under the weak patent regime in India. The development of manufacturing processes

made India a world leader in the production of generic drugs. Thus, India's experience contradicts the arguments advanced by Pfizer and PhRMA. These claims and counter claims lead into a worldwide debate on the desirability of stringent IPRs, considering their impact on the access to medicines in the developing countries. There is little doubt that the R&D in the pharmaceutical sector needs large investments. Whether these investments justify the level of protection advocated by the proponents of stringent IPRs is a question requiring further investigation. Against this backdrop, this chapter examines the appropriateness of TRIPS in the developing countries.

The rest of chapter is set out as follows. Section 8.2 discusses the macroeconomic context in which pharmaceutical product patents were implemented in the developed countries by comparing their stages of economic development with those of the developing countries at the time of implementation of TRIPS regime. This discussion leads into Section 8.3 which considers the social implications of stringent IPRs by focusing on the cost and benefits of implementing TRIPS in developing countries. Section 8.4 considers several alternatives for improving the current regime. Section 8.5 provides the main conclusions.

8.2 Patents in developed countries

The purpose of this section is to consider whether the TRIPS agreement has been prematurely imposed on the poor countries, depriving them of the same opportunities that the developed countries themselves had enjoyed at the early stages of economic development. Intellectual property has been a key economic driver in a large number of advanced economies. For example, intellectual property constitutes America's largest export (Posner 2002). Historically, many countries including the US benefited from copying technologies developed in advanced economies (UNDP 2005, p. 135). The US was copying British patents and copyrights in the 19th Century. For example, the US permitted wholesale reprinting (piracy) of British authors' work causing British rights holders to suffer financial losses. The difference in price of imitated and that of the original product was huge. A locally produced copy of *A Christmas Carol* by Charles Dickens cost just six cents in 1843 compared with the British edition at $2.50 (Hesse 2002). Similar or more significant differences were noticeable between the prices of originator drugs and those of Indian generics (see chapters 4-6 for

details). According to the Human Development Report (2005), Japan, Korea, China and Taiwan all upgraded their technological capabilities through reverse engineering, a technical term for copying someone else's work and developing innovative skills (UNDP 2005). If India, Brazil and other developing countries are copying the patented products, they are doing so because it has been a part of the transition process to eventually transform their economies to fully developed economies.

The US intellectual property regime not only permitted copying of elsewhere patented products, but also discriminated against foreign producers. The US provided incentives for domestic innovation and denied any protection for foreign technology (Hawthorne 2003). This provided the US producers access to foreign technology at a cost lower than other nations. This asymmetry between British and US patent laws favoured inventors in the then developing economy of the US, rather than Britain, the more industrialized economy of the time (Jeremy 2004). In today terms, the US patent law was a clear case of discrimination against foreign firms and imports in contrast to the doctrine of national treatment under the TRIPS agreement extended to all firms regardless of their origin.

8.2.1 Introduction of pharmaceutical product patents

The introduction of pharmaceutical product patents has generally been a two stage process. Stage one introduced only 'process' patents, encouraging participation in the drug development process. By design, Stage one may be called an *inclusive phase*, because it did not exclude anyone from making the product. Under stage two, introducing 'product' patents was phased in, after high level of innovative capabilities had been developed. This stage barred participation by others in any shape or form of the property and as such may be called an *exclusive phase*. A large number of developed countries, particularly in Europe, had delayed the introduction of pharmaceutical product patents till they had attained certain level of economic development. According to Basheer (2008), the delay was necessary, because learning and mastering to imitate are necessary steps to developing capabilities to innovate, a key to creating intellectual property (cited in Kumar 2008). In a memoir to the

Reichstag[59], the German Association of Chemical Industry explicitly describes the rationale behind the patenting of 'process' versus 'product' as follows:

> ... the same chemical product can be obtained by different processes and methods and even starting from initially different materials and components. Hence, there is social value in patenting a new process, as it rewards the innovator without preventing further innovation. There is negative social value in patenting a specific product, as this would exclude all others from producing it, even through different processes. (cited in Boldrin & Levine 2005, p. 3)

The Indian Patent Act 1970 was heavily criticised by the developed countries in the years preceding the implementation of TRIPS. The Patent Act 1970 was, in fact, based on the 'German system of allowing the patenting of methods or processes that led to drugs, but not allowing the patenting of the drugs themselves' (Drahos 2002b, p. 165).

During the development of the US pharmaceutical industry, foreign companies faced problems of high tariffs and discriminatory patent rules, as noted above. Unlike today, there were no pharmaceutical companies as such in 19th Century in the US or in Europe. Pharmacists or druggists made and mixed their own compounds from ingredients mostly supplied by German companies. E. Merck & Co, one of the pioneers in pharmaceutical innovation was based in Darmstadt (Germany). The company exported fine chemicals to the US in 1890 and noted that 'in light of *feeble* US drug regulations, problems developed – Merck labels were *illegally* placed on other companies' chemicals' resulting in significant losses of revenue (Hawthorne 2003, p. 21). Placing Merck labels on non-Merck products was illegal at German law but permissible in the US. Discriminatory treatment of foreign companies and high tariffs were eroding their market sales. Ultimately, these companies shifted to the US to manufacture locally.

Around the same time, other countries also had discriminatory rules against foreign companies and imports. For example, Switzerland had 'the [most] selective patent law ever enacted in modern times' (Schiff 1971, p. 93). The 1888 Swiss legislation discriminated against foreign companies and encouraged domestic imitators. The Swiss patent law did not include chemical compounds until 1907 when only process patents were introduced. Patents for pharmaceutical products were first introduced in

[59] The German Parliament until 1945.

Switzerland in 1977. Today, Switzerland is home to some of the most innovative companies in pharmaceutical industry including Novartis and Roche.

Similar to Switzerland, Italy also did not provide pharmaceutical product patents. The Italian industry consisted of a large number of small and medium sized independent pharmaceutical firms. In 1978, following a court ruling in favour of the MNCs, Italy had to introduce product patents. Scherer and Weisburst (1995 suggest that no significant increase in the discovery of innovative drugs was achieved after the Italian Supreme Court mandated the issue of pharmaceutical product patents. Another study suggests that the introduction of product patents in Italy did not only fail to translate the stringent protection into significant innovation progress, the domestic pharmaceutical industry in Italy was on the verge of collapse as a consequent of the regime change. According to Boldrin and Levine {, 2005 #400), 'the Italian pharmaceutical industry is, in fact, practically disappearing, together with the most valuable and patentable drugs it did not discover since 1978' (p. 9). Going by the Italian experience, the implementation of TRIPS in India is likely to put an end not only to imitation but also to innovation, suggest Boldrin and Levine.

In Argentina, pharmaceuticals were explicitly excluded from the patent legislation passed in 1864 (Rogers 1994). After copying drugs developed elsewhere for more than 130 years, the country introduced TRIPS compliant patent regime in 2000. The Patents and Designs Act 1911 had provided pharmaceutical product patents in India, but abolished under the Patent Act 1970. The United Kingdom first introduced patents for pharmaceuticals in 1949, France in 1960 and Germany in 1968 (Chaudhuri 2005, p. 321). Table 8.1 below shows comparisons of national output per capita in the selected countries at the time of the introduction of pharmaceutical product patents.

It is clear from the figures in Table 8.1 that all the developed countries had a five-digit GDP per capita at the time of adoption of pharmaceutical product patents. For example, Switzerland had GDP per capita of US$36,965 (1977), Norway had US$30,389 (1992), and Japan had US$24,043 (1976). This level of economic development compares with less than $500 GDP per capita in India and China at the adoption of product patents. The argument here is that a large number of developed countries did not introduce product patents in pharmaceuticals until certain level of

economic development had been attained. The implementation of TRIPS and TRIPS-plus conditions in developing countries is denying the poor countries the same opportunities as enjoyed by the developed countries when they implemented product patents. Under the WTO obligations, the least developed countries (LDCs) like Malawi are due to implement the TRIPS agreement in 2016. It is highly unlikely that the LDCs will be close to the level of development of say India or China, let alone reaching the level of a country listed under the developed countries in the Table.

Table 8.1: GDP per capita on adoption of pharmaceutical product patents (selected countries)

Developed countries	Year	GDP p/capita (1995 US$)
Japan	1976	24,043
Switzerland	1977	36,965
Italy	1978	13,465
Holland	1978	20,881
Sweden	1978	21,896
Canada	1983	16,296
Denmark	1983	28,010
Austria	1987	25,099
Spain	1992	14,430
Portugal	1992	10,469
Greece	1992	10,897
Norway	1992	30,389
Developing countries		
China	1992/93	424
Brazil	1996	4,482
Argentina	2000	8,100*
Uruguay	2001	6,208*
Egypt	2005	1,191*
India	2005	450*
Pakistan	2005	508*
Malawi	(2016)	156

Note: Figures marked with * refer to GDP per capita of 1999.
Source: Based on Lanjouw (2002).

On the basis of the evidence presented, it can be concluded that the TRIPS agreement has been prematurely imposed on the poor countries depriving them of the same opportunities that the developed countries themselves had enjoyed at the early stages of economic development. The forced introduction of pharmaceutical product patents places the poor countries at a significant disadvantage on two accounts. First, the raised level of patent protection cuts short the process of learning and mastering of imitation harming the pace of industry development in the poor countries. Second, the patents induced monopolies provide the MNCs significant control over these markets

with no or little competition from the local manufacturers restricting access to medicines. The TRIPS agreement fails to recognise and take into account the different levels of economic development across member states and the diversity in their needs. TRIPS is simply a 'one size fits all' concept with significant disadvantages to the poor countries.

8.3 Costs and benefits of TRIPS

The aim of this section is to consider the costs and benefits of patents in general and the TRIPS agreement in particular. The significance of this section would be in the informed assessment of the implications of the TRIPS agreement. Because 'it is far more difficult to measure the positive effect of patents on innovation' (Lanjouw, JO & Cockburn 2001, p. 266), discussions on the costs and benefits of patents generally tend to be restricted to emphasising the benefits. 'The costs of the patent system are usually ignored altogether or presented as trivial' (Macdonald 2002, p. 31). Yet, there are significant economic and social costs indeed.

The strengthening of the patent system has raised the costs of healthcare worldwide. These costs are more pronounced in the developing than in developed countries. The introduction of TRIPS has delayed the entry of low cost generics increasing the costs of healthcare in all countries, including the US. Drug prices fall by 60-70 per cent after generics enter the US market, where significant proportion of the population pays out-of-pocket for medicines. The absence of generics means that consumers would be forced to purchase the originator drugs at monopoly prices. Consequently, consumers would spend less elsewhere reducing social welfare. Prescription drugs in the developed countries, except the US, are significantly subsidised by universal health insurance programmes and the consumer spending is limited to co-payments. But the additional public expenditure on health, as a consequence of TRIPS, would be offset by delaying or cancelling other development programmes.

8.3.1 Costs and benefits to developing countries

In the developing countries, the effect is more far reaching than the developed world for a number of reasons. First, medicines constitute around two thirds of the total healthcare costs in developing countries compared with around 15-20 per cent in

developed countries. Second, most of the drug expenditure is met by out-of-pocket household spending. Monopoly drug prices mean that the consumers are forced to make choices. The poor have to choose between seeking or not seeking treatment for a medical condition (World Bank 2002). The costs of treatment often results in cancelling a child's education, postponing a child's marriage or running the family into deeper debt (Government of India 2006e).

The main benefit to the developing countries of signing the TRIPS agreement was that it enabled them to access the markets of the developed countries. The poor countries have limited capability to export goods in the manufacturing or services sectors. Generally, the developing countries' economies are based on agricultural sector. Countries, such as India, China and Brazil with substantial pharmaceutical and other manufacturing industries might be slightly better off than the rest of poor countries. The US and the European countries provide substantial subsidies to the agricultural sector, which they were to dismantle as a part of the deal to establish the WTO. So far, these countries have reneged on the undertaking to dismantle the subsidies. The position taken by the US and the EU has significantly reduced the scope of benefits of TRIPS to developing countries. The Nobel laureate economist Joseph Stiglitz (2002a) holds that the US and the Europe gained significantly from trade liberalisation and establishing of the WTO at the expense of poor countries. The Uruguay Round of negotiations opened the markets of the poor countries:

> ... to manufactured goods produced in the industrialised countries, but did not open up the markets of Europe and the US for agricultural products in which poor countries often have a comparative advantage' and 'sub-Saharan Africa, the poorest region of the world, lost by about two per cent because of terms-of-trade effects. (Stiglitz 2002a, p. A20)

There is considerable cost to implement the WTO agreements. Finger and Schuler (2001) find that the implementation phase alone of the new responsibilities, including TRIPS would cost each poor country around $150 million. This amount, accounting for the costs of acquiring and maintaining additional human and other resources, exceeds a year's development budget in many of the least developed countries, suggest Finger and Schuler. The total economic costs of TRIPS and other agreements for developing countries are significantly higher but vary across countries.

A number of studies have examined the costs and benefits. For example, Finger (2002), studies the impact of TRIPS on different groups of countries. He uses a scale 0 to 9 to signify a net positive effect and a minus symbol to indicate a net negative effect of TRIPS. A score of 0 would equalise the costs and benefits. Finger concludes that while South Korea (-0.9) would be the least *badly-off* and Brazil (-1.6) would be relatively worse-*off* than South Korea, Mexico (-2.0) would be the worst-*off* under TRIPS. This examination suggests that the costs of TRIPS outweigh the benefits in South Korea by 90 per cent, in Brazil by 160 per cent and in Mexico 200 per cent. The US had the highest positive score (7.5) suggesting that the net gain to the US to be 750 per cent. It is not surprising that the US used all methods of persuasion, including coercion, to ensure intellectual property formed a part of the WTO ambit.

Oxfam (2002) estimates the annual costs of TRIPS in terms of high drugs prices at US$40 billion. The developed countries already had product patents for pharmaceuticals before the TRIPS agreements; thus, the additional costs primarily would come from developing countries, argues Oxfam. For example, the costs of pharmaceuticals are estimated to increase by US$425 million annually in Argentina alone, suggests Norgue (cited in Finger 2002, p. 13). Jack and Lanjouw (2005) suggest that because some countries have post-TRIPS higher drug prices, and nowhere are the prices lower, social welfare is certainly reduced. Similarly, Jack (2005) suggests that 'because ... poor countries ... will have higher prices as a result of TRIPS, a welfare function with any aversion to inequality would suggest that welfare falls steeply' (p. 63).

Two studies compare the welfare costs of strengthening the IPRS in India to the society against the gains to the pharmaceutical companies. Dutta (2005) simulates the welfare effects of patents enforcement in India for a single drug still under patent in the US. India would incur over $1 million annually in net costs or a 7 per cent reduction in consumer welfare against a small profit to the global patent holder, concludes Dutta. Another study measures the impact of withdrawing four domestic pharmaceutical product groups in the fluoroquinolone sub-segment. Chaudhuri, Goldberg and Jia (2003) find that in the absence of any price regulation and/or compulsory licensing, total annual welfare losses to the Indian economy would be around US$713 million. Of this, lost profits of domestic producers would constitute

about US$50 million or 7 per cent of the total losses while the rest would be losses of consumer welfare. The financial benefits to MNCs would be about US$57 million.

These studies clearly suggest that costs of implementing TRIPS in developing countries, including India, are significantly higher than the benefits. Moreover, the costs are certain whereas the potential benefits are not certain and are 'may be' at best. It is therefore not surprising that India, Brazil and other developing countries vehemently opposed the inclusion of intellectual property in the Uruguay Round of negotiations. The threat of retaliatory sanctions by the US under the Special 301 provisions eventually forced the developing to sign the WTO agreements (Balasubramaniam 2002). Special 301 provisions remain the best example of a public law at the service of private industry in the US (Drahos 2002b).

8.3.2 Implications for developed countries

Healthcare costs in developed countries have also increased significantly because of strengthening of the patent regime in compliance with the TRIPS agreement. For example, the patent term in the US had to be extended from 17 years to 20 years in compliance of TRIPS. Applications filed on or after 8 June 1995 would be granted a 20-year term from the filing date (Patent Lens 2009). A study by Professor Schondelmeyer of University of Minnesota concludes that the cost of 3-year extension of the patent term would exceed six billion dollars over the next 20 years. The annual savings lost by American consumers due to the delayed entry of less expensive generic drugs are likely to range from US$200 million to more than US$500 million, suggests the Schondelmeyer report (cited in Jorge 2004). A similar extension of 3 years of patent term in Canada on 25 products would cost C$200 million annually in welfare losses, estimates Rhein (2001, p. 25). As this estimate represents only a fraction of the entire range of medicines, it can be safely assumed that the total size of the losses in Canada would be significantly higher.

As a part of the US-Australia Free Trade Agreement (FTA) signed in 2004, Australia had to introduce a range of measures to strengthen patent protection, including the ever-greening of patents. Drahos et al. (2004) study the cost of these changes to Australia's regime and conclude that the cost of medicines under Australia's

Pharmaceutical Benefits Scheme (PBS) would rise by at least a third. The Australia Institute concludes that the measures in the FTA are 'likely to delay the development of generic drugs in Australia by around three years' (cited in Drahos et al. 2004, p. 2). After examining the cost of five drugs for the period 2006-2009, the Institute finds that the PBS would have to pay $1.1 billion more with the strengthened patent regime than without it. For the financial year 2005-2006, the PBS contributed A$5.4 billion towards the costs of medicines. Against the findings of the Australia Institute measuring the impact on just five drugs, the estimates by Drahos et al. seem quite conservative. All three nations; namely the US, Canada, and Australia already had a stringent patent regime including pharmaceutical product patents. Therefore, deriving any additional benefits from extending the patent period in these countries would be highly unlikely. Yet, the increase in healthcare costs is significant. In the light of these studies, the Oxfam estimates for the developing countries (i.e. paying additional $40 billion to the developed countries) do not appear unreasonable.

8.3.3 Further implications for developing countries

Theoretically, the strengthening of patent regime may bring a range of benefits to India. The new regime may lead to increase in outsourcing, innovative activities, transfer of technology, and induce foreign investments in India. Some of these activities are, in fact, already taking place in India. Nonetheless, how much of these benefits can be attributed to TRIPS or globalisation remains questionable (see chapters 4 and 5 for details). Most of these activities, in all likelihood, might have taken place in the absence of TRIPS. For example, MNCs save 50-60 per cent on costs by shifting some of their core functions to low cost countries like India. Casting doubts over benefits of TRIPS to developing countries, Jorge (2004) suggests that not one new research and development or transfer of technology has taken place as a result of higher patents protection. Finger and Schuler (2001) conclude that the obligations 'imposed by the WTO agreements on customs, ... intellectual property rights ... can be characterized as the advanced countries saying to the others, Do it my way' (p. 23). The WTO agreements fail to consider the difference in the needs of the developing countries. They suggest that these agreements including TRIPS are self evident for inappropriate diagnosis and inappropriate remedy for developing countries.

The problem stems from the flawed design of the TRIPS agreement. While TRIPS obliges developing nations to provide protection for drugs under patent under, there is no obligation on MNCs to transfer technology or to invest into the developing nations. The absence of reciprocal obligations to commit both sides leads to an imbalance of costs and benefits. Moreover, as noted before, the costs are a certainty because member countries are committed to honour the agreement and the benefits remain a 'may be'. While it could be argued that it is too early to pass a judgement on the benefits, there could be no disagreement that the benefits would depend on the decisions made in the corporate offices of MNCs. A number of studies on multi-country theoretical models suggest that the incremental profits from extending stringent IPRs to poor countries may not stimulate significant additional R&D investments (see for example, Chin & Grossman 1990; Deardof 1992).

Three leading economists and Nobel Laureates have expressed serious concerns over the issues of globalisation, WTO and TRIPS requirements forcing poor countries to adopt stringent patents regimes. Amritya Sen (2002) suggests that there are serious problems with the global institutional arrangements designed for a fair distribution of benefits including those for fair trade, medical initiatives, educational exchanges, facilities for technological dissemination. Sen believes that an overhaul of these arrangements is required for a number reasons, not only for the 'inefficient and inequitable trade restrictions that repress exports from poor countries', but also for the 'patent laws that inhibit the use of lifesaving drugs for diseases like AIDS and that give inadequate incentive for medical research aimed at developing non-repeating medicines (such as vaccines)' (p. A6).

Jeffery Sachs (2000) argues that today's world is divided not by ideology but by technology. Countries and regions can be categorised in terms of their capabilities to innovate. North America, most of Europe and Australia are *technological innovators*. These regions are the leaders in innovation. *Technological adopters* including Eastern Europe, parts of South America, South Africa and India are the followers (imitators). The countries comprising most of Asia and Africa, as well as Central America are the net users and termed as *technologically excluded.* Sachs suggests that there is an urgent need to address this great imbalance:

> At the government-to-government level, the international community should make a firm commitment to promote scientific and technological capacity in the poor countries. As part of this, rich countries should exercise restraint in the use of property rights. Rich countries are unilaterally asserting rights of private ownership over human and plant genetic sequences, or basic computer codes, or chemical compounds long in use in herbal medicines. These approaches are of dubious legitimacy and will worsen global inequities. A better balance needs to be struck between incentives for innovation on one hand, and the interests of the poorest on the other. (p. 8)

Joseph Stiglitz (2002a) argues that corporate advocates of protection of intellectual property rights have exaggerated its importance. The current structure of intellectual property rights does not only not-serve its welfare purpose but has become harmful to the society, particularly to the developing countries. Stiglitz sees a need to review the structure and suggests that:

> Intellectual property rights, such as patents and trade marks, need to balance the interests of producers with those of users – not only users in developing countries, but researchers in developed countries. If we underprice the profitability of innovation to the inventor, we deter invention. If we overprice its cost to the research community and the end user, we retard its diffusion and beneficial effects on living standards. (p. A20)

There are a number of options for better balancing of the rights of innovators against those of the users of new drugs in poor countries. If the patents regime is totally abolished, new methods for providing incentives for innovative activities would need to be developed. Chaudhuri, Goldberg, and Jia (2003) suggest that 'patents may be a particularly inefficient way of encouraging discovery' (p. 7) and that a number of previously used alternatives, including direct subsidies for research, prizes and tournaments, and patent buyouts should be adopted. The advantage of direct subsidies is that the research can be directed to discover drugs of national interest. Ground breaking innovations can be rewarded by cash-prizes in recognition for the contribution of the innovator. The downside of this approach may be insufficient stimulation to innovation if the recognition does not bring significant financial rewards. Alternatively, government could buyout a patent and place it in the public domain. This method should provide immediate access to the would-be manufacturers and increase market competition.

Frederic Scherer (2002), Professor Emeritus at Harvard University, has examined whether global welfare would be higher under a worldwide system of pharmaceutical product patents or under a framework that allows poor countries to free-ride on the new drugs developed in the industrialised countries. Scherer's study is based on Nordhaus (1969), which found a positive correlation between the number of new

drugs developed annually and the R&D expenditure. Scherer also examined how quasi-rents appropriated by innovators vary with the number of new drugs marketed. He considers three key variables in this examination: (1) the relative increase in producer's surplus that can be achieved through additional sales on patented drugs in poor countries; (2) the number of additional pharmaceutical products;[60] and (3) the average difference in the marginal utility of income for the third world relative to the first world. Accepting the notion that 'the richer a man becomes the less is the marginal utility of money to him' Scherer assigns 'greater weight to the benefits realised by poor nations than to those of rich nation inhabitants (p. 4) and concludes that global welfare would be maximised by letting the poor countries free-ride on the patented drugs of the developed countries, at the expense of plausible discovery impairment. Scherer argues that during the debate over TRIPS someone like Kofi Annan should have said to the MNCs that:

> We will support your demand for strong patent rights throughout the world if you will commit 20 per cent of your research and development budgets to diseases specific to less-developed nations. (p. 9)

Scherer's argument is based on a trade-off struck between the pharmaceutical industry and the government in Canada. The industry persuaded the Canadian authorities to abandon its vigorously enforced compulsory licensing regime. In exchange, the industry agreed to establish in Canada R&D activities proportional to Canada's share of companies' drug sales. The TRIPS agreement commits member developing states to raise the protection of IPRs. But the agreement is silent on committing MNCs, the major beneficiaries of TRIPS, to undertake research for drugs specifically for tropical diseases. The industry, of its own initiative, has been reluctant to invest into discovering drugs for the poor countries.

Notwithstanding the above arguments, some experts warn against abolishing or weakening the patents regime. Their argument is based on the premise that drug prices always fall without patents and on patent expiry. Lower prices would mean a decline in profits, a fall in investment in R&D, leading in turn to a reduction in the number of new drugs discovered. For example, Lichtenberg (2006) estimates that if drug prices in certain cancer groups fell by 10 per cent, innovation would decline by

[60] It is assumed that each product would have identical demand functions.

5-6 per cent in the long run. A steeper decline in prices would lead to more drastic reduction in innovation. Abbott and Vernon (2005) estimate that 40-50 per cent reduction in drug prices in the US would result in 30-60 per cent lesser innovative activities (cited in Lichtenberg 2006).

Hughes, Moore and Snyder (2002) suggest although accelerating generics entry would yield substantial gains in consumer surplus by providing greater access to the current stock of pharmaceuticals, the loss to future consumers would be significantly greater than the gains of today. Putting a dollar value, Hughes, Moore and Snyder argue that society would lose 3 dollars in benefits of innovation for every dollar gained through easier access today.

Drug prices generally rise at a rate significantly higher than the consumer price index (CPI). Santerre and Vernon (2005) argue that if the drugs prices in the US had risen in line with the CPI between 1981 and 2000, the nation would have saved $319 billion, at a cost of 198 fewer new drugs brought into the market. They further conclude that at a cost of around $1.6 billion a drug, these costs are significantly lower than the welfare costs without the new drugs. The industry bodies representing innovator companies also vehemently oppose a review or weakening of TRIPS. For example, Harvey Bale, director-general of the International Federation of Pharmaceutical Manufacturers Association (IFPMA), warns that continuing debates on patents are hampering drug companies' decisions making on whether to enter into AIDS research (Bureau of National Affairs 2001).

The above studies suggest that while reduction in drug prices would benefit consumers in the short term, the decrease in future welfare would outweigh today's gains from lower drug prices. These studies implicitly advocate further strengthening of the patents regime. Because they suggest the higher prices the society pays today, the more benefits the future consumers would get.

These studies overlook a number of factors, however. First, these studies fail to recognise the first-mover advantage in a fully competitive market. Being first is the most critical consideration in marketing pharmaceuticals. According to Gassmann, Reepmeyer and Zedtwitz (2008):

> Time-to-market is extremely important in breakthrough pharmaceuticals. The first in the market captures between 40 per cent and 60 per cent of the market, and the second only around 15 per cent. Coming in third already means a negative business. (p. 16)

Hence, the market competition would propel companies to innovate for securing a competitive advantage. Second, the direction of innovation is determined by potential returns on investments and not by the number of patients or by the disease pattern. The future drugs are decided by the size of expected profits. The pharmaceutical R&D does not consider reducing the number of people suffering from specific diseases.

Third, many of the so-called innovations are minor modifications of existing compounds known as active pharmaceutical ingredients. Lleras-Muney and Lichtenberg (2002) suggest that 'there is a very large difference in the number of drugs and innovation: today are about 80,000 different drugs, but only about 2000 different active [pharmaceutical] ingredients' (p. 12). The active pharmaceutical ingredients (APIs) are the actual drugs with therapeutic value. The APIs are used in the manufacture of formulations in different strengths and forms such as injectibles, tablets etc. While the discovery of an API would be considered ground breaking, developing new forms, strengths and finding new uses of the same API would be minor modifications. The costs of discovering and developing a new API are significantly higher than minor modifications.

Several studies show that pharmaceutical R&D is driven by buying power of target market thereby ignoring needs of poor nations. R&D funds are invested more often into life style and chronic diseases of wealthy nations for attractive returns. It is commonly argued that the high costs of drug development force the industry to charge higher prices for drugs. Scherer (2001), suggests that the relationship between the drug prices and the R&D costs is not seen in the right context and often misrepresented. He argues that in reality, it's the other way around: prices drive costs. The more a company can charge for a drug, the more it will spend on developing and marketing it. And that is perhaps why MNCs invest in innovations for drugs suitable for markets where the companies can charge the highest prices. The drugs developed specifically for poor countries would be low priced compared with those developed for the wealthy nations. It is not surprising therefore that the drug companies are less

interested in developing drugs for tropical diseases. Even the innovative activities of the Indian pharmaceutical industry are focused on the lucrative markets of developed countries rather than developing drugs to fill the current vacuum of unmet needs of the domestic market.

Since the launch of Tagamet in 1976, the first blockbuster drug, the industry focus has been to search for the next blockbuster(s). Tagamet's huge financial success demonstrated that the introduction of just one blockbuster product could change the company fortunes and enable it to double or triple in size. This single event changed the mindset of pharmaceutical industry to what Nordmann (1997) calls 'blockbuster mentality' (p. 27). Recently, a spokesman for a MNC summed up the intentions of his company, which reflects the industry-wide view. He suggested that 'his company would rather find a cure for a bald American than a dying African' and that 'we have a financial commitment to our shareholders, therefore we have to focus on the $1.5 billion blockbuster drugs for the cardiovascular, metabolic and anti-infection market in the more developed countries' (cited in Chataway, M 2000, p. 21). Pfizer, the world's largest pharmaceutical company has earmarked $17 billion to scrutinize hundreds of drug and biotechnology companies over the next two years in search of the next blockbuster medicine (Pettypiece 2006). It is a pity that not even one-tenth or one-hundredth of that amount is reported to have been earmarked for the development of drugs relevant to poor countries. Blockbuster drugs are few and far between. Most of the new products are minor changes to existing drugs aimed at serving the rich nations. Less than 3 per cent of the global expenditure on pharmaceutical research is directed towards finding a cure for the so-called diseases of the poor nations (see Table 8.2). In the following quotation, Drahos (2002a) sums up nicely the dilemma the developing countries face with respect to access to medicines specific to their needs: 'If the poor want more patent-based R&D for malaria they will have to hope that it overtakes obesity and impotence as a problem in Western societies' (p. 6).

As figures in Table 8.2 show, diarrhoeal diseases, malaria, measles and tetanus collectively account for more than four million deaths annually in poor countries. Another half million deaths are caused by pertussis and syphilis. Yet, pharmaceutical companies have shown little interest in tropical diseases, such as malaria and tuberculosis simply because of lack of potential for hefty returns. Tuberculosis (TB)

alone annually kills nearly 1.7 million worldwide (WHO 2002c). India accounts for one third of the global TB burden and has the largest number of sufferers with active TB in the world (Misra, Chatterjee & Rao 2003). In many cases, the problem is not that there are no medicines for the disease. The problem is that parasites and bacteria develop resistance to drugs commonly used to treat malaria and tuberculosis rendering those drugs ineffective (WHO 2007). The second line drugs and then third line drugs need to be developed to stay ahead of parasites and bacteria. It is a process of continuous research and development to find effective treatment. Lehman (2003) suggests that traditional folks medicines are most likely to provide the key material of possible new drugs to address local and regional disease burdens. But such innovation has to be backed up by favourable government policies that is currently not the case in poor countries, argues Lehman.

Table 8.2: Select diseases with 99 per cent of the global disease burden in low- and middle-income countries (2000)

Disease	Disability adjusted life years (DALYs) (000s)	Deaths per year
Chagas disease	680	21,299
Dengue	433	12,037
Ancylostomiasis and necatoriasis (hookworm)	1,829	5,650
Japanese encephalitis	426	3,502
Lymphatic filariasis	5,549	404
Malaria	40,213	1,079,877
Onchocerciasis (river blindness)	951	n.a.
Schistosomiasis	1,713	11,473
Tetanus	9,766	308,662
Trachoma	1,181	14
Trichuriasis	1,640	2,123
Trypanosomiasis	1,585	49,668
Leishmaniasis	1,810	40,913
Measles	27,549	776,626
Poliomyelitis	184	675
Syphilis	5,574	196,533
Diphtheria	114	3,394
Leprosy	141	2,268
Pertussis	12,768	296,099
Diarrhoeal diseases	62,227	2,124,032

Source: Kremer (2002, p. 71).

Moran (2001) suggests that 1,223 new drugs were developed between 1975 and 1996, of which, only 11 were for tropical diseases. Of these 11, five were spin-offs from veterinary research (humans share some diseases with dogs and horses). A handful came from US military research during the Vietnam War when tropical diseases were,

briefly, an issue. Three came from pharmaceutical industry R&D, often accidentally while looking for cures for Western diseases (Moran 2001). A recent survey published in The Economist (2005a) indicates finds that of around 1,500 drugs launched in the last three decades, less than 20 were tropical disease specific. This amounts to around 0.01 per cent of the discovery output.

About three quarter of the global population lives in the developing and least developed countries consuming only 14 per cent of the global drug supply (Torbet 1999). Based on *The Economist* study noted on average, 50 new drugs were discovered annually over the last 30 years. More recently, the annual average of new drugs introduced has been closer to 20. It would too ambitious to expect that implementing TRIPS would greatly improve drug discovery for the diseases in the poor countries. Hypothetically, if just 1 drug was annually developed for the tropical diseases because of the poor countries agreeing to TRIPS, this would constitute 5 per cent of total R&D output of the more recent average. Undoubtedly, the development of just 1 new drug every year could save many lives in the developing world. But each new drug developed specifically for the diseases of the poor countries would come at a cost of $40 billion,[61] compared with the estimated costs[62] of $800 million for a new drug for the rest of the world. The poor countries would be paying 50 times more for a new drug than their wealthy counterparts. While this hypothesis seem like a rough deal for the poor countries, but even this is highly unlikely despite TRIPS. The irony is that development of a new drug would make it available on the market, but not necessarily affordable to the poor. This situation would not significantly differ from today's reality where millions of poor remain without access to medicines. So, what can be done to improve upon the current situation?

8.3.4 Recent investigations of protection of pharmaceutical patents

Of the recent literature available on the issue of intellectual property, especially on pharmaceutical patents, two recent reports are highly important. The first of these is a report of the Commission on Intellectual Property Rights (CIPR) (2002). The CIPR

[61] Oxfam (2002) estimates, the poor countries would contribute $40 billion annually in TRIPS inflicted additional costs.

[62] Deliberate use of this figure rather than the recent estimates of $1.3 billion, because the *actual* outlay is less than half of the new estimates and the developing countries would be *actually* paying additional costs.

was established and based in London in 2001. The second report is the report of the European Commission's inquiry of the pharmaceutical sector (discussed later in the section). The terms of reference required the CIPR to particularly consider the interests of the developing countries. The CIPR was made up of experts from diverse backgrounds from a mix of developing and developed countries. The tasks assigned to the CIPR were to consider:

- how national IPR regimes could best be designed to benefit developing countries within the context of international agreements, including TRIPS;
- how the international framework of rules and agreements might be improved and developed – for instance in the area of traditional knowledge – and the relationship between IPR rules and regimes covering access to genetic resources; and
- the broader policy framework needed to complement intellectual property regimes including for instance controlling anti-competitive practices through competition policy and law.

The experts visited a range of countries, including Brazil, China, India and South Africa. They also consulted senior government officials, the private sector as well as NGOs across Europe and the US. The CIPR commissioned 17 research papers and held 8 workshops in London. A large conference was also held in London in February 2002 with a view to identifying the issues and exploring the scope for moving the issues forward. The CIPR submitted its final report in September 2002.

The CIPR report recognises the diversity in the development stages and innovative capabilities among developing countries. For example, China, India and some smaller developing countries have world class capacity in a number of science and technology sectors, such as space, nuclear technology, biotechnology, pharmaceuticals, software development and aviation. By comparison, this capacity is relatively weak in countries in Sub-Saharan Africa (except South Africa). This diversity plays an important part in reaching the conclusions of the report.

The report considers the impact of IPRs in the developed as well as in the developing countries and is explicitly concerned that 'the costs of getting the IP system 'wrong'

in a developing country are likely to be far higher than in developed countries' (p. 4). This is because developed countries generally have adequate checks and balances in the competition regulations (e.g. Antitrust law) to prevent the IPRs inappropriately affecting public interest. This is not the case in most developing countries, making them considerably more vulnerable to inappropriate IP regimes. Thus, the report stresses that the 'standards of IP protection that may be suitable for developed countries may cause greater costs than benefits when applied in developing countries' (p. 5). To achieve an optimal balance in costs and benefits, the IPRs would vary depending on economic and social circumstances of each country. The report emphasises that IPRs should be considered as a tool to help society in the promotion of fulfilling human economic and social rights. The most fundamental human rights should not become subordinates to the requirement of IP protection under any circumstances. The IPRs are granted by governments for limited times whereas human rights are inalienable and universal.

The report is mindful that the granting of IPRs effectively provides benefits to those who have the knowledge and the inventive power, and increases the costs of access to those without. It is particularly apprehensive about industry interests overriding basic human rights in public policy formulation. It holds that:

> IP rights nowadays generally treated as economic and commercial rights, as is the case in TRIPS, and are more often held by companies rather than individual inventors. But describing them as 'rights' should not be allowed to conceal the very real dilemmas raised by their application in developing countries, where the extra costs they impose may be at the expense of the essential prerequisites of life for poor people. (Commission on Intellectual Property Rights 2002, p. 6)

The CIPR warns that IP policy in the developing countries is often formulated on the interests of the 'producer' and the end consumer is generally ignored. During IPR talks, negotiating teams from developed countries are mainly influenced by producer interests, because they see export opportunities. Developing countries, the consumers of IP, are often too weak to represent their own interests against those of the developed countries. The developing countries in this context are *second comers* in a world that has been shaped by the *first comers*. The report makes it very clear that IP regimes should be devised on the basis of a country's own needs and the level of economic development. It explicitly contends that:

> ... intellectual property systems may, if we are not careful, introduce distortions that are detrimental to the interests of developing countries. Very 'high' standards of protection may be in the public interest in developed countries with highly sophisticated scientific and technological infrastructures, but this does not mean the same standards are appropriate in all developing countries. (Commission on Intellectual Property Rights 2002, p. 8)

The main recommendations of the report are as follows:

- to ensure that global IP systems are designed to 'contribute to the development of developing countries by stimulating innovation and technology transfer relevant to them', while also providing them the 'products of technology at the most competitive prices possible'; and
- to ensure that 'the IP system facilitates, rather than hinders, the application of the rapid advances in science and technology for the benefit of developing countries' (p. 8).

With respect to pharmaceuticals, the report specifically recommends that developing countries should:

- limit the scope of subject matter that can be patented;
- apply standards such that only patents which meet strict requirements for patentability are granted and that the breadth of each patent is commensurate with the inventive contribution and the disclosure made;
- facilitate competition by restricting the ability of the patentees to prohibit others from building on or designing around patented inventions; and
- provide extensive safeguards to ensure that patent rights are not exploited inappropriately (p. 49).

The Indian Patent Act appears, to a certain extent, to have incorporated the recommendations of the report. Section 3(d) explicitly limits the scope of patentable subject matter, which has become a subject of international debate. It is designed to encourage genuine inventions of useful technologies but prevent granting rights to frivolous innovations. The application of the strict standards of Section 3(d) has been challenged by MNCs (e.g. Novartis)[63] and the cases are before Indian courts. The third recommendation implicitly refers to prevent ever-greening and excessive

[63] See Chapter 5 for more details.

patenting, which would block further innovation. The wide range of provisions for compulsory licensing in the Indian Act could be seen as a testimony to the final recommendation of the report.

The CIPR report also expresses concerns about the standards of patenting being lowered in the developed countries, particularly in the US, because too many patents are issued for inventions that are trivial and pressure exerted on patent examiners. Many of the patents would not prove valid if challenged in courts (p. 126). This concern is also shared by other experts. For example, Wyllie (2005) argues that the pharmaceutical industry should consider itself fortunate that 'definitions of novelty and innovation by the USA and the European patent offices are seldom rigorously applied' (Wyllie 2005, p. 1359).

Following the CIPR report, two separate enquiries were undertaken in the US. First, the Federal Trade Commission (along with the Department of Justice) investigated a wide range of issues related to patenting. The FTC report titled '*To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*' was published in 2003. This report considers that:

> Competition can stimulate innovation. Competition among firms can spur the invention of new or better products or more efficient processes. Firms may race to be the first to market an innovative technology. Companies may invent lower cost manufacturing processes, thereby increasing their profits and enhancing their ability to compete. Competition can prompt firms to identify consumers' unmet needs and develop new products or services to satisfy them. (Federal Trade Commission 2003, pp. 1-2)

But patents also can stimulate innovation. The FTC report emphasises that the U.S. Constitution authorizes Congress 'to promote the progress of science and useful arts, by securing for limited times to . . . inventors the exclusive right to their respective . . . discoveries (p. 2). There is a need to find a balance between IPRs and competition. While granting patents on obvious invention can harm competition, overzealous Antitrust enforcement can undermine the innovation that patents promote. Similar to the CIPR report, the FTC report also warns against excessive and frivolous patenting. Because one firm's questionable patent may lead its competitors to abandon further research in the areas that the patent improperly covers. The FTC report is explicitly concerned that:

> More patents in more industries and with greater breadth are not always the best ways to maximize consumer welfare. A questionable patent can raise costs and prevent competition and innovation that otherwise would benefit consumers. (p. 18)

The FTC report makes a particular reference to the biotech industry in which firms refrain from entering or continuing research projects in order to avoid infringing questionable patents. In *Bonito Boats v. Thunder Craft Boats,* (1989), the Supreme Court held that 'free competition is the base line on which the patent system's incentive to creative effort depends' (p. 3).

Some of the recommendations of the FTC report are as follows.

Publication of all patent applications 18 months after filing.

Until recently, patents were only published when granted. Early publication would avoid other firms investing (between the filing date and issuance of patent) in innovative activities that might infringe the patent to be issued. India already publishes filed patent applications, which provide the basis for pre-grant opposition.

Consider possible harm to competition – along with other possible benefits and costs – before extending the scope of patentable subject matter.

The FTC warns that over the last two decades, patentable subject matter has expanded at the expense of market competition creating an imbalance in favour of patentees. The pendulum needs to swing back to centre to rebalance. The current Indian Patent Act appears to be specific about what can be patented. So far the Indian courts have applied the law in the right spirit favouring the consumer and the Indian industry.

Challenges to the validity of a patent to be determined based on a 'Preponderance of the Evidence'.

At present, an issued patent is viewed valid in the US. The onus is on the challenger 'to prove its invalidity by clear and convincing evidence' (p.8). The FTC finds this requirement unjustified. An overly strong presumption of a patent's validity is inappropriate. The FTC suggests that courts should require only a "preponderance of the evidence" to rebut the presumption of validity.

Allow post-grant review of and opposition to patents.

> An administrative procedure is recommended for post-grant review and opposition to allow for meaningful challenges to patent validity short of federal court litigation. In India, application opposing a patent can be filed within 12 months from the date of grant.

The FTC report is mindful of patent litigations in US courts and the large funds required to fight them. The US would reduce patent litigations if it introduced pre-grant opposition similar to India. This would not jeopardise the innovative activities of competitors and save in litigation costs. This report highlights the lax practices adopted in issuing patents. While competition and patents both induce innovation, non-genuine (invalid) patents unnecessarily block competitors' innovative activities, finds the report.

The second enquiry in the US was undertaken by the National Academies Board on Science Technology and Economic Policy. The report '*A Patent System for the 21st Century*' was published in 2004. This report considers that the patent system has worked well for 200 years with a high level of innovation. While this report agrees, to a great extent, that a significant number of patents granted are sub-standard, it does not see a need for fundamental changes. This report also recommends a review after issuance of a patent (post-grant opposition). It also recommends limited protection from patent infringement liability be afforded to academic research. In 2002, Federal Court ruled that even non-commercial scientific research was not exempt and refused to provide to relief to university research. Both enquiries in the US have highlighted the problem areas within the current system of patents. The current system appears to allow exploitation that results in blocking rather than inducing innovation. This raises the cost of innovation as well as delaying further progress.

In the United Kingdom, the House of Commons appointed a Health Committee to examine the expenditure, administration, and policy of the Department of Health and its associated bodies. The report 'The influence of the pharmaceutical industry' was published in 2005. While the investigation does not explicitly focus on patents, it

finds the current direction of pharmaceutical R&D less than satisfactory. The report had no doubt in industry's ability 'to produce excellent science and important drugs' but questioned 'its ability to put the health of the nation consistently before the needs and expectations of its shareholders' (House of Commons Health Committee 2005, p. 97). It expresses concerns that in recent years, large pharmaceutical companies have become ever more focused on a marketing-based approach. The focus of new drugs should be on increasing real therapeutic benefits for sufferers and not just raising revenues. Sir Richard Sykes'[64] remarks in the report succinctly describe the situation pharmaceutical industry finds itself today:

> Today the industry has got a very bad name. That is very unfortunate for an industry that we should look up to and believe in, and that we should be supporting. I think there have to be some big changes. (House of Commons Health Committee 2005, p. 101)

The report acknowledges that in a free market society, 'pharmaceutical companies will inevitably continue to be the dominant influence in deciding what research is undertaken' (p. 5). This cannot however continue unchallenged because 'we need an industry, which is led by the values of its scientists not those of its marketing force, concludes the report (p. 6). The recommendations focus on improving and making the regulatory process transparent currently dominated by secrecy. While no patent specific issues were investigated, the general conduct of the industry does not appear to have the spirit, the industry reaps the rewards for. The report finds that on numerous occasions, the industry withheld critical test data to obtain marketing approvals. The industry influenced the decisions of the authorities, pressurised them to accelerate the approval leading to authorities compromising on efficacy and safety issues. In recent years, a number of drugs, such as Vioxx have been withdrawn from markets for safety reasons.

European Commission inquiry

In January 2008, the European Commission launched an investigation into the pharmaceutical sector. There were several reasons for this enquiry. First, the Commission had received information suggesting that competition in the sector may be restricted or distorted. Second, the number of innovative novel medicines reaching the market had declined. Third, introduction of generics had been delayed, as compared with what might be generally expected. The scope of this inquiry was

[64] Rector, Imperial College, London

limited to prescription drugs and to the period 2000-2007. A preliminary report was presented in Brussels on 28 November 2008 to coincide with the public consultation. The final report is expected by mid 2009.

The inquiry considered among other things certain blockbusters with patent expiry falling in the period of investigation and reports on certain patent settlements. A range of pharmaceutical companies, most of them originators, but also some generic companies were selected and unannounced inspections were conducted at these companies. These inspections resulted in more than 20,000 pages being copied, bringing to light 'documents that could not have been gathered otherwise' (e.g. through information requests) (European Commission 2008, p. 24). Subsequently, the inquiry met with other stakeholders, including industry associations representing originator as well as generic companies, consumer groups, insurance companies, doctors and pharmacists. More than 200 questionnaires were sent out to largest originator and generic companies. In total, more than 6,000 submissions were received making it 'one of the most thorough investigations of the European pharmaceutical sector ever' (EC 2008, p. 25).

The report emphasises the importance of patents in the sector to allow originator companies to recoup their substantial investments and to reward for their innovative efforts. However, the preliminary findings also suggest that originator companies develop and practise defensive patenting strategies primarily to block the development of new competing products (p. 402). The following findings of the report provide a strategic view of the industry behaviour with regards to exploiting the patents system:

> Originator companies have designed and implemented strategies (a "tool-box" of instruments) aimed at ensuring continued revenue streams for their medicines..... the successful implementation of these strategies include filing for up to 1300 patents EUwide in relation to a single medicine (so-called "patent clusters"), engaging in disputes with generic companies leading to nearly 700 cases of reported patent litigation, concluding settlement agreements with generic companies which may delay generic entry and intervening in national procedures for the approval of generic medicines. The additional costs caused by delays to generic entry can be very significant for the public health budgets and ultimately the consumer. (European Commission 2008, p. 401)

The concerns raised by the above reports highlight a significant shift from and within the concept of patenting. It appears that the scope of patents has been significantly widened in recent years. Notwithstanding the patent system needs to keep pace with

the development of new technologies, granting patents for frivolous innovations has lowered the quality of patents. Companies employ considerable resources on blocking introduction of competitor products through unnecessary and excessive patenting, which is counterproductive to the spirit of patents. On the one hand, these practices raise the costs of R&D for competing research companies (e.g. for royalties). On the other hand, the introduction of new products is delayed. In both cases, the consumer pays higher costs.

8.4 Which way ahead?

The primary aim of this section is to consider alternatives to improve access to medicines in poor countries. This section seeks to add to the current debate on TRIPS and its appropriateness for the pharmaceutical industry. On the one hand, leading economists suggest significant changes to the TRIPS agreement labelled as too stringent and denying access to medicines in developing countries. Equally, there are calls from the *big pharma*[65] not to dismantle or weaken the TRIPS patent regime in any way. Because doing so would be counter-productive, argues the industry. Considering the dichotomy of the views, the level of controversy TRIPS has raised is not surprising. The wide coverage in the literature is a testimony to the significance of the controversy. Of all the intellectual property within TRIPS, the issue of pharmaceutical product patents has been the most controversial one (Alsegård 2004). However, the TRIPS agreement is a set of rules on which all WTO members agreed. It may not suit the circumstances and interests of every member state; nevertheless, it is an agreed set of rules. This section considers a range of measures to improve upon the current system of patents. These measures could be viewed as a form of compromises in the bigger scheme of things.

8.4.1 Differential pricing

Differential pricing refers to a practice under which products are sold at a high price in high-income countries and at low prices in poor countries. It should be clear from the outset that differential pricing would apply to patented products, because other firms are barred from competing. Advocates of this strategy suggest that charging differential prices in different markets is a better way to provide medicine at

[65] Around 100 world's largest pharmaceutical companies based in the US, EU and Japan.

affordable prices than a global price. For example, Danzon (2001) argues that low drug prices in poor countries would contribute to increasing access to medicines, while prices in high income countries would help companies recoup R&D investments. This pricing method is a way to balance between providing medicine to the needy and charging a higher price to those who can afford to pay for it. Different price regimes in different markets allow firms to continue to invest in the R&D activities as the returns from the rich nations make up for the low prices in the poor nations.

The concept of differential pricing sounds fair to consumers in both groups of nations. If drug prices were adjusted to buyer's ability to pay, there could be a range of prices for the same products across countries with different income levels. A recent World Bank study provides a guide, which could be considered for designing the pricing structure. According to the World Bank (2003), countries with less than $745 gross domestic product (GDP) per capita are classified as low income countries. Countries with higher than $745 GDP per capita have a range of classifications (see Table 8.3).

Table 8.3: Classification of countries and GDP per capita, US$ (2002)

No.	Classification	Income level
1	Low income	Less than 745
2	Lower Middle income	Between 745 and 2,975
3	Upper Middle income	Between 2,976 and 9,206
4	High income	More than 9,206

Source: World Bank (2003).

Companies would need to further adjust the pricing levels because upper and lower gap in second and third income groups is far too large. While the income structure in Table 8.3 provides a guide, it does not reflect the reality on the ground. For example, India's rising GDP per capita might place the country in the lower middle income bracket and raise the prices above the lowest mark. This would be counter-productive because more than 800 million Indians do not have access to medicines (WHO 2004b) and India arguably has the world's lowest drug prices.

There are two issues with the concept of differential pricing. First, companies run the risk of parallel trade, i.e. unauthorized export of drugs from low price countries into high price countries, because 'arbitrage is a natural reaction to price differences' (Barton, J 2001, p. 11). This problem was recently highlighted when GSK's low priced HIV/AIDS drugs destined for Africa were found being sold in Belgium,

Germany and the Netherlands (Darbourne 2003). Similarly, differential pricing has been the center of a recent dispute within the EU. MNCs had supplied products to Portuguese pharmacies at a lower rate than their counterparts in northern European countries. The products intended for sale in Portugal were found selling in France and other higher priced markets. Second, as suggested by Kremer (2002), differential pricing could unleash political backlash from consumer groups in high income countries once they find out significant price differences pressing for lower prices at home. For example, the case of importing antiretrovirals (ARVs) into South Africa in 2001, to a great extent, exposed the significant difference in price of the same drug manufactured by different companies. If the ARVs cost just a few hundred dollars in Brazil, the US AIDS activists might object to paying $10,000 per year (Kremer 2002).

8.4.2 Differential patenting

Under differential patenting, the world would be divided in two broad categories; namely, the rich and the poor countries. Pharmaceutical firms will have to choose between developed (assumed rich) and developing (assumed poor) when applying for patent protection for drugs for global diseases. Products developed for global diseases, such as cancer or cardiovascular, would be patented in the rich countries (e.g. US), but patents would not be enforced in poor countries. This would allow generics to enter the poor markets forcing down the prices in the poor countries. Should the patentee sue the generics manufacturer for patent infringement in poor countries, its patent in the rich market would be deemed invalid, suggests Lanjouw (2002), the pioneering advocate of this approach. She suggests that the basis of the proposed framework already exists in the US. Under the current US law, inventors must apply first for a US patent for an invention made in the US. The law in the United Kingdom also has similar requirements. Patent applications in other countries must not be filed within six months of the filing date in the US (or within six weeks in the UK). For subsequent applications in other countries, the inventor must obtain a 'foreign filing licence' from the US patent and trademark office (PTO). Under the proposed mechanism for a cancer drug for example, the applicant would need to make a declaration to the US PTO similar to the following:

> I, the undersigned, request a license to make foreign patent filings covering the invention described in US patent application No. X, with the understanding that this permission will not

> be used to restrict the sale or manufacture of drugs for Cancer in India by suing for patent infringement in India. (Lanjouw, J 2002, p. 8)

Lanjouw argues that originators would recoup their investments in the rich markets where they would have monopoly pricing. For the fear of jeopardising the patent in a rich market, originators would not object to generics entering the poor markets. This would extend access to medicines in the poor countries. Drugs for tropical diseases have almost no sale potential in rich countries, and as such would be patented in poor countries. The problem with this approach is that enforcing patents in poor countries would push up the prices but not create purchasing power. In the absence of purchasing power, a reality in poor countries, how are the returns on investments going to be generated? Kremer (2002) also points out, Lanjouw's 'proposal is robust to errors in the list of global diseases ... [because] ... incentives for R&D on diseases of developing countries are inadequate' (pp. 77-78). New ways to provide incentives for investors or finance the R&D would still be required. International assistance programs as well as public policies in poor countries could incorporate funding the essential medicines.

8.4.3 Donating drugs

Under this proposal, the industry simply donates the needed drugs to the poor countries. Advocates of this approach suggest that there is no need to take out patents or adopt differential pricing strategies, because there is always a chance of these strategies backfiring (e.g. parallel trade). For example, Kremer (2002) argues that pharmaceutical firms in wealthy countries could benefit from donating drugs to poor countries. Because this 'could bolster firms' reputations, rather than posing a public relations challenge in maintaining prices in developed nations' (p.78). He suggests that government in developed nations provide enhanced tax deductions to pharmaceutical firms that make donations of approved drugs to developing nations. The current provision by the US government is based on the product's manufacturing cost, which is often very low. Kremer therefore suggests that developed nations provide a tax relief based on either on a given percentage of the US price (or in that country) of the drug to be donated or on estimate of social benefits or measured in dollars per Disability Adjusted Life Years (DALY) saved.

A number of issues in Kremer's proposal need to be considered. First, Barton (2001) finds the concept of donating drugs 'wonderful and ... extremely helpful' but questions the long term sustainability of the concept (p.16). In 2000, Boehringer Ingelheim announced to supply nevirapine free for five years to prevent mother-to-child transmission of HIV. Merck has also been donating ivermectin to treat river blindness for a long time. However, a commitment to supplying drugs at marginal cost may be a better option in the long run, argues Barton. Under the strategy adopted by UNAIDS, Boehringer Ingelheim, Bristol-Myer Sqibb, GSK and Merck have agreed to supply Rwanda, Senegal and Uganda drugs at concessional rates, which is more sustainable than simply donating drugs (Barton, J 2001).

Second, the concept of donating drugs is based on voluntary offer. Thus, an element of risk is there that firms may not continue to donate if such donation did not suit their political or commercial interests. And that is why, when producers wanted to donate antiretrovirals to African countries, the 'activists insisted on countries paying for the drugs at low prices' (Kremer 2002, p. 78). Third, the quality of donated drugs is often questionable. Past experiences of the World Health Organization in Albania and Macedonia suggest that many gifts of unusable drugs were donated (cited in Saunders 1999). A number of other countries, where disasters aid was provided have had the same experience. Armenian earth quake, Mitch and George hurricanes in Central America, the civil war in Rwanda, Sierra Leone, Bosnia, Croatia, and many countries of the former Soviet Union had all accumulated large amounts of unusable donated drugs. According to a Tanzanian nun, in-charge of drug supply at a remote mission hospital, only 10 per cent [of the donated drugs] were useful and the rest ended up on the hospital bonfire' (cited in Saunders 1999, p. 7).

8.4.4 Orphan Drugs Act as a model

Under the US law, 'orphan drug' is described as a drug for a disease or medical condition affecting less than 200,000 population in the US (Government of the United States 2008). This number of patients is far too small to generate sufficient returns on investments for a new drug. Recognising this, the US Congress passed the Orphan Drug Act in 1983 providing incentives to invest into developing drugs for diseases in this category. This Act offered economic incentives, including R&D tax credits,

clinical research grants programmes, accelerated approval process at the FDA and a guaranteed seven year market exclusivity from the date of marketing approval (Grabowski 2002). This exclusivity was independent of any patent protection afforded by the PTO. While less than 10 drugs for orphan diseases were discovered in ten years preceding the Orphan Drug Act, more than 200 drugs and biologicals were developed between 1983 and 1999 (Government of the United States 2008; Grabowski 2002).

Grabowski (2002, 2005) argues that the lack of potential returns places tropical diseases in a condition similar to the orphan diseases in the US. He suggests an Act similar to the Orphan Drugs Act at the international level to provide exclusive rights. He further suggests that funding for developing these drugs could come from governments, NGOs or public-private partnerships.

The Orphan Drugs Act works well in the US because of purchasing power of the population. The added exclusivity extends the number of years, in which the innovator can recoup its investments compensating for the small patient population. In contrast, the poor in developing countries do not have the same purchasing power. Not only the funding for the development of the drug has to be arranged, but also the purchase of drug has to be funded publicly or through international aid. An Act at the international level similar to the Orphan Drugs Act, could work in conjunction with the TRIPS agreement.

8.4.5 Incremental value based rewards

This concept refers to variable rewards based on the level of innovation. A ground breaking innovation would warrant a full 20-year protection, while an incremental innovation (minor improvement) would be judged for its contribution and rewarded accordingly. This type of system of rewarding would be ideal for pharmaceutical industry, where new inventions are rare and minor improvements are quite common. Hollis (2005) suggests that pharmaceutical markets do not function effectively enough to stimulate drug research and development. This is because on the one hand, significant proportions of research are focused on drugs with relatively little incremental therapeutic value. On the other hand, inadequate incentives are provided to innovate in areas of great therapeutic value. Hollis suggests a system to reward

innovators based on incremental therapeutic value of their innovation. The more therapeutic value over existing drugs a new drug would offer the more benefits the innovators would receive. This would align innovators' incentives with the social objectives and possibly lead to a better way to allocating R&D investment. Hollis further suggests that the rewards would be paid directly to innovators and patents compulsorily licensed to enable competitive pricing, which, to a certain extent, would solve the problem of access to essential drugs.

In theory, rewarding innovators on incremental value would be a fair system. The implementation might become complex, however. Assessing the incremental value requires an unbiased approach by the authorities that is acceptable to innovators. Failure to get agreements would only lead to litigations unnecessarily wasting valuable human and other resources. Furthermore, this concept does not treat all inventions equally, and as such, would contravene the TRIPS agreement.

8.4.6 Advance purchase commitments

Advance purchase commitments (APCs) refer to one or more sponsors (e.g. governments) committing to a minimum price and volume for an eligible product. APAs are considered suitable for developing vaccines for immunising large populations in poor countries. If no suitable product were developed, no payments would be made (Berndt et al. 2005). This model is based on the experience of the United Kingdom. In 1994, the UK government committed in advance to purchase the treatment for brain swelling (Foroohar 2006). Developing countries have about 90 per cent of the global disease burden, yet only 3 per cent of the R&D expenditure of the pharmaceutical industry is directed to address the needs of these countries. The current gap in R&D required and R&D available highlights the enormity of the problem. Numerous promising drug projects, particularly for the disease of the poor are dropped for the lack of funding (Berry 2005). APCs guarantee minimum sales helping investors calculate the level of risk they can take.

Kremer and Glennerster (2004) suggest that under the APC model, developer of malaria or HIV vaccine could receive around $3 billion. This figure is based immunising 200 million people at $15 to $20 each in developed countries. In

developing countries, the price could be dropped to $1-a-shot. Miguel and Kremer (2002) suggest that school based mass treatment of intestinal worm infections would cost as little as $7 per DALY saved and such treatments could reduce the disease burden by more than 70 per cent (cited in Kremer 2002). A major advantage of this model is that no public monies are committed if no positive results shown. As Light (2005) points out, a major drawback of this model is that it is more suitable to 'big pharma' strategy than small innovators. Only large pharmaceutical companies could invest hundreds of millions of dollars in a gamble of no certainty of success. Lofgren (2005) concludes that an effective response to the neglected disease calamity requires more than what the APC model offers.

8.4.7 Public-Private Partnerships (PPPs)

In recent years, another model has emerged to address the 'neglected disease' dilemma. Under this model, the risk is shared by sponsors/governments providing part of the R&D funding. In contrast, the APC model requires the developer to fund its own R&D with only successful products providing guaranteed sales. Unlike the APC model, the PPP model is suitable for all small and large innovators. In 2004, a plethora of 92 PPP collaborative projects were in progress with promising results. The list of sponsors included the Medicines for Malaria Venture, the TB Alliance, the Institute for OneWorld Health, and the Drugs for Neglected Diseases Initiative. According to Moran (2005), 63 of these projects were for neglected diseases, with two drugs close to registration. A further 18 drugs were at advance stages of clinical trials and 8-9 new drugs are expected by 2010.

Around 80 per cent of the funding for PPP projects has come from private philanthropists, such as the Bill and Melinda Gates (BMG) Foundation (Moran 2005). The BMG Foundation contributed $450 million, Wellcome Trust (UK) $27.1 million and the Canadian Institutes of Health Research $4.5 million. The 'Grand Challenges in Global Health' provides a good example of how funding is distributed under the PPP model. According to ScripNews (2005f), $436 million have been allocated to scientific institutes worldwide. Table 8.4 provides a snapshot of the projects in progress collaborated under the Public-Private Partnerships.

Table 8.4: Selected recipients of funds under the Grand Challenges in Global Health grants

Investigator	Research grant
Vaccine Delivery	
Lorne Babiuk (University of Saskatchewan, Canada)	$5.6 million for neonate (single-dose vaccines)
Roy Curtiss (Arizona State University, US)	$14.8 million for anti-pneumococcal vaccine
Abraham Sonenshein (Tufts, US)	$5 million for bacterial spores as vaccine delivery systems
Colin Gardner (TransForm Pharmaceuticals, US)	$8.8 million for increasing vaccine stability
David Lo (Neurome, US)	$3.9 million for mucosal vaccine delivery
James Baker (University of Michigan, US)	$6.3 million for nano-emulsions as adjuvants for nasal-spray vaccines
Robert Sievers (Aktiv-Dry)	$19.5 million for needle-free respirable powder vaccine
David Edwards (Harvard University, US)	$7.6 million for needle-free vaccination via nano-particle aerosols
Vaccines	
Richard Flavell (Yale and Howard Hughes Medical Institute, US)	$17 million for mouse model to evaluate live-attenuated vaccines
Rudi Balling (German Research Centre for Biotechnology)	$9 million for HIV and HCV vaccines
Adrian Hill (University of Oxford, UK)	$10 million for vector vaccine
Ralph Steiman (Rockefeller University, US)	$14 million for flavivirus vector
Robin Shattock (University of London)	$19.7 million for protection against HIV
Stefan Kappe (Seattle Biomedical Research Institute, US)	$13.5 million for malaria vaccine
Treatments	
Barton Finlay (University of British Columbia, Canada)	$8.7 million for therapeutics to treat infectious diseases
Douglas Young (Imperial College, UK)	$20 million for TB drugs
David Baltimore (California Institute of Technology, US)	$13.9 million for HIV immunity
Rafi Ahmed (Emory University, US)	$12.5 million for hepatitis virus infections
Peter Andersen (Statens Serum Institute, Denmark)	$11.3 million for post-exposure TB vaccine

Source: Based on Scrip News (2005f, p. 15).

Most of the projects involve developing new delivery methods for vaccines using latest (e.g nano, needle free) technologies. The new methods of delivery would offer significant advantages over conventional methods. First, the new methods would eliminate the need for administering vaccines by qualified medical personnel. Second, administering new vaccines would not require any equipment such as syringes. New vaccines are expected to be developed in form of powder or a spray. Third, these methods would significantly increase immunisation at the village level. Other projects involving vaccines for malaria, TB, HIV and vector would be expected to save many lives in the developing world if successful.

8.4.8 Open access

This model refers to open (unrestricted) access to data, ideas, and insight for researchers in science and technology (Barton, J 2003). The rationale behind this model is that a research scientist or engineer with access to the work of predecessors is more effective than without it. And his/her contribution to scientific/technological progress will be greater if others have access to his/her work. In recent years, 'open

access' model has gained significant attention for two main reasons. First, the current framework in the US limits licensing of publicly funded research to domestic firms (Maskus & Reichman 2004). Second, the EU has also introduced similar framework; thus, both the US and the EU placing companies/researchers from foreign countries at significant disadvantage. These are protectionist measures, which raise the cost of research and erect unnecessary barriers to advances in research.

Firms based in the developed world are not disadvantaged by these rules to the extent as the firms in the developing countries are. Firms based in the EU gain against the losses in the US. But firms from developing countries get locked out from participating in research in advance technologies. The quality of research in the poor countries could be as good as that of those based in the US or the EU, but they lack the resources to advancements. Consequently, developing countries remain unable to develop capabilities to match those in the developed world. This raises the cost of acquisition of new technologies and slows the pace of development in low and middle income countries.

Experts such as Barton and Maskus (2004) suggest a multilateral agreement under the WTO to ensure global 'open access'. They provide the following reasons in their justification for such an agreement:

- the recent 'significant policy shift toward making knowledge a private commodity, despite its inherent character as a public good, raising fundamental questions for science, education, and the diffusion of information';

- despite the promise held that stronger technology protection under TRIPS 'would expand flows of knowledge to poor countries, very little gains have emerged in this regard';

- the exclusive rights under TRIPS have 'the potential for limiting access of developing countries to even publicly generated basic research that might otherwise enable greater competition and local innovation'; and

- 'the economics of knowledge creation and the non-rival nature of information implies that global investments in basic science and technology are underfunded in comparison with a global optimum. Knowledge is a prime example of a global public good that can be more effectively provided by cooperative multilateral actions' (p. 370).

The 'open access' model could provide an impetus into innovation, reducing the cost of information on previous studies. However, if no agreement is reached at the international level, it could place the providers of 'open access' at a disadvantage. Large MNCs could access the research results under 'open access' and build on them placing the follow up innovation under patent. The Central Drug Research Institute (CDRI), India's leading research institute, is currently trialling a number of projects under the PPP collaborative arrangements with 'open access' model.

The discussion above demonstrates the manifold shortcomings of the current patent regime. The alternative models also suffer from a common shortcoming. They all offer only partial solutions to the problem of providing affordable healthcare in poor countries. The TRIPS regime is not concerned with affordability or drug pricing. Donating drugs would certainly the poor in developing countries but would not be sustainable in the long run. Moreover, this approach would limit access to *donated* drugs, which, at best, would account for a fraction of the drugs required. The other models fail to understand the enormity of the crisis the poor face in paying for medicines.

Another important factor overlooked in the current regime as well as in most of the models noted above is the basic premise for patents. The basic premise to granting patents is to reward inventors and spur innovation in order to improve human life. The spirit of patents is to accelerate the process of scientific and technical progress. The recent report of the EU Commission reveals the extent of manipulation of the system by firms, some of which were found to have filed for up to 1,300 patents EU wide for a single drug. A few hundred patents for a single drug are not uncommon in the US. This type of industry conduct is purely driven by greed contravening the basic premise of patents. The level of excessive patenting permitted under the current

regime undermines the spirit of patenting. Policy makers need to seriously review the whole concept of patents and revisit the reasons for granting patents.

In addition to the proposals noted above, we suggest additionally that the option of *minimum patenting* (explained below) should also be considered. The *minimum patenting* model would apply exclusively to drugs and pharmaceuticals. Unlike other industries, the drugs and pharmaceutical industry has a direct impact on human health. Thus, the industry needs to be treated with special care. Health is also an inalienable and universal right. The Right to Life is enshrined under the Constitution of India. Under the proposed *minimum patenting* model, while pharmaceutical product patents would continue to be granted, process patents would be limited to a single process that is actually used in the manufacture of the patented product. While the TRIPS agreement obliges member countries to provide patents for both *products and processes in all fields of technology* (Article 27), members are under no obligation to provide for *excessive* patenting. The Agreement provides that *members may... adopt measures necessary to protect public health* (Article 8). And limiting patents to product and a single process would be a necessary measure for protecting public health in poor countries. Companies manufacture a product using a process and deserve to be granted patent protection for what they have produced and how they have produced it. However, granting more patents than that for the same product is not rewarding innovation, but hindering it. Once a product is patented, no matter how many processes are developed by the firm's competitors, the same product cannot be marketed until the patent expires on the originator product. The practice of excessive patenting contravenes the spirit in which patents are granted, delays technological progress, raises health costs, and in the case of pharmaceuticals, literally denies access to medicines.

All the models discussed above are thought-out strategies by different experts. The experts may differ in their approach to addressing the issues they see in TRIPS. But they are unanimous in their dissatisfaction with the TRIPS agreement. Their main concern is the restrictive nature of TRIPS with respect to access to medicines in poor countries. The expectation under most models is that if the medicine is made available, half the battle is won. It may be partly true too. However, affordability is the real battle for the poor, which is not addressed under any of the models.

8.5 Conclusions

This chapter set out to examine whether the TRIPS agreement is appropriate for the developing countries. A large number of developed countries did not introduce pharmaceutical product patents until they had achieved certain stage of economic development. The TRIPS agreement disregards this reality and forces all member states to adopt stringent patent protection, including pharmaceutical product patents, irrespective of their stage of development. TRIPS is a 'one size fits all' regime creating numerous problems for the poor in developing countries. Copying technologies developed in the advance economies is a necessary step to developing innovative capabilities. While most of the developed countries, including the US, benefited from copying discoveries and inventions of others, TRIPS denies developing countries the same opportunity.

Costs of TRIPS are considerable and certain, while benefits remain a 'may be' at best. Healthcare costs to all countries, including the US, have increased significantly as a consequence of TRIPS. But the developing countries are the biggest losers under the new regime. Large pharmaceutical companies based in the developed countries are the big winners.

A large number of experts find the TRIPS regime unsatisfactory and suggest alternatives to improve upon the current situation. Suggested models include donating drugs, differential patenting, differential pricing, replicating the Orphan Drug Act at the global level, Advance Purchase Commitments (APCs), Public-Private Partnerships (PPPs), and 'open access'. A proposal for minimum patenting has also been added to the list. These models offer a variety of compromises, but also highlight the multiple deficiencies of the current patent protection regime. Each of these proposals provides a partial solution to the problems generated by the current regime. But each potential solution suffers from some drawbacks.

These alternative models might induce investments into developing new drugs for tropical diseases. But the fundamental problem of affordability of drugs in poor countries remains unresolved under these models. This is why developing countries,

like India, need to consider alternative approaches for providing equitable access to healthcare, including access to medicines to all sections of the society.

Such a model – IndiaHealth - has been proposed in Chapter 7 of this thesis for addressing the problem of access to health care and medicines in India. It must be noted that the introduction of the IndiaHealth proposal is not an alternative to the current model of TRIPS, but represents the kind of broader strategy that must be developed in India in the wake of the implementation the TRIPS to ensure better access to medicines. Otherwise medicines will become even more inaccessible than they are now due to the eventual (but certain) rise in drug prices. The fact is that other developing countries will also need to develop similar strategies to deal with their specific situations. This fact further enhances the potential contribution of this thesis, as it can show the right way for countries other than India.

Chapter 9

Conclusions

9.1 Introduction

Based on the discussion in the previous chapters, the main conclusions of this thesis are brought together in this chapter. As has been stated above, the thesis deals with the implications of the implementation of the TRIPS agreement for the pharmaceutical industry and the access to medicines in India, acknowledging that the introduction of the TRIPS compliant regime of patent protection from 1 January 2005 marked a major shift in India's public policy on the protection of intellectual property rights (IPRs) and will have important repercussions for several industries and sectors. However, the focus of this thesis is only on the pharmaceutical industry and healthcare in India.

In order to fully explore the issues arising in the pharmaceutical industry and healthcare, it became essential to gain a good understanding of how the global pharmaceutical industry operates, what is involved in bringing new medicinal drugs onto the market, and what role is played by the regulatory frameworks both at the WTO and the government in India? As a result, Chapters 2 and 3 were devoted to covering these topics before the key questions highlighted in Chapter 1 were addressed.

It was noted in Chapter 2 that having replaced the General Agreement on Tariffs and Trade (GATT), the WTO has become one of the most powerful multilateral institutions today. Unlike GATT, the jurisdiction of the WTO includes trade related aspects of intellectual property rights (TRIPS). The WTO has enforcement mechanism to ensure implementation of its decisions, a power the GATT did not have. The TRIPS agreement stipulates minimum standards for protection of intellectual property. The Agreement has considerably raised the level of protection in the developing countries, a large number of which did not previously provide product patents for pharmaceuticals. All WTO member countries, except the least developed

countries (LDCs), are obliged under the TRIPS Agreement to provide product as well as process patents for 20 years. The least developed countries have until 2016 to implement the same provisions.

The Doha Declaration on TRIPS and Public Health reaffirms the rights of member states to protect public health and emphasises the benefits of certain flexibilities, such as compulsory licensing and parallel imports, that are built into the TRIPS agreement for use by member countries, should the need arise. The least developed countries, which have insufficient capacity to manufacture pharmaceuticals to meet their own public health needs, can import low-cost generics during the protection period.

In recent years, the US and the EU countries have negotiated with developing countries bilateral and regional agreements on free trade, investment and other issues. These agreements have forced developing countries to forfeit their right to use flexibilities provided under TRIPS raising the protection standards to TRIPS-plus level. Thanks to such constraints, not only the poor countries, but also countries like Singapore and Australia, are unable to make full use of the flexibilities provided under TRIPS.

The structure and the role of global pharmaceutical industry in developing new drugs were discussed in Chapter 3, where it was noted that this industry is dominated by large MNCs that are principally based in the EU, Japan and the US and hold most of the pharmaceutical patents worldwide. Through mergers and acquisitions, the MNCs are progressively getting larger and typically have much larger new product pipelines than ever before. In particular, the US dominates global pharmaceutical industry in its capacity as being both the largest single manufacturer and the largest single consumer of pharmaceuticals. In recent years, there has been a shift of R&D from the European countries, who until recently were the leaders in pharmaceutical innovation, to the US, which has further intensified this trend.

The global pharmaceutical industry has enjoyed consistently high rates of growth in sales revenues for many years. Global pharmaceutical sales increased from US$356 billion in 2000 to US$643 billion in 2006. In 2004, the global pharmaceutical sales crossed the half a trillion dollar mark for the first time. The world market growth

recorded annually around 9.5 per cent in 2001 and 2002, peaked at 16.4 per cent in 2003 and declined to 12.5 per cent in 2004. The growth has slowed down to less than 8 per cent per annum since then.

The development strategy of the large pharmaceutical MNCs has also shifted in recent years towards developing the so-called 'blockbuster' drugs. These blockbuster drugs have become the backbone of the large MNCs for recouping their R&D investments. The increasing concentration of the large companies on blockbuster drugs has the worrying implication that the industry may be guilty of ignoring the development of those drugs that are badly needed by the populations of the developing countries, simply because the sales revenues from these drugs are not as high as from selling the blockbusters.

9.2 Answering specific questions

9.2.1 How does the regime change impact on India's pharmaceutical exports, particularly exports of the low-cost imitations of patented drugs to the poor countries?

The discussion in Chapter 4 described in some detail how India's pharmaceutical industry developed initially under the protection of the anti-competitive government policies introduced in the 1970s, but has continued its rapid growth in subsequent years even after the introduction of industrial de-licensing as a part of the economic reforms in 1991. Today, the Indian pharmaceutical industry has grown into a globally competitive indigenous industry that is increasingly integrating into the global industry through not only imports and exports, but also via FDI, outsourcing and contracting arrangements with overseas partners.

A net importer of pharmaceuticals until the late 1980s, India is now a net exporter of pharmaceuticals. The economic liberalisation and the reforms to industrial policies introduced since 1991 provided a boost to India's exports of pharmaceuticals. The highly regulated markets, including the US, are the top ten destinations for India pharmaceutical exports. India's pharmaceutical industry has also contributed significantly to increasing access to medicines in the importing countries by supplying less expensive medicines.

While overseas MNCs once dominated the Indian pharmaceutical market, they now account for less than a quarter of the domestic market. Leading domestic firms generate significant share of their revenues in overseas markets. But the industry has a large number of small manufacturing firms that account for around half of the domestic supply by volume.

The likely impact of TRIPS on India's pharmaceutical exports is also considered in Chapter 4. Based on the data examined, we have concluded that in terms of value of exports, this impact is likely to be quite small - only around 1 per cent of India's pharmaceutical exports may be in jeopardy due to TRIPS. However, the overall impact may be greater if the number of patients who benefit from India's low-priced exports of drugs is considered, especially in the area of HIV/AIDS. Moreover, the implementation of the new patent regime would close all future opportunities to develop new processes for providing cheaper generic drugs. This loss would adversely affect access to medicines for the poor not only in India, but also in the other developing countries. Thus, the overall impact of TRIPS on potential exports and patient welfare is likely to be considerably greater than simply the value of exports lost.

After addressing the issue of how India's exports might increase access to medicines, we conclude that the Indian pharmaceutical industry has contributed, and continues to contribute, significantly to lowering drugs prices in the importing countries. Leading Indian firms, including Ranbaxy, DRL, Cipla, Sun Pharma, Torrent, Wockhardt, Nicholas Piramal, Lupin, and Zydus Cadilla earn significant proportions of their sales revenues from overseas markets. With its exports selling at low prices, India's pharmaceutical industry is contributing to extend access to medicines in the importing countries.

9.2.2 What is the effect of TRIPS on foreign direct investment (FDI) into the Indian pharmaceutical industry?

After examining the likely impact of the implementation of TRIPS on the flows of FDI into India's pharmaceuticals industry in Chapter 4, we reached the conclusion

that this impact is likely to be insignificant. Indeed, the empirical evidence challenges the assumption, often implicit in the advocacy literature, that FDI inflows are positively correlated with more stringent patent protection regimes. We note that in India, the level of FDI into the pharmaceutical sector rose after product patents were abolished, fell to its lowest levels between 1980 and 1990, but started to rise again following the economic reforms in 1991. Today, the pharmaceutical sector in India is one of the top ten sectors to attract FDI. Globally, India ranks second behind China, but ahead of the US and the UK, in respect of investor confidence. Foreign direct investment (FDI) into the pharmaceutical industry is not affected only by the protection of intellectual property rights (IPRs). Other factors, including R&D and manufacturing costs, availability and costs of skilled labour, exports potential, and compliance certification for quality also play a significant role in investment decisions of overseas firms.

9.2.3 How is the business model of domestic firms changing after TRIPS?

In the wake of the recent changes to the industrial landscape, India pharmaceutical firms have adopted a mixture of new business models. Leading Indian pharmaceutical companies are expanding through overseas acquisitions and exports now constitute a significant share of their annual sales revenue. Other firms are opting for alliances and contract manufacturing roles. There are indications that some Indian firms may relocate their manufacturing operations to the least developed countries (LDCs) to take advantage of the delayed implementation of TRIPS in those countries. The survival of small manufacturers could be jeopardised by the changing dynamics in the market, which would be counterproductive from the access to medicines perspective. With the abolition of highly protective measures that once favoured the Indian pharmaceutical industry, the new industrial landscape foreshadows significant challenges for the indigenous players.

9.2.4 What impact does the regime change have on the innovative activities within the Indian pharmaceutical industry?

In Chapter 5, we also examined the innovative activities originating in India. These activities were measured in terms of patent filings in the US and in India. While these activities related to the entire industrial sector, the Indian institutional activity within

the pharmaceutical industry shows a significant increase in recent years, particularly with its patent filings in the US. The US filings by Indian pharmaceutical institutions increased more than 25 times in the ten years to 2002. By contrast, the increase in the US filings by India-based foreign enterprises was negligible during the same period.

The patent filings at the Indian Patent Office also show a similar trend. The level of increase in the filings by Indian institutions within the pharmaceutical industry is relatively lower than the rate of change in their filings in the US over the study periods. In fact, the patent filings in India by foreign enterprises declined during the same period. This examination shows that in anticipation of TRIPS being implemented in India, Indian institutions began investing heavily in pharmaceutical innovation. The same is not found in the case of foreign enterprises.

Although innovative activities in India have increased substantially over the last decade and India is increasingly becoming a significant player in filing patent applications in the US, innovative activity is heavily concentrated in India's public institutes under the ambit of the Council of Scientific and Industrial Research (CSIR). Only a small number of pharmaceutical companies other than public institutes are engaged in patent filings in the US. This suggests that in terms of innovative activities only a limited number of Indian firms are globally competitive. This fact poses a challenge for the Indian government to develop more effective incentive mechanisms for better outcomes.

9.2.5 How effective have the price controls in India been in providing access to medicines until now and what form of price controls is India likely to have in future?

The effectiveness of India's price controls on drug prices is discussed in Chapter 6. After their introduction in the 1960s, price controls became most rigid in the 1970s, but have been progressively amended and gradually relaxed since the 1980s, reducing, in turn, the number of drugs under price control. India's price controls have had limited success in lowering drug prices, which are admittedly low relative to many other countries, but not sufficiently low relative to household incomes and other relevant factors affecting affordability of healthcare. Only one-in-three Indians are considered to be able to afford to buy medicines in India.

Our examination of India's price controls on medical drugs reveals that the price controls do not help in making affordable even those medicines that are considered by the government-appointed experts to be essential medicines. In the lead up to the implementation of the TRIPS agreement in 2005, there were apprehensions among citizen groups and other stakeholders that after 2005 drug prices would rise substantially in India, which would further erode the drug affordability. Our analysis of post-2005 price changes confirms those fears.

The findings of our examination of the so-called voluntary price reductions announced by several pharmaceutical firms in 2006 are reported in Chapter 6. During negotiations with the government regarding the scope of drug price controls, eleven firms announced that prices of a total of 886 formulations would be voluntarily reduced from 1 October 2006. After undertaking an item by item examination of that list, we found that the list of 886 items also included items such as a pregnancy test card, 7 Ayurvedic medicines, at least 31 forms of iron, vitamins or other nutritional supplements, and had only 134 drugs that were listed in the CIMS. Furthermore, out of these 134 items, 103 items had a price higher than the agreed price while 16 items had a lower price. Consequently, this price reduction agreement would have minimum impact on the sales revenue of the companies involved. The implications for the consumer are that despite the widely publicised price reductions, most of these drugs continue to be sold at higher prices and benefits of the claimed price reductions to the consumer would be limited.

9.2.6 How can India extend access to medicines to its entire population?

The issues related to the access to medicines are a central concern in this thesis and are discussed in Chapter 7. First, the factors that deny access to medicines are explored and secondly a new model is developed for providing better access to healthcare and to medicines for the entire population of India. While the number of the poor in India living below the poverty line has declined over the last three decades, poverty remains the largest impediment to access to medicine in India. In the past, government policies have focused mainly on controlling drug prices rather than providing healthcare. There is no doubt that the share of India's population with

access to medicines has increased since the 1980s. However, around two thirds of the population still remains without access to medicines.

India's public expenditure on health is significantly low even by the standards of the developing countries. Correspondingly, the share of private health expenditure is very high, as most of the healthcare costs are met by out-of-pocket household expenditure and the coverage of health insurance is almost nonexistent. Without a comprehensive programme to pay for these medicines through additional public health expenditure, India's policy on controlling drug prices will remain incapable of providing affordable healthcare.

It was concluded that in terms of India's provision of healthcare, implications of both the low public spending on health and the high share of drugs relative to the total health care costs have contributed to significantly high private health expenditure. Both these issues need to be addressed together. India's past experience showed that controlling drug prices alone was not sufficient to provide an affordable healthcare to all. Indian policy makers could learn from other countries and consider the options discussed earlier to develop a strategy or set of strategies to negotiate and maintain low drug prices. There is a need to streamline the hierarchical nature of the regulatory structure, recognise drug pricing and affordability as inseparable and interdependent in providing healthcare. Any future policy would need to be developed in full recognition of this reality.

At the current stage of economic development, India needs to introduce policies, which raise the health status of the poor. The population projections indicate that India's population could reach two billion by the middle of the century. With the people generally living longer, the share of the aged is expected to increase significantly, although India will enjoy a favourable age-structure of its population and will benefit from a rising share of working-age population (the so-called 'demographic dividend) over the next three decades. Eventually, however, demographic change would require a significant shift in the health policy and allocation of additional resources. India would need to raise its public expenditure on health from the current level of 0.9 per cent of GDP.

We have developed a model – IndiaHealth – which has been presented in Chapter 7 for addressing the problem of access to health care and medicines in India. It must be noted that the introduction of the IndiaHealth proposal is not an alternative to the current model of TRIPS, but represents the kind of broader strategy that must be developed in India in the wake of the implementation the TRIPS to ensure better access to medicines. Otherwise medicines will become even more inaccessible than they are now due to the eventual (but certain) rise in drug prices. The fact is that other developing countries will also need to develop similar strategies to deal with their specific situations. This fact further enhances the potential contribution of this thesis, as it can show the right way for countries other than India.

The IndiaHealth model considers demographic characteristics and income levels. The demographics provide a basis for the estimates of healthcare requirements (e.g. elderly population tend to be more frequent user of healthcare than the younger people). Data on the income levels is used to determine patient co-payments ensuring affordability of prescribed drugs. For example, population living below the poverty line (BPL) of $1-a-day would make no co-payments towards the cost of medicines. These costs are covered by the public expenditure on health. Based on the income levels of the Indian population, there is a three-tier co-payment schedule. After reaching the SafetyNet threshold in a calendar year, the patient co-payments are reduced for the remainder of the year. This model would provide access to both the allopathic and the traditional healthcare providers. An important feature of the model is that it includes the assumption that practitioners of traditional Indian medicines would be authorised to prescribe medicines in the same way as doctors and dispensers of the allopathic medicine. Because these practitioners of traditional Indian medicines are easily accessible at the village level, their inclusion in the overall healthcare programme would play a significant role in extending access to medicines to India's entire population.

The proposed model does not claim to be the ultimate goal for India, but would be a helpful step in the right direction for achieving the objective of *health for all*. Our costing suggests that the increase in the public expenditure on health required to fund the IndiaHealth programme is well within the level of commitment already given by the UPA government in its Common Minimum Programme. Our estimates indicate

that by raising public expenditure on health care to 1.62 percent of GDP by 2010, India should be able to overcome the barriers to affordability of medicines. Going forward, the ratio of public expenditure on health is expected to fall to 1.24 percent of GDP by 2015. The implementation of this model, or another variation of it, should relieve India's households of significant health expenditure and help the country to achieve better health outcomes. Sensitivity analysis for further variations in certain parameters of the model is presented in Appendix D and E.

9.2.7 Is TRIPS Agreement fair to the developing countries?

Finally, we return to the fundamental issue about the fairness of the TRIPS regime from the standpoint of the developing countries. Although the stated objectives of IPRs under the TRIPS agreement include *mutual advantage of producers and users* and *to a balance of rights and obligations*, the TRIPS Agreement clearly favours the drug producers. The Agreement obliges members to provide for criminal proceedings with penalties of imprisonment and/or fines for commercial infringers of copyrights and other intellectual property rights. The Agreement calls for punishing [small] firms/individuals inflicting a monetary damage to the right holder. The Agreement would indeed be balancing the *rights and obligations of producers and users* if it also called for the same kind of treatment for companies for excessive patenting (such as filing up to 1,300 patents on a single medicine). This level of patenting of 'anything and everything' denies access to medicines and has a realistic potential for loss of life. This issue needs to be addressed in the next review of TRIPS. Independent of TRIPS, developing countries need to consider amending their regimes to introduce provisions similar to those of Article 61 of TRIPS and fill this gap.

It is noted at the outset of this discussion that a large number of the developed countries did not introduce pharmaceutical product patents until they had achieved certain stage of economic development. The TRIPS agreement disregards this reality and forces all member states to adopt stringent patent protection, including pharmaceutical product patents, irrespective of their stage of development. TRIPS is a 'one size fits all' regime creating numerous problems for the poor in developing countries. Copying technologies developed in the advance economies is a necessary step to developing innovative capabilities. While most of the developed countries,

including the US, benefited from copying discoveries and inventions of others, TRIPS denies developing countries the same opportunity.

The critics of TRIPS also question the underlying rationale behind the TRIPS agreement by pointing out, for example, that while pharmaceutical firms may be justified in asking for patent protection to recover their developmental costs, as pharmaceutical research is expensive and involves a process spanning over several years, the industry's claims regarding R&D costs and the time required for developing new drugs appear to be exaggerated. The methodology used in the studies on which these claims has been widely criticised for inflating costs. The industry has also attracted criticism for spending significantly more on marketing than it does on R&D, and for indulging in unethical practices, such as providing perks to physicians in return for prescribing their medicines. Some critics have asserted that if ethical standards were effectively enforced, the methods employed by pharmaceutical firms to promote new and expensive drugs would breach these standards in most countries.

Thus, while the costs of TRIPS are certain, its benefits remain a potential 'may be' at best. Healthcare costs to all countries, including the US, have increased significantly as a consequence of TRIPS. But the developing countries are the biggest losers under the new regime. Large pharmaceutical companies based in the developed countries are the big winners.

A large number of experts find the TRIPS regime unsatisfactory and suggest alternatives to improve upon the current situation. Suggested models include donating drugs, differential patenting, differential pricing, replicating the Orphan Drug Act at the global level, Advance Purchase Commitments (APCs), Public-Private Partnerships (PPPs), and 'open access'. A proposal for minimum patenting has also been added to the list. These models offer a variety of compromises, but also highlight the multiple deficiencies of the current patent protection regime. Each of these proposals provides a partial solution to the problems generated by the current regime. But each potential solution suffers from some drawbacks.

These alternative models might induce investments into developing new drugs for tropical diseases. But the fundamental problem of affordability of drugs in poor

countries remains unresolved under these models. This is why developing countries, like India, need to consider alternative approaches for providing equitable access to healthcare, including access to medicines to all sections of the society.

In addition to discussing these alternatives, we have also suggested in Chapter 8 our own option of *minimum patenting* for further consideration. The *minimum patenting* model would apply exclusively to drugs and pharmaceuticals. Under the proposed *minimum patenting* model, while pharmaceutical product patents would continue to be granted, process patents would be limited to a single process that is actually used in the manufacture of the patented product. While the TRIPS agreement obliges member countries to provide patents for both *products and processes in all fields of technology* (Article 27), members are under no obligation to provide for *excessive* patenting. The Agreement provides that *members may... adopt measures necessary to protect public health* (Article 8). And limiting patents to product and a single process would be a necessary measure for protecting public health in poor countries. Companies manufacture a product using a process and deserve to be granted patent protection for what they have produced and how they have produced it. However, granting more patents than that for the same product is not rewarding innovation, but hindering it. Once a product is patented, no matter how many processes are developed by the firm's competitors, the same product cannot be marketed until the patent expires on the originator product. The practice of excessive patenting contravenes the spirit in which patents are granted, delays technological progress, raises health costs, and in the case of pharmaceuticals, literally denies access to medicines.

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Appendix A

List of publications during this study

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Appendix B

The impact of the new regime on India's pharmaceutical exports

Appendix Table B.1: India's pharmaceutical exports with itemised value (US$ million) (2000-01 to 2002-03)

Item no.	Product	2000-01	2001-02	2002-03
1	Acetazolamide - formulations thereof		0.0195	0.0008
2	Actyl Slcylc acid (Aspirin) in tablets & other formulations of Aspirin	1.1355	0.9209	2.1568
3	Acyclovir - formulations thereof	1.2405	0.383	0.3768
4	Adhesive dressings and other articles having an adhesive layer	4.6794	4.7015	5.4994
5	Adhesive gauze bandage	0.6463	0.8199	0.7638
6	Adhesive tape (medicinal)	0.2127	0.3463	0.2986
7	Aglutinating or blood sera of cow-calf etc.			0.0003
8	Albendazole and fenbendazole preparations	0.8273	0.8663	1.403
9	Allylestrenol - formulations thereof in tablets etc.			0.0642
10	Aluminium hydroxide gel	0.2302	0.3169	0.4827
11	Aluminium hydroxide gel in tablets, liquid etc with mag hydrx & mg trisilicte etc in tablets liquid etc.	1.0422	0.7368	0.9712
12	Amclos in capsules Injections etc.	2.9143	3.6704	5.4526
13	Amikacin	0.047	0.0575	0.0056
14	Amikacin and its salts	0.0254	0.0073	0.1256
15	Amitriptiline and chlorodia zepoxide formulations thereof	0.0242	0.0341	0.176
16	Amodiaquine and Chloroquine(as phosphate or sulphate) - formulations thereof in tablets, injections etc.	4.9532	4.7519	3.3909
17	Amoxycillin with clavulanic acid and probenicid preparations	0.8138	0.3523	1.3674
18	Amoxycyllin in capsules, Injections etc.	36.637	36.3607	34.6955
19	Ampicillin with sulbactum - formulations	0.2532	0.8483	0.8739
20	Ampicillin in capsules, injections etc.	20.0882	19.614	13.6147
21	Anaesthetic agents (e.g. Lignoeaeshelect) used in human/veterinary medicine/surgery			
22	Analgin (Novalgin, Bralgin) in tablets syrup injection etc. with/without other compound like paracetamol	2.4385	3.7604	5.3608
23	Anti bacterial serums & anti serum Nes	0.0458	0.174	0.198
24	Anti rabies vaccine	0.9351	2.1561	1.3492
25	Anti-D Immunoglobulin	0.0029	0.0074	0.0173
26	Anti malarials, n.e.s.(e.g. Sulphadoxine, Pyrimethamine, Mepacrine, Artemesinin and Artesunates preparations) in tablets etc.	0.9845	1.0589	1.2827
27	Antisera and other blood fractions	4.8009	2.8812	3.3089
28	Astemizole - formulations thereof		0.0134	0.0117
29	Atenolol - formulations in tablets etc..	2.8365	3.5537	3.8485
30	Ayurvedic & Unani medicines	27.4001	31.0365	45.2556
31	Ayurvedic & Unani Medicines	21.166	19.4101	108.8646
32	Bandages without adhesive layer	0.3745	1.2424	1.522
33	Becampicillin	0.0385		0.0617
34	Beclomethasone comb - formulations thereof	0.1449	0.1141	0.808
35	Benzoin tincture	0.0024	0.6493	0.0031

36	Blood plasma	4.1847	2.1936	2.1937
37	Blood-grouping reagents	0.1662	0.0328	0.1806
38	Bovine albumin and drugs of animal origin	0.2129	0.2381	0.0605
39	Bromocriptine - formulations thereof in tablets, injections etc.	0.0068		
40	Bupivacaine HCL	0.0098		
41	Calcium lactate tablets etc.	0.6423	0.1318	2.481
42	Calcium sennoside	2.6044	2.5126	2.3757
43	Captopril, Lisinopril, Enalapril, Ramipril, Perindopril, Benzepril - formulations thereof in tablets etc.	0.9767	2.0792	2.1802
44	Cefaclor and its salts	4.2715	0.9306	3.0169
45	Cefadroxyl in capsules, injections etc.			
46	Cefadroxyl in capsules, injections etc.	1.4766	1.5725	1.6556
47	Cefazolin Injection	1.645	0.8172	1.2028
48	Cefixime and its salts	1.2236	0.4418	0.5096
49	Ceflazidime and its salts	0.0164	0.0745	0.2289
50	Cefotaxime	1.7895	2.3638	2.0944
51	Ceftizoxime and its salts	0.012	0.5994	0.165
52	Ceftriaxone	1.8063	1.2057	2.4967
53	Cefuroxime and its salts	0.2851	1.6845	19.7356
54	Cephalexin - formulations thereof in Capsules etc.	40.3411	28.5132	33.8199
55	Cephaloridine	0.4023	0.9936	0.15
56	Cetirazine - formulations thereof	0.5851	0.6107	0.5041
57	Cetrimide (Savlon)	0.1198	0.1024	0.1999
58	Chemical and medicinal contraceptives foam tablets, chemical and medicinal contraceptives jellies, paste, cream etc.	1.0637	3.0159	3.2307
59	Chloramphenicol and Streptomycin - formulations thereof, in capsules etc.			
60	Chlormphenicol capsules, injections etc.	10.7714	13.3796	23.9242
61	Chloropheniramine Maleate with or without other compounds (excl. steroids alkaloids) - formulations thereof in syrup etc.	2.5147	3.4167	4.5649
62	Chloroxylenols (Dettol)	0.0158	0.0643	0.0431
63	Chlorpropamide - formulations thereof	0.1244	0.1182	0.1378
64	Chemical contraceptive preparations based On hormones/ spermicides	7.029	4.4139	4.3789
65	Cimetidine tablets etc.	1.2307	0.9635	0.9302
66	Ciprofloxacine in capsules, tablets etc.	13.7849	10.8208	15.083
67	Clobetasole - formulations thereof		0.0174	0.0145
68	Clobetasone - formulations thereof			
69	Clostebol - formulations thereof in tablets, capsules etc.		0.0009	
70	Clotrimazole - formulations thereof	0.4765	0.5914	0.7924
71	Cloxacillin in capsules, injections etc.	4.377	5.5683	4.038
72	Containing alkaloids or derivatives thereof but not containing hormones, other products of heading No. 29.37 or antibiotics	9.965	12.4396	9.9231
73	Containing insulin	0.129	0.135	0.3544
74	Containing other antibiotics.	113.0233	101.3192	150.9585
75	Containing penicillins or derivatives thereof, with a penicillanic acid structure, or streptomycins or their derivatives	81.4436	86.1668	77.4353
76	Cotton wool medicated	1.7444	1.1213	0.8571
77	Cream, drop etc. for local action on ear, nose & Oropharynx containing steroids such as betamethasone hydrocortisone etc.	7.4636	5.5	6.3438
78	Danazol tablets, injections etc.	0.4976	1.2183	0.7819
79	Dapsone (DDS), Clofazamine, Acedapsone (DADDS), Solapsone etc. drugs for leprosy	0.1909	0.0723	0.1043

80	Dental cements and other dental fillings bone reconstruction cements	0.6061	2.1393	2.7216
81	Diazepam, Lorazepam, Clonazepan, Nitrazepan, Oxazepan - formulations thereof in tablets, injections etc. (e.g. Campose, Valium)	0.5961	0.3798	0.5173
82	Diethyl Carbamazine Citrate - formulations thereof in tablets, syrup etc.	0.0398	0.1026	0.4009
83	Diptheria Antisera	0.0738	0.1044	0.0957
84	Distilled water for injection in ampoules or otherwise	0.9669	2.9113	2.0094
85	Doxorubicine (Doxorubicine Meiji) injection or in other forms	0.2074	0.102	1.3526
86	Doxycycline in capsule, tablets etc.	1.0387	1.737	1.3348
87	Dxamtasne tablets etc. incl. eye/ear drops	2.9199	2.8304	2.4342
88	Enrofloxacin	3.1401	2.1172	1.7393
89	Enzymes - formulations containing diastase, papain, pectin, pepsin etc.	5.5606	6.162	3.9169
90	Erythromycin in capsules, injections, ointments etc.	4.9086	4.7419	5.4964
91	Ethambutol - formulations thereof in tablets, capsules etc.	6.2952	4.0296	3.5865
92	Ethinyloestradiol - formulations thereof in tablets etc.	0.0249	0.0579	
93	Extracts of glands or other organs or of their secretions	0.659	0.3923	0.3894
94	Eye drops, cream containing corticosteroids (Betamethasones Hydrocortisone) etc.			
95	Famotidine - formulations thereof in tablets etc.	0.469	0.9431	1.3379
96	First-Aid boxes and kits	0.7443	0.3166	0.4511
97	Flucinolone - formulations thereof in tablets, injections etc.	0.0088	0.031	0.0022
98	Fluticasone - formulations thereof in tablets, capsules etc		0.029	0.0025
99	Folic acid and Niacinamide (Vitamin B9) in Tablets & other formulations with/without other additives	0.5163	0.972	0.698
100	Formulations based on 8-hydroxy quinolines namely: iodo/di-iodo hydroxy quinolines, quinodochlor etc.	0.2001	0.0596	0.1148
101	Formulations of Atropin sulphate, Atropin methonitrate etc. in tablets, eye drops, ointments etc.	1.3992	0.6525	0.4999
102	Formulations of bromohexin with dextromethorphan, phenyl propanalomine, dyphenhydramine in expectorant preparation	0.8878	0.6998	1.3718
103	Formulations of Caffeine & Its salts	0.0891	0.9463	0.0618
104	Formulations of ephedrine and pseudoephedrine in tablets, expectorant preparations	3.2232	1.1964	1.7184
105	Formulations of Ergot preparata, Ergota mine and Methylergometrine in tablets, injections etc. (e.g. methyl ergometrine maleate preparations)	0.2064	0.317	0.1768
106	Formulations of Papaverine hydrochloride	0.0896	0.0946	0.1537
107	Formulations of Reserpine & other Rauwol Fia alkaloids in tablets etc.	0.7065	3.6998	0.4864
108	Formulations of other hormones or products with a hormone function and other steroids N.E.S.			
109	Formulations for Pituitry hormones Injections etc.	0.7766	0.3876	0.6341
110	Framycetin			
111	Formulations of other vegetable alkaloids & its derivatives	0.9429	1.0112	0.8915
112	Garlic oil capsules (garlic pearls)	0.1646	0.3244	0.1123
113	Gemfibrozil		0.0338	0.0238
114	Gentamycin in capsules, injections etc.	0.8639	1.401	1.9652
115	Glands and other organs for organotherapeutic uses, dried, whether or not powdered; extracts of glands or other organs or of their secretions for organotherapeutic uses; heparin and its salts; other human or animal substances prepared for therapeutic	8.7027	7.6288	7.896
116	Glands and other organs, dried, whether or not powdered	7.307	6.6601	6.4948
117	Gonadotrophins - human follicle stimulating hormones & Lute/Ns/Ng hormones formulations in powder form	0.001	0.0004	0.0103
118	Gripe water	0.0639	0.1443	0.0459
119	Haemoglobin powder	0.0117		

120	Halcinonide - formulations thereof in tablets etc.			
121	Heparin	0.1051		0.0838
122	Heparin salts other human/animals Substances for therapeutic/Prophylactic use N.E.S.	0.7367	0.5764	1.0119
123	Hepato Bilary preparations like - L Aspertate	0.0352	0.015	
124	Homeopathic medicine	1.9665	0.7859	1.2191
125	Homoeopathic medicine	0.4809	0.4289	0.4788
126	Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera and other blood fractions; vaccines, toxins, cultures of microorganisms (excluding yeasts) and similar products.	51.192	60.3624	75.7177
127	Human gamma globulin	0.0123		0.0024
128	Hydrocortisone salts/injectibles	0.2076	0.0859	0.6958
129	Ibuprofen with/without other compound in tablet etc.	12.9462	8.7691	13.375
130	Immunosuppressants excluding foregoing articles N.E.S. (e.g. cyclosporin, azathioprine)		0.0071	0.0183
131	Inhaler, spacers and nebulising solutions based on Salbutamol, Terbutaline, Salmetrol, Beclomethasone, Budesunide sodium chromoglycate etc.	1.704	2.5727	3.4037
132	Insulin (bovine/pork) injection	0.0015		0.0102
133	Insulin (human) injection	0.1273	0.1148	0.2928
134	Insulin in other forms			
135	Insulin in other forms	0.0002	0.0203	0.0514
136	Insulin Injection			
137	Iodine, colloidal or tincture	0.0431	0.3141	0.438
138	Iron preparations of Frrs Fumrt/Frs Slft/Frc Amnm/Ctrt/Frs Glucnt Himglbn other iron Compounds	1.5204	1.3238	1.6945
139	Isafgul husk and phylliun hust preparation	0.0022	0.0827	0.0233
140	Isoprenaline - formulations thereof in tablets, injections etc.		0.0333	0.002
141	Isosorbide, mononitrate, denitrate in tablets etc.	0.1404	0.1719	0.1221
142	Isoxsuprine Hcl in tablets etc. (e..g. Duvadilan tablets)	0.0841	0.1139	0.3338
143	Kanamycin and its salts	0.0644	0.7053	0.1398
144	L-Asparaginase injection or in other forms equivalents and preparations N.E.S.		0.026	0.0466
145	Lansoprazole - formulations thereof in tablets etc.	0.3771	0.5935	0.4615
146	Leptazole B. P. or equivalent (Cardiazole) with other compounds in syrup etc.			
147	Lignocaine/Lidocaine	0.1188	0.1342	0.0992
148	Liquid extracts of liver	0.0865	0.12	0.0245
149	Liver extracts dry	0.0028	0.0028	
150	Lomefloxacin	0.058	0.0647	0.3452
151	Loratadine - formulations thereof	0.7121	1.0176	1.101
152	Lynestrenol - formulations thereof in tablets, injections etc.	0.0045	0.0738	
153	Medicaments containing alkaloids/therapeutic derivatives but Not/ hormones/other products of Hdng No. 29.37/Antbt	0.0346	0.0217	0.2974
154	Medicaments containing penicillins/ therapeutic derivatives with alkaloids /penicillinic acid structure, Streptomycins / therapeutic derivatives	3.7704	4.7226	6.3294
155	Mebendazole - formulations thereof in tablets etc.	2.7494	3.0793	1.8947
156	Medicaments containing adrenal cortical hormones	0.1579	0.0008	0.0247
157	Medicaments (excluding goods of heading No. 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale.	715.4867	783.2131	1022.9128
158	Medicaments (excluding goods of heading No. 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms of packaging for retail sale.	150.5855	188.8111	276.8513

159	Medicaments cont. other antibiotics	1.3673	6.6062	19.0025
160	Medicaments containing insulin	0.1802	0.1158	0.1042
161	Medicated lint	1.2415	2.415	1.8496
162	Medicinal castor oil B.P.	0.0777	0.0069	0.003
163	Menthol crystal	28.4718	33.2236	34.9992
164	Merbromin N.F.12(Mercurochrome)	0.4386	0.013	0.085
165	Methoxsalen in capsules, solutions etc.	0.1167	0.0387	0.0068
166	Methyl Dopa formulations in tablets etc.	0.0524	0.1331	0.0861
167	Metoclo Pramide Hcl (Perinorm liquid) formulations	0.818	1.279	0.8784
168	Metronidazole - formulations single and in combination with furazolidone and diloxanide furoate	6.2381	10.9173	9.9042
169	Microbial cultures	0.0063	0.0522	0.0142
170	Microbial rennet			
171	Milk of magnesia	0.0422		0.0009
172	Mineral & parenteral nutritional supplements/containing calcium salts with vitamins in tablets etc.	0.4798	0.4616	0.3317
173	Mixed vaccines for Dpt-Triple anti gen	3.6343	5.3266	5.0936
174	Mixed vaccines for M.M.R.	15.5915	15.8609	21.0468
175	Mixed vaccines for T.A.B. or T.A.B.C.	0.0077	0.2535	0.0025
176	Multivitamins containing vitamin A, B-Gr. C, D or Ny two of these in tablets, capsules, injectibles, etc.	3.85	5.6047	3.1297
177	Multivitamins, others in tablets, capsules, injectibles, etc.			
178	Nalidixic acid preparation, single/in combination with metronidazole	0.4341	0.258	0.4662
179	Nandrolone - formulations thereof in injections etc.			
180	Nandrolone, Stanozol Oxymetholone etc. anabolic drugs in capsules, syrup etc.(e.g. Pronabol, Stromba,Neurabol)			
181	Neomycin and its salts	0.004	0.0574	0.0286
182	Netilmycin and its salts			
183	Neurobion injection or in other forms			
184	Nifedipine, amilosipine, felodipine and netrendipine tablets etc. (e.g. depin capsules)	1.4753	1.4712	1.853
185	Norethisterone - formulations thereof in tablets etc.			
186	Norfloxacine - formulations thereof in capsules etc.	5.738	2.2532	2.2319
187	Ofloxacin	0.0359	0.1409	0.1572
188	Omeprazole - formulations thereof	1.5143	2.7145	5.983
189	Ointments & Slvs with vitamins for topical use skin diseases insect bites & inflammations			
190	Opacifying preparations for X-Ray exams; diagnostic agents designed to be administered to the patient	0.0563	0.0398	0.1552
191	Othe NSAIDS formulations containing Flurbiprofen, Ketoprofen, Phenacetin, Diclofenac sodium/potassium, Ketoralac preparation etc.	7.4851	8.2505	9.7771
192	Other	3.3604	5.006	4.6704
193	Other	7.1808	4.0791	3.9572
194	Other	16.2456	19.8047	25.0398
195	Other	17.4477	18.1686	21.6225
196	Other	133.9392	134.6856	226.1582
197	Other amino acid/protein preparations with/without vitamins, spirulina and the like	1.8	1.7042	2.1723
198	Other anaesthetic agents Ketamine, Halothine, Thiopentane	0.041	0.0879	0.1398
199	Other analgesics, antipyreties (Naproxen, mefenamic acid etc) in tablets, syrup, capsules, injections etc.	3.017	5.4793	8.2339
200	Other antacid etc.	0.4587	2.6992	0.921
201	Other antibiotics/Its derivatives put up for Rtl Sl			

202	Other anthelmintics in tablets, syrups etc. (e.g. Piperazine, Niclosamide, Praziquanted)	1.055	1.4186	1.7411
203	Other anti amoebial/anti protozoal formulations	2.4095	2.0571	1.6131
204	Other anti-histamines, anti-asthmatics, broncho-spasm relaxants, expectorants, not containing alkaloids, steroids in syrup, tablets, injections (e.g. Procainamide, Deriphylline, Terbutaline, Digoxine) and preparation in injections etc.	1.6555	0.8051	1.8313
205	Other anti-tuberculous formulations in tablets etc. of Pyrazinamide/Thiacetazone, isoniazide etc. (excluding Refampicin)	4.7854	4.1664	3.8996
206	Other antibiotics (other than heading no. 300310)	0.151	4.3511	15.8192
207	Other antibiotics or derivatives thereof, put up for retail sale			
208	Other antibiotics with penicillinic acid structure streptomycin/Its derivatives in capsules, injections etc.			
209	Other bacteriological products	2.1417	0.4772	0.3619
210	Other bandages	2.654	2.4479	3.0111
211	Other carcino-chemotherapeutic drugs (e.g. Cyclophosphamide, Chlorambucil, Paclitaxel, Tamoxiphen)	0.9364	1.3763	1.4316
212	Other cultures of microorganisms etc.	1.1767	0.8964	1.3761
213	Other extracts of glands or other organs or of their secretions	0.061	0.0282	0.0189
214	Other fluids for intra-venous application plasma-expander, electroloytic fluid excl. normal saline for nutritional/therapeutic use e.g. Dextros	3.8271	5.0701	4.7822
215	Other formulations containing Tetracycline derivatives (e.g. Oxytetracycline, minocycline) in capsules, injections, ointment etc.	0.7516	0.457	1.1956
216	Other glands/organs dried whether or not powdered	1.3172	0.0278	0.0665
217	Other hormones formulations	1.5986	2.6493	1.735
218	Other human vaccines	4.1121	9.5425	19.7126
219	Other medicaments not put up in Msrd dress/packings			
220	Other medicaments	11.2939	42.6592	24.9595
221	Other medicaments (excluding goods of heading 3002,3005,3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms of packings for retail sale	439.4341	512.3678	698.095
222	Other medicaments containing vitamins or other products of heading No. 29.36.	53.8862	52.6151	64.4993
223	Other medicaments not put up in measured doses or in packing	78.0938	74.3837	74.412
224	Other Progestogens and Oestogen nes (progesterone medroxy progesterone salts)	0.4591	0.1827	0.3836
225	Other saline water	0.2421	0.2676	0.2928
226	Other sedatives & tranquilizers (e.g. Alprazolam, Zopicline, Amitryptiline, Flunarazine) formulations in tablets etc.	0.489	0.7978	0.2759
227	Other vaccines for veterinary medicine			
228	Others	0.5967	1.5203	2.5069
229	Others	7.375	12.7846	8.6381
230	Others put up for retail sale	36.7423	34.0736	44.852
231	Oxyphn/Phenyl Butazon in tablets, capsules etc.	0.6963	0.4493	0.362
232	Oxytocin - formulations thereof	0.1633	0.2623	0.1699
233	Pancreatin & dried powder of pancreas	5.9898	6.6323	6.4283
234	Paracetamol panadol in tablets. syrup etc.	15.6572	21.2346	23.6093
235	Pefloxacin	0.1352	0.0086	0.0607
236	Penicillin in capsules, injections etc.	3.3911	3.8766	4.7695
237	Pharmaceutical goods specified in Note 3 to this Chapter.	12.6496	9.5635	10.9809
238	Pharmaceutical products.	946.6562	1059.2864	1404.5285
239	Phenformin; Metformin - formulations thereof	1.2187	3.5113	5.9503
240	Pheniramine maleate (Avil) - formulations thereof in tablets ointments etc.	0.0249	0.0467	0.0086

241	Phenytoin sodium in tablets, capsules etc. and Phenobarbital tablets etc.	0.1059	0.2389	0.0694
242	Phthalyl Sulphathiazol (Thalazole) tablets	0.1495	0.324	0.3936
243	Pilocarpine - formulations thereof	0.0042		
244	Plaster of Paris (surgical)	1.1664	1.0874	1.4259
245	Polymixin 'B' and its salts	0.1079	0.104	0.1338
246	Poultice of Kaolin		0.2274	0.4417
247	Prednisolone tablets, injections etc.	1.7448	1.0116	1.2042
248	Propranololm Metoprolol, Bisoprolol, Pindolol - formulations thereof in tablets etc.	0.15	0.0701	0.201
249	Proprietory and medicines N.E.S.			
250	Proprietory medicines, N.E.S.	254.0211	315.0083	458.2079
251	Pyrantel - formulations thereof	0.3325	0.4328	0.1287
252	Rabies antisera	0.0627		
253	Ranitidine(as Hcl) tablets etc. (e.g. Histac injection)	11.9988	18.4137	21.5091
254	Rifmpicine - formulations in capsules etc.	6.4356	4.3492	6.2875
255	Roxatidine - formulations thereof in tablets etc.	0.0393	0.0061	0.3418
256	Roxythromycin, Azithromycin, Clarithromycin in capsules, injections etc.	3.0088	2.4282	3.8423
257	Salbutamol sulphate with or without other compounds (excl. alkaloids, steroids) - formulations thereof in syrup etc.	2.4175	1.8168	3.3426
258	Simvastatin; Lvastatin; Atrovastatin	0.2691	1.9269	4.3967
259	Snake venom	0.4036	0.2413	0.2621
260	Snake venom antisera	0.4101	0.3784	0.7839
261	Somatropin - formulations thereof			
262	Stanozolol - formulations thereof in tablets etc.			0.0063
263	Sterile Laminaria & Laminaria tents.& sterile absorbable surgical/dental haemostatics	0.2439	0.1899	0.1438
264	Sterile surgical catgut, similar materials & Sterile tissue adhesives for surgical wound closure	3.8037	2.4311	2.9495
265	Sterile surgical catgut, similar sterile suture materials and sterile tissue adhesives for surgical wound closure; sterile laminaria and sterile laminaria tents; sterile absorbable surgical or dental haemostatics	4.0476	2.621	3.0933
266	Streptomycin & its salts in capsules injections etc.	2.1862	0.7264	1.5977
267	Sulpha drugs N.E.S.	4.8773	0.2036	1.1451
268	Sulphacetamide - formulations in ointment, drops etc.	0.1095	0.1127	0.1219
269	Sulphadiazine formulations in tablets, syrups, ointment etc.	0.5461	0.2104	0.2396
270	Sulphamethazine (Sulphadimidine BP) in tablets etc.	0.0625	0.1031	0.1329
271	Sulphamethoxazole & Trimethoprim/ (Co- Tri Moxazole) in tablets, syrup etc.	12.7095	5.758	7.1488
272	Syntocinone injection	0.0407	0.0018	0.0355
273	Tablets, capsules etc. of vitamin 'B' group	2.0383	2.477	3.4521
274	Tablets, capsules, syrup etc. of vitamin A & D) except salves ointments & vaccines	0.9985	1.0267	0.6537
275	Terbutaline - formulations thereof in injections etc.		0.0082	0.0037
276	Terfenadine - formulations thereof	0.0297	0.1152	0.0033
277	Tetanus Antisera		0.0308	0.035
278	Tetracycline in capsules, injections, ointments etc.	3.2197	3.7014	2.9422
279	Theophylline, Amino phylline and Etophylline formulations like tablets, syrup etc.	0.4027	0.3732	0.3647
280	Timolol maleate - formulations thereof	0.0646	0.0344	0.0558
281	Tinidazole formulations including combination formulations with diloxanide furoate/furazolidone/anti bacterials like Ciprofloxacin	0.6109	0.409	1.6687
282	Tobramycin and its salts			
283	Tolbutamide - formulations thereof	0.0417	0.083	0.0582

284	Tolnafiate - formulations thereof	0.017	0.0433	0.0129
285	Tonic appetite stimulants containing vitamins with glycerophos Clsm etc in cpsules etc.	3.7714	2.5039	2.351
286	Tonics based on vitamins glycerophosphates, ginseng preparations	0.7664	0.6927	0.8616
287	Toxins	3.8561	2.6533	2.205
288	Triamcinolone formulations thereof in tablets, injections etc.		0.0014	0.1501
289	Trimethoprim in combination with Sulphadiazine/Sulphamoxole	0.7826	0.6325	0.5732
290	Tripoline - formulations thereof		0.0295	
291	Vaccine for hepatitis `A' and `C'	0.0045	0.2331	0.0297
292	Vaccine for hepatitis `B'		0.0311	0.3781
293	Vaccine for typhoid	0.028	0.001	0.0072
294	Vaccines for cholera	3.2076	5.6524	3.0987
295	Vaccines for diphtheria	6.0151	6.9691	6.4825
296	Vaccines for human medicine	37.1139	51.5175	66.2119
297	Vaccines for polio		0.2718	0.0191
298	Vaccines for tuberculins (B.C.G.)	0	0.0052	0.1172
299	Vaccines for veterinary medicine	2.0964	1.8846	2.2396
300	Vaccines for whooping cough (Pertusis)			
301	Vaccines for tetanus (Ttns Txd-Ft,Apt,Ptah etc.)	3.5751	5.2068	8.8575
302	Veterinary medicinal formulation, not for Human use N.E.S.	4.5763	3.269	2.9151
303	Veterinary vaccine against Foot & Mouth disease			
304	Vicks inhaler, vaporub etc.	2.2757	2.4099	3.5161
305	Vitamin 'C' in tablets, syrup etc. salves ointments & vaccines	0.1218	0.4982	0.4577
306	Vitamin 'D' in tablets, capsules, syrup Et	0.1863	0.1633	0.4086
307	Vitamin E in capsules, tablets, syrup etc.	1.0595	1.0983	3.4365
308	Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or put up in forms of packings for retail sale for medical, surgical, dental or veterinary purp	8.0398	9.7075	10.1697
309	Zidovudine - formulations thereof	0.064	0.3348	0.8683

Source: DGCIS as cited in IndianData.com (2005).

Appendix C

Examination of drug prices the domestic firms agreed to reduce

Appendix Table C.1: Voluntary price reduction - market prices versus claimed prices

CIMS	DT	IDR	Original	Name of the formulation and strength	Therapeutic Category/ Composition		Claimed prices					Market prices			
Page/reference			S. No.			Pack Size	Old price (Rs.)	New price (Rs.)	Reduction %age	Old price per unit	New price per unit	CIMS	DT	IDR	Status
	305	187	13	Bacipen 250	Antibacterial	Cap 10	30.80	28.50	7.47%	3.08	2.85		2.88	2.88	H
	305	187	14	Bacipen 500	Antibacterial	Cap 10	57.60	53.00	7.99%	5.76	5.30		5.38	5.38	H
		191	15	Odinol 25mg	Cardiovascular	Tab 14	11.50	8.50	26.09 %	0.82	0.61			0.71	H
		191	16	Odinol 50mg	Cardiovascular	Tab 14	19.00	16.00	15.79 %	1.36	1.14			1.25	H
		204	17	Alcephin 250	Antibacterial	Cap 10	62.00	51.00	17.74 %	6.20	5.10			6.20	H
		204	18	Alcephin 500	Antibacterial	Cap 10	110.00	95.50	13.18 %	11.00	9.55			11.00	H
		204	19	Alcephin Dry.Syr.	Antibacterial	Dry syrup 30 ml	23.85	21.00	11.95 %	0.80/ ml	.70/ml			0.70/ ml	E
		204	20	Alcephin Kid Tab.	Antibacterial	Tab 10	29.95	21.00	29.88 %	3.00	2.10			3.00	H
295	696	312	50	Alsigra 50	Antifungals	Tab 4	72.00	51.00	29.17 %	7.20	5.10	7.20	7.20	7.20	H
268		273	72	Forminal 1000	Antidiabetics	Tab 10	16.05	12.50	22.12 %	1.61	1.25	1.50		1.50	H
270	966	297	75	Piolem 15	Antidiabetics drug	Tab 10	18.00	16.00	11.11 %	1.80	1.60	1.80	1.80	1.80	H
270	966	297	76	Piolem 30	Antidiabetics drug	Tab 10	35.00	32.00	8.57%	3.50	3.20	3.50	3.50	3.50	H
	1,051		101	Folinal plus	Iron&Vitamins supplements	Syrup 300 ml	72.00	63.50	11.81 %	0.24/ ml	0.21/ ml		0.37/ ml		H
	312	180	111	AMOXIL DRY SYRUP	Amoxycillin dry syrup	Dry syrup 30 ml	25.68	22.47	12.50 %	1.00/ ml	0.86/ ml		0.47/ ml	0.49/ ml	L
	312	180	114	AMOXIL 250 MG CAPS	Amoxilcillin 250 mg Caps	Cap 20X10	802.50	748.32	6.75%	4.01	3.74		3.10	3.58	L
	312	180	115	AMOXIL 500 MG CAPS	Amoxilcillin 500 mg Caps	Cap 20X10	1510.84	1337.41	11.48 %	7.55	6.69		5.90	5.50	L
	528		164	CADFLO CAPS	Fluoxetine 20mg	30 X 10 C	898.80	791.80	11.90 %	3.00	2.64		2.35		L
	418		173	CADITHRO 50MG TABS	Roxythromycin 50mg.	20 X 10 T	1005.80	963.00	4.26%	5.03	4.82		4.70		L
	418		174	CADITHRO 150MG TABLETS	Roxythromycin 150mg.	20 X 10T	1647.80	1498.00	9.09%	8.24	7.49		11.13		H
476	825	212	176	CETICAD TABLETS	Cetrizine HCl 10mg.	50 X 10 T	1281.86	805.71	37.15 %	2.56	1.61	2.60	2.60	2.60	H
188	548	236	178	DOMCOLIC 50X10 TABLETS	Domperidone 10mg	50 X 10 T	1352.48	1070.00	20.89 %	2.70	2.14	2.53	2.53	2.53	H
373	479		184	FLUMED 150MG	Fluconazole 150mg	tab 20 X 1	684.80	577.80	15.63 %	34.20	28.85	30.00	26.00		M
73	629	264	190	LANZOFAST 30mg. Caps	Lansoprazole 30mg as enteric coated granules	20 X 10 C	1070.00	856.00	20.00 %	5.35	4.14	4.93	4.90	4.93	H

	250		198	NIMDUS-P TABLETS	Nimesulide 100mg.+Paracetamol 500mg		20 X 10T	620.60	513.60	17.24 %	3.10	2.57		2.90		H
	250		199	NIMDUS-PLUS TABLETS	Nimesulide 100mg.+ Paracetamol 500mg		50 x 10	1551.50	1086.05	30.00 %	3.10	2.17		2.90		H
	354		201	ORIPHEX 125 DT TABLETS	Cephalexin 125mg.	Tab	20 X 10T	628.95	588.50	6.43%	3.14	2.94		3.25		H
318		204	203	ORIPHEX 250 CAPSULES	Cephalexin 250mg.	Cap	20 X 10C	1305.40	1177.00	9.84%	6.53	5.89	6.50		6.50	H
318		204	204	ORIPHEX 500 CAPSULES	Cephalexin 500mg.	Cap	10 X 10C	1150.25	1016.50	11.63 %	11.50	10.17	12.10		12.10	H
308	306	187	210	ZYCILLIN 250mg CAP	Ampicillin Trihydrate 250mg.		20 X 10C	642.00	535.00	16.67 %	3.21	2.68	3.00	3.00	3.00	H
308	306	187	211	ZYCILLIN 500mg CAP	Ampicillin Trihydrate 500mg.		20 X 10C	1241.20	1070.00	13.79 %	6.21	5.35	5.80	5.80	5.80	H
380	510	173	330	Zelbend Tab	Albendazole I.P. 400mg, excipient qs		20 x 10	2675.00	2247.00	16.00 %	13.38	11.23	10.00	10.00	10.00	L
	409		404	CADIMYCETIN 500 CAPSULE	Chloramphenicol 500mg		10 X 10 C	730.28	642.00	12.09 %	7.30	6.42		6.83		H
	409		405	CADIMYCETIN 250 CAPSULES	Chloramphenicol 250mg		20 X 10C	770.40	663.40	13.89 %	3.85	3.31		3.60		H
	1094		419	CADPRO GRANULES 250GM GB	Protein Granules		250 gm	149.75	136.96	8.54%	0.60/gm	0.55/gm		0.50/gm		L
155	148	239	425	CANVAS 5MG TAB	Enalapril 5mg Tab		30 x 10	635.58	535.00	15.82 %	2.12	1.78	0.07	0.07	0.07	L
	318		495	ZOX LB 250 CAPSULES	Amoxycillin 250mg+Lacto Bacillus		10 X 10C	406.60	321.00	21.05 %	4.07	3.21		3.80		H
	318		496	ZOX LB 500 CAPSULES	Amoxycillin 500mg+Lacto Bacillus		10 X 10C	757.56	695.50	8.19%	7.58	6.96		7.08		H
380	508	173	501	Alzad Suspension	Albendazole 5ml-IP-200mg.		10 ml Bot	21.61	17.41	19.43 %	2.16/ml	1.74/ml	1.83/ml	1.83/ml	1.83/ml	H
380	508	173	502	Alzad Tabs	Albendazole IP - 400mg.		1 Tab	14.80	11.87	19.81 %	14.80	11.87	12.00	2.56	12.00	H
112		240	532	ENPRIL 10MG	Enalapril 10 mg		10 Tab	54.86	49.37	10.00 %	5.49	4.94	2.18		2.18	L
112		240	533	ENPRIL 5MG	Enalapril 5mg		10 Tab	30.60	27.54	10.00 %	3.06	2.75	1.20		1.20	L
118	154	269	544	LOZITAN 50MG	Losarten 50mg		10 Tab	46.42	32.49	30.00 %	4.64	3.25	3.90	3.90	3.90	H
332		209	559	NOSOCEF 250MG	Ceftriaxone 250mg Inj.		1 vial	47.48	37.98	20.00 %	47.48	37.98	48.80		48.80	H
322	344	205	565	O-POWERCEF 100mg	Cefixime 100mg DT		10 Tab	137.15	109.72	20.00 %	13.72	10.97	27.00	27.00	27.00	H
322		205	566	O-POWERCEF 200MG	Cefixime 200mg		4 Tab	100.23	80.18	20.00 %	25.06	20.05	49.00		49.00	H
322		205	567	O-POWERCEF DS	cefixime 50mG/5ml		30 ml	63.30	50.64	20.00 %	2.11/ml	1.69/ml	3.27/ml		3.27/ml	H
207	209	292	573	PYREXON 650 MG	Paracetamol-IP- 650mg DT	Tab	6 Tab	9.59	8.63	10.00 %	1.60	1.44	1.35	1.35	1.35	L
74	621	288	574	RESEC CAP 20mg	Omeprazole - IP-20 mg	Cap	10 Cap	46.95	37.56	20.00 %	4.70	3.76	3.98	3.95	3.98	H
		195	602	BECLASONE - C 15 gm.	Topical Steroids	Cream	15gm	22.90	14.80	35.37 %	1.53/gm	0.99/gm			1.53/gm	H
		195	603	BECLASONE - C 5 gm	Topical Steroids	Cream	5gm	11.75	8.60	26.81 %	2.35/gm	1.72/gm			2.35/gm	H
		195	604	BECLASONE - GM 15 gm.	Topical Steroids	Cream	15gm	24.90	16.90	32.13 %	1.66/gm	1.13/gm			1.66/gm	H

		195	605	BECLASONE - GM 5 gm.	Topical Steroids	Crea m	5g m	13.90	9.60	30.94 %	2.78/g m	1.92/g m			2.78/g m	H
		219	608	CIPROBIOTI C - 250 1x10	Anti-Bacterial	Tab	10	30.66	11.60	62.17 %	3.07	1.16			2.88	H
		219	609	CIPROBIOTI C - 500 1x10	Anti-Bacterial	Tab	10	59.42	20.40	65.67 %	5.94	2.04			5.87	H
		220	610	CIPROBIOTI C - TN - 250 1x10	Anti-Bacterial	Tab	10	34.64	22.20	35.91 %	3.46	2.22			2.99	H
		220	611	CIPROBIOTI C - TN - 500 1x10	Anti-Bacterial	Tab	10	67.94	39.10	42.45 %	6.79	3.91			5.99	H
297		181	671	RANOXYL CAPSULES 250mg - 10's	Amoxicillin 250mg	Cap	10	42.00	37.80	10.00 %	4.20	3.78	3.00		3.00	L
297		181	672	RANOXYL CAPSULES 500mg - 10's	Amoxicillin 500mg	Cap	10	67.20	60.48	10.00 %	6.72	6.05	5.30		5.30	L
297		181	675	RANOXYL DRY SYRUP 60 ML.	Amoxicillin 125mg / 5ml	Dry syrup	60 ml	29.40	26.46	10.00 %	0.49/ ml	0.44/ ml	0.42/ ml		0.42/ ml	L
155	149	240	688	Invoril 5 Tabs, 10's	Enalapril 5mg	Tab	10	23.73	18.98	20.02 %	2.38	1.90	1.88	1.88	1.88	L
380		173	702	Lupibend 400	Anthelmintics	Tab	50X 1	626.7 6	575.0 0	8.26%	12.54	11.50	12.00		12.00	H
382		270	703	Lupimeb	Anthelmintics	Tab	20X 6	240.2 6	219.2 0	8.76%	2.00	1.10	1.92		1.92	H
76		288	710	Lupome -D	Antipeptic Ulcerants	Cap	20X 10	940.1 4	835.6 0	11.12 %	4.70	4.18	4.18		4.18	E
134		178	711	Defidin 5mg	Antihypertensives	Tab	5X6 X10	678.9 9	600.6 0	11.55 %	2.26	2.00	2.17		2.17	H
380		173	716	Lupibend Syp 10Ml	Anthelmintics	Syrup	10 ML	21.94	18.80	14.30 %	2.19/ ml	1.88/ ml	2.10		2.10/ ml	H
354		285	723	Eufox 200	Antibiotics	Tab	10X 10	887.9 1	731.2 0	17.65 %	8.88	7.31	7.31		7.31	E
356		286	725	Eufox-Tz	Antibiotics	Tab	10X 10	1044. 60	835.6 0	20.01 %	10.45	8.36	8.36		8.36	E
509		275	742	Lupigyl Gel	Anthelmintics	Gel	30g ms	28.20	20.35	27.85 %	0.94/g m	0.68/g m	1.35/g m		1.35/g m	H
232		281	748	Lupisulide Gel	Pain Management	Gel	30g ms	25.07	16.70	33.39 %	0.84/g m	0.56/g m	1.20/g m		1.20/g m	H
232		281	753	Lupisulide	Pain Management	Tab	5X5 x10	626.7 6	391.7 5	37.50 %	2.50	1.56	2.40		2.40	H
76		291	762	Lupipan 40	Antipeptic Ulcerants	Tab	10x 10	626.7 6	313.4 0	50.00 %	6.27	3.13	6.00		6.00	H
320	354	204	768	ROFEX 500MG CAPSULES	ANHYDROUS CEPHALAXIN 500 MG		10X 10	118.1 8	105.0 0	11.15 %	1.18	1.05	10.57	11.82	10.57	H
320	354	204	771	ROFEX 250MG CAPSULES	CEPHALAXIN 250 MG		20X 10	62.66	60.00	4.25%	0.31	0.30	5.94	6.27	5.94	H
		281	786	Nicip tabs	Analgesics / Antipyretics / Anti-inflammatory		10's	25.00	21.00	16.00 %	2.50	2.10			2.50	H
		212	787	Cetcip tabs	Antiallergic		10's	33.65	25.00	25.71 %	3.37	2.50			2.75	H
		287	788	Omecip 10 caps	Antacid		10's	24.00	19.50	18.75 %	2.40	1.95			2.40	H
		287	789	Omecip 20 caps	Antacid		15's	58.50	46.00	21.37 %	3.90	3.07			3.90	H
		281	790	Nodard tabs	Analgesics / Antipyretics / Anti-inflammatory		10's	25.00	21.00	16.00 %	2.50	2.10			2.50	H
232		282	792	Niciflex-T tabs	Analgesics / Antipyretics / Anti-inflammatory		10's	55.00	40.00	27.27 %	5.50	4.00	5.50		5.50	H
189		236	793	Vomistop 10 DT	Antiemetics / Antinauseants		10's	24.00	16.00	33.33 %	2.40	1.60	2.40		2.40	H
408		330	794	Bromex syrup	Anti Cough & Cold Preparations		100 ml	27.00	22.00	18.52 %	0.27/ ml	0.22/ ml	0.27/ ml		0.27/ ml	H
308		187	796	Megasyn 250 caps	Antibiotics		10's	30.00	24.00	20.00 %	3.00	2.40	3.00		3.00	H
241		230	798	Verub gel	Pain relieving ointment		30g m	37.00	30.00	18.92 %	1.23/g m	1.00/g m	1.23/g m		1.23/g m	H

		313	799	Burnheal dusting powder	Antiseptic powder	10g m	21.00	16.00	23.81 %	2.10/g m	1.60/g m			2.10/g m	H
		293	800	Paracod tabs	Analgesics / Antipyretics / Anti-inflammatory	10's	31.00	25.00	19.35 %	3.10	2.50			3.10	H
382		264	801	Levomol 50 tabs	Anthelmintics	1's	7.75	6.00	22.58 %	7.75	6.00	7.75		7.75	H
382		264	802	Levomol 150 tabs	Anthelmintics	1's	15.70	13.50	14.01 %	15.70	13.50	15.70		15.70	H
		238	803	Vominate tabs	Antiemetics / Antinauseants	10's	19.50	15.00	23.08 %	1.95	1.50			1.95	H
344			804	Q-Gat 200 tabs	Antibiotics & Antibacterials	5's	40.00	33.00	17.50 %	8.00	6.60	8.00			H
242		383	806	Powergel	Pain relieving ointment	30g m	37.00	30.00	18.92 %	1.23/g m	1.00/g m	1.23/g m		1.23/g m	H
196		296	807	Phenotone 30 tabs	Antiepileptic drugs	10's	7.40	6.00	18.92 %	0.74	0.60	0.74		0.74	H
196		296	808	Phenotone 60 tabs	Antiepileptic drugs	10's	10.20	9.00	11.76 %	1.02	0.90	1.02		1.02	H
		346	809	Fericip caps	Vitamins Supplements	10's	73.34	55.00	25.01 %	7.33	5.50			4.50	H
		173	810	Alfarich 0.25 caps	Vitamins Supplements	10's	65.00	50.00	23.08 %	6.50	5.00			5.00	E
518		195	811	Becderm cream	Topical preparations	15g m	18.00	15.00	16.67 %	1.20/g m	1.00/g m	1.20/g m		1.20/g m	H
408		330	813	Bromex tabs	Anti Cough & Cold Preparations	10's	12.00	9.00	25.00 %	1.20	0.90	1.20		1.20	H
519			814	Cloderm cream	Antifungal cream	15g m	28.00	24.00	14.29 %	1.87	1.60	2.13/g m			H
409		331	815	Cofdex Forte syrup	Anti Cough & Cold Preparations	100 ml	35.00	29.00	17.14 %	0.35/ ml	0.29/ ml	0.35/ ml		0.35/ ml	H
		335	816	Ridcof syrup	Anti Cough & Cold Preparations	60 ml	20.00	17.00	15.00 %	0.33/ ml	0.28/ ml			0.33/ ml	H
409		331	817	Cofdex Plus syrup	Anti Cough & Cold Preparations	60 ml	27.00	23.00	14.81 %	0.27/ ml	0.23/ ml	0.27/ ml		0.27/ ml	H
		332	818	Dexcof syrup	Anti Cough & Cold Preparations	100 ml	30.00	27.00	10.00 %	0.30/ ml	0.27/ ml			0.30/ ml	H
236		299	819	Dolocip DT	Analgesics / Antipyretics / Anti-inflammatory	10's	44.50	25.00	43.82 %	4.45	2.50	3.00		3.00	H
73		255	823	Helipac Kit tabs	Antacid	6's Kit	25.20	20.00	20.63 %	4.20	3.33	4.20		4.20	H
228		254	824	Osteocip tabs	Analgesics / Antipyretics / Anti-inflammatory	10's	150.00	100.00	33.33 %	15.00	10.00	15.00		15.00	h
411		333	825	Lexcof syrup	Anti Cough & Cold Preparations	50 ml	26.00	23.00	11.54 %	0.52/ ml	0.46/ ml	0.52/ ml		0.52/ ml	H
428		349	827	Maxiferon soft caps	Vitamins / Nutritional Supplements	10's	27.00	23.00	14.81 %	2.70	2.30	2.70		2.70	H
73		278	828	Mosapid 5 tabs	Antacid	10's	27.00	20.00	25.93 %	2.70	2.00	2.70		2.70	H
		318	831	Toscof syrup	Anti Cough & Cold Preparations	100 ml	30.00	24.00	20.00 %	0.30/ ml	0.24/ ml			0.30/ ml	H
82		371	832	Urisoda granules	Systemic Alkalizer	4g m	8.50	6.00	29.41 %	2.13/g m	1.50/g m	2.13/g m		2.13/g m	H
		275	833	Vominorm Injection	Antiemetics / Antinauseants	2ml	6.00	4.00	33.33 %	3.00	2.00			3.00	H
178		229	834	Zepose Injection	Antidepressant	2ml	12.00	6.00	50.00 %	6.00/ ml	3.00/ ml	6.00/ ml		6.00/ ml	H
302	326	184	835	Clavam 375 mg 10's	Amoxicillin + Clavulanate Potassium tablets	10's	296.40	197.08	33.51 %	29.64	19.91	28.50	28.50	28.50	H
302	326	184	836	Clavam 625 mg 10's	Amoxicillin + Clavulanate Potassium tablets	10's	379.60	207.48	45.34 %	37.96	20.75	19.95	36.50	19.95	H
302	326	184	837	Clavam Dry Syrup 30 ml	Amoxicillin And Clavulanate	30 ml	72.80	48.78	33.00 %	2.43/ ml	1.63/ ml	2.50/ ml	2.33/ ml	2.50/ ml	H
302	326	184	839	Clavam 1000 mg 10's	Amoxicillin + Clavulanate Potassium tablets	10's	483.60	311.48	35.59 %	48.36	31.15	29.95	46.50	29.95	H
302		184	840	Clavam DT tabs 10's	Amoxicillin + Clavulanate Potassium tablets	10's	132.60	82.68	37.65 %	13.26	8.27	12.75		12.75	H

	1127		845	Gemfos 4's	Risedronate Sodium tablets	4's	208.00	124.80	40.00%	52.00	31.20		50.00		H
330	351	209	847	Tazid 250 mg Injection	Ceftazidime for Injection	Vial	86.32	78.00	9.64%	86.32	78.00	85.00	75.00	85.00	H
330	351	209	848	Tazid 500 mg Injection	Ceftazidime for Injection	Vial	161.20	145.60	9.68%	161.20	145.60	140.00	162.00	140.00	M
330	351	209	849	Tazid 1000 mg Injection	Ceftazidime for Injection	Vial	280.80	192.40	31.48%	280.80	192.40	270.00	185.00	270.00	H
	382		850	Zocef 250 mg Injection	Cefuroxime Sodium Injection	Vial	58.76	46.80	20.35%	58.76	46.80		56.50		H
336	382	211	851	Zocef 750 mg Injection	Cefuroxime Sodium Injection	Vial	118.56	99.84	15.79%	118.56	99.84	99.84	114.00	99.84	M
	382		852	Zocef 1.5 gm Injection	Cefuroxime Sodium Injection	Vial	225.68	187.20	17.05%	225.68	187.20		217.00		H
	382		853	Zocef 125 mg tabs 10's	Cefuroxime Axetil Tablets	10's	161.20	135.20	16.13%	16.12	13.52		15.50		H
	382		854	Zocef 250 mg tabs 10's	Cefuroxime Axetil Tablets	10's	338.00	206.96	38.77%	33.80	20.70		32.50		H
	382		855	Zocef 500 mg tabs 10's	Cefuroxime Axetil Tablets	10's	676.00	395.20	41.54%	67.60	39.52		65.00		H
	367	209	859	Cefxo	Ceftriaxone 1 gm	Vial	98.00	82.00	16.32%	98.00	82.00		75.00	75.00	L
	367	209	860	Cefxo	Ceftriaxone 250 mg Inj	Vial	43.00	35.80	16.74%	43.00	35.80		30.00	30.00	L
	367	209	861	Cefxo	Ceftriaxone 500 mg Inj	Vial	58.00	48.30	16.72%	58.00	48.30		50.00	50.00	H
476		212	864	Oncet	Cetirizine Dihydrochloride Tab	10's	25.00	15.00	40.00%	2.50	1.50	1.00		1.00	L
382	507	270	876	Helmintol	Mebendazole 100 mg Tab.	6's	6.95	5.80	16.55%	1.16	0.97	0.99	1.16	0.99	H
	245	281	878	Nimsaid	Nimesulide Tab	10's	24.00	20.00	16.67%	2.40	2.00		1.87	1.87	L
	697	313	882	Vigreks 100	Sildenafil Citrate 100 mg	4's	108.00	90.00	16.67%	27.00	22.50		25.00	25.00	H
	697	313	883	Vigreks 50	Sildenafil Citrate 50 mg	4's	72.00	60.00	16.67%	18.00	15.00		14.90	14.90	L

Note: CIMS, DT (Drug Today) and IDR are considered to reflect the market prices.

The letter in the last column represents the status of the market price relative to the claimed price reduction.

H=the market price is higher than the claimed price;

L= the market price is lower than the claimed price;

E= the market price is equal to the claimed price; and

M= the market price is mixed, which means at least in one of the reference books the price is higher while in the other books the price is lower than the claimed price.

Source: Author calculations based on Government of India {, 2006 #1590}, CIMS {, 2007 #1649}, Drug Today {, 2007 #1651} and IDR {, 2008 #1652}.

Appendix D

Sensitivity test: Case 1

Payment schedule for the lowest category remains unchanged. For the other categories, the co-payments raised from Rs. 25 to Rs. 30. and from Rs. 50 to Rs. 60. The Safety Net thresholds raised from Rs. 1,125 to Rs. 1,350 and from Rs. 2,000 to Rs. 2,400.

Appendix Table D.1: Entitlements of IndiaHealth cards at a glance

S. No	Income p.a.	Category	Colour	Co-payment per prescription	SafetyNet Threshold	Co-payment (post SafetyNet) per prescription
	(Rs.)			(Rs.)	(Rs.)	(Rs.)
1	None	S-Card	Brown	Nil	N. A.	Nil
2	<15,000	B1-Card	Red	Nil	N. A	Nil
3	15,001 - 40,000	B2-Card	Yellow	10	500	Nil
4	15,001 - 40,000	A1-Card	White/Yellow	10	500	Nil
5	40,001 -100,000	A2-Card	White/Purple	30	1,350	10
6	40,001 - 100,000	M1-Card	Purple	30	1,350	10
7	>100,000	A3-Card	White/Green	60	2,400	30
8	>100,000	M2-Card	Green	60	2,400	30

Note: The threshold would kick in at 40 prescriptions for B2 and A1 Categories, at 45 prescriptions for M1and A2 categories and at 50 prescriptions for M2 and A3 categories.

Source: Author

Appendix Table D.2: Calculating health and medicine expenditure (Rs.)

Category	Population	Health (monthly)		Medicine (monthly)	
	(Million.)	Per capita (Rs.)	Total Rs. (Million.)	Per capita (Rs.)	Total Rs. (Million.)
Rural	798	44	35112	28.16	22471.68
Urban	342	71	24282	39.76	13597.92
Total (India)	1140		59394		36069.6
Based on the above Table		Health (yearly)		Medicine (yearly)	
Rural			421344		269660.2
Urban			291384		163175
Total (India)			712728		432835.2
Per person		625.2		379.68	
Per family		3126		1898.4	

Source: Government of India (2007).

Appendix Table D.3: Expenditure on medicines under current and proposed models

S. No.	Category	Estimated population (million)	Estimated no. of cards (million)	Total drug expenditure – India (Rs. million)	Total out-of-pocket co-payments (Rs. million)	Government contribution (Rs. million)	Average OOP med. exp per family (Rs.)	Average out-of-pocket drug expenditure per family (Rs.)
				(current)	*(proposed)*	*(proposed)*	*(proposed)*	*(current)*
1	2	3	4	5	6	7=(5-6)	8	9
1	S-Card	40	40.00	15187.2	0	15187.2	0	1898.4
2	B1-Card	350	86.50	132888	0	132888	0	1898.4
3	B2-Card	450	85.50	170856	42750	128106	500	1898.4
4	A1-Card	5	2.50	1898.4	1250	648.4	500	1898.4
5	A2-Card	5	2.50	1898.4	3712.5	0	1485	1898.4
6	M1-Card	190	38.00	72139.2	56430	15709.2	1485	1898.4
7	A3-Card	5	2.50	1898.4	6600	0	2640	1898.4
8	M2-Card	95	19.00	36069.6	50160	0	2640	1898.4
	Total	1,140	276.50	432,835	160,903	271,933	582	1898.4
				100%	37.17	62.83		

Note: At 5%, 17.5 million elderly population would be issued with 8.75 million B1-Cards. At 5 members per family, 332.5 million population would be issued with 66.5 million B1-Cards (Aged). At 5% of 450 million of B2- population, 22.5 million elderly population would be issued with 11.25 million B1-Cards (Aged) Thus, the number of cards issued in B1 category would be higher and in B2 would be lower than straight forward dividing the total population by 5 in those categories.

Source: Author calculations based on Government of India (2007).

Appendix Table D.4: Projected population of India by age groups (percentage of total) (2000-2050)

	0-4	5-14 Years	15-64	65-79	80+	Total
2000	12.2	22.8	60.4	4.0	0.6	100
2005	11.2	21.8	62.0	4.3	0.7	100
2010	10.4	20.3	64.0	4.5	0.8	100
2015	9.6	19.1	65.5	4.9	0.9	100
2020	8.8	17.9	66.6	5.6	1.1	100
2025	8.0	16.8	67.5	6.5	1.2	100
2030	7.3	15.6	68.3	7.4	1.4	100
2035	6.7	14.4	68.9	8.2	1.8	100
2040	6.5	13.3	68.9	9.1	2.2	100
2045	6.2	12.6	68.4	10.1	2.7	100
2050	5.9	12.3	67.3	11.4	3.1	100

Source: United Nations (United Nations 2005, medium variant).

Appendix Table D.5: Estimates of total out-of-pocket *medicine* expenditure (Rs. million) and population groups (million)

Year	Total	0-4 (factor1.2)		5-64 (factor 1)		65+ (factor 4.5)		Total OOP med. exp	Total OOP med exp Incl. 5% CAGR
	Pop-ulation	Pop-ulation	Med. Exp.	Pop-ulation	Med. Exp.	Pop-ulation	Med. Exp.		
1	2	3	4	5	6	7	8	9 (4+6+8)	10
2006	1140	126.5	57635	956.5	363164	57.0	97388	518187	518187.3
2007	1160	127.6	58137	973.8	369732	58.6	100122	527991	554390.1
2008	1181	127.5	58091	993.2	377098	60.2	102855	538045	593194.1
2009	1201	127.3	58000	1011.2	383932	62.5	106785	548717	635208.9
2010	1220	126.9	57818	1028.5	390501	64.7	110544	558862	679300.7
2011	1237	126.2	57499	1044.0	396386	66.8	114132	568016	724948.9
2012	1254	125.4	57134	1059.6	402309	69.0	117891	577334	773682.5
2013	1271	124.6	56770	1075.3	408270	71.2	121649	586689	825530.5
2014	1287	124.8	56861	1088.8	413396	73.4	125408	595665	880068.1
2015	1303	125.1	56998	1102.3	418521	75.6	129167	604686	938066.4

Source: Author estimates based on United Nations (2005); and Government of India (2007).

Appendix Table D.6: Estimates of total out-of-pocket *health* expenditure (Rs. million) and population groups (million)

Year	Total	0-4 (factor1.2)		5-64 (factor 1)		65+ (factor 4.5)		Total OOP health.exp.	Total OOP health exp. incl. 5% CAGR
	Pop-ulation	Pop-ulation	Health exp.	Pop-ulation	Health exp.	Pop-ulation	Health exp.		
1	2	3	4	5	6	7	8	9 (4+6+8)	10
2006	1140	126.5	94905	956.5	598004	57	160364	853273	853273
2007	1160	127.6	95731	973.8	608820	58.6	164865	869416	912886
2008	1181	127.5	95656	993.2	620949	60.2	169367	885971	976783
2009	1201	127.3	95506	1011.2	632202	62.5	175838	903545	1045967
2010	1220	126.9	95205	1028.5	643018	64.7	182027	920251	1118570
2011	1237	126.2	94680	1044	652709	66.8	187935	935324	1193737
2012	1254	125.4	94080	1059.6	662462	69	194125	950667	1273984
2013	1271	124.6	93480	1075.3	672278	71.2	200314	966072	1359360
2014	1287	124.8	93630	1088.8	680718	73.4	206504	980851	1449164
2015	1303	125.1	93855	1102.3	689158	75.6	212693	995706	1544667

Source: Author estimates based on United Nations (2005); and Government of India (2007).

Appendix Table D.7: Projected distribution of total health expenditure (Rs. million)

	Current situation		Proposed programme			
Year	Total OOP health exp. incl. 5% CAGR	Estimated total health exp. (THE)	Public health exp. (PHE)	Total OOP health exp.	GDP	PHE as
	-72%	-100%	62.83%	37.17%	estimates	% of GDP
2006	853273	1185101	744551	440551	39743850	1.87
2007	912886	1267898	796568	471329	45453590	1.75
2008	976783	1356643	852323	504320	50916870	1.67
2009	1045967	1452731	912692	540040	57361880	1.59
2010	1118570	1553570	976045	577525	64612270	1.51
2011	1193737	1657968	1041634	616334	72713230	1.43
2012	1273984	1769422	1111656	657767	81814440	1.36
2013	1359360	1888000	1186153	701846	92075660	1.29
2014	1449164	2012728	1264515	748213	103585118	1.22
2015	1544667	2145371	1347849	797522	116533257	1.16

Source: Author estimates based on Government of India (2005, 2007); and IMF (2008).

Appendix E

Sensitivity test: Case 2

Co-payment for the lowest category raised to Rs. 15 and Safety Net threshold raised to Rs. 750. The payment schedule for the other categories remains unchanged.

Appendix Table E.1: Entitlements of IndiaHealth cards at a glance

S. No	Income p.a.	Category	Colour	Co-payment per prescription	SafetyNet Threshold	Co-payment (post SafetyNet) per prescription
	(Rs.)			(Rs.)	(Rs.)	(Rs.)
1	None	S-Card	Brown	Nil	N. A.	Nil
2	<15,000	B1-Card	Red	Nil	N. A	Nil
3	15,001 - 40,000	B2-Card	Yellow	15	750	Nil
4	15,001 - 40,000	A1-Card	White/Yellow	15	750	Nil
5	40,001 -100,000	A2-Card	White/Purple	25	1,125	15
6	40,001 - 100,000	M1-Card	Purple	25	1,125	15
7	>100,000	A3-Card	White/Green	50	2,000	25
8	>100,000	M2-Card	Green	50	2,000	25

Note: The threshold would kick in at 40 prescriptions for B2 and A1 Categories, at 45 prescriptions for M1and A2 categories and at 50 prescriptions for M2 and A3 categories.

Source: Author

Appendix Table: E.2: Calculating health and medicine expenditure (Rs.)

Category	Population (Million)	Health (monthly)		Medicine (monthly)	
India	1140	Per capita (Rs.)	Total Rs. (Million.)	Per capita (Rs.)	Total Rs. (Million.)
Rural	798	44	35112	28.16	22471.68
Urban	342	71	24282	39.76	13597.92
Total (India)			59394		36069.6
Based on the above Table		Health (yearly)		Medicine (yearly)	
Rural			421344		269660.2
Urban			291384		163175
Total (India)			712728		432835.2
Per person		625.2		379.68	
Per family		3126		1898.4	

Source: Government of India (2007).

Appendix Table E.3: Expenditure on medicines under current and proposed models

S. No.	Category	Estimated population (million)	Estimated no. of cards (million)	Total drug expenditure – India (Rs. million)	Total out-of-pocket co-payments (Rs. million)	Government contribution (Rs. million)	Average out-of-pocket co-payments per family (Rs.)	Average out-of-pocket drug expenditure per family (Rs.)
				(current)	(proposed)	(proposed)	(proposed)	(current)
1	2	3	4	5	6	7=(5-6)	8	9
1	S-Card	40	40.00	15187.2	0	15187.2	0	1898.4
2	B1-Card	350	86.50	132888	0	132888	0	1898.4
3	B2-Card	450	85.50	170856	64125	106731	750	1898.4
4	A1-Card	5	2.50	1898.4	1875	23.4	750	1898.4
5	A2-Card	5	2.50	1898.4	3093.75	0	1238	1898.4
6	M1-Card	190	38.00	72139.2	47025	25114.2	1238	1898.4
7	A3-Card	5	2.50	1898.4	5500	0	2200	1898.4
8	M2-Card	95	19.00	36069.6	41800	0	2200	1898.4
	Total	1,100	236.50	432,835	163,419	269,416	691	1898.4
				100%	37.76	62.24		

Note: At 5%, 17.5 million elderly population would be issued with 8.75 million B1-Cards (Aged). At 5 members per family, 332.5 million population would be issued with 66.5 million B1-Cards. At 5% of 450 million of B2-population, 22.5 million elderly population would be issued with 11.25 million B1-Cards (Aged). Thus, the number of cards issued in B1 category would be higher and in B2 would be lower than straight forward dividing the total population by 5 in those categories.

Source: Government of India (2007).

Appendix Table E.4: Projected population of India by age groups (percentage of total)

Year	0-4	5-14	15-64	65-79	80+	Total
2000	12.2	22.8	60.4	4.0	0.6	100
2005	11.2	21.8	62.o	4.3	0.7	100
2010	10.4	20.3	64.o	4.5	0.8	100
2015	9.6	19.1	65.5	4.9	0.9	100
2020	8.8	17.9	66.6	5.6	1.1	100
2025	8.o	16.8	67.5	6.5	1.2	100
2030	7.3	15.6	68.3	7.4	1.4	100
2035	6.7	14.4	68.9	8.2	1.8	100
2040	6.5	13.3	68.9	9.1	2.2	100
2045	6.2	12.6	68.4	10.1	2.7	100
2050	5.9	12.3	67.3	11.4	3.1	100

Source: United Nations (2005).

Appendix Table E.5: Estimates of total out-of-pocket *medicine* expenditure (Rs. million) and population groups (million)

Year	Total popu-lation	0-4 (factor1.2)		5-64 (factor 1)		65+ (factor 4.5)		Total OOP med. exp.	Total OOP med. exp. Incl. 5% CAGR
		Popu-lation	Med. Exp.	Popu-lation	Med. Exp.	Popu-lation	Med. Exp.		
1	2	3	4	5	6	7	8	9 (4+6+8)	10
2006	1140	126.5	57635	956.5	363164	57.0	97388	518187	518187
2007	1160	127.6	58137	973.8	369732	58.6	100122	527991	554390
2008	1181	127.5	58091	993.2	377098	60.2	102855	538045	593194
2009	1201	127.3	58000	1011.2	383932	62.5	106785	548717	635209
2010	1220	126.9	57818	1028.5	390501	64.7	110544	558862	679301
2011	1237	126.2	57499	1044.0	396386	66.8	114132	568016	724949
2012	1254	125.4	57134	1059.6	402309	69.0	117891	577334	773683
2013	1271	124.6	56770	1075.3	408270	71.2	121649	586689	825531
2014	1287	124.8	56861	1088.8	413396	73.4	125408	595665	880068
2015	1303	125.1	56998	1102.3	418521	75.6	129167	604686	938066

Source: Author estimates based on United Nations (2005); and Government of India (2007).

Appendix Table E.6: Estimates of total out-of-pocket *health* expenditure (Rs. million) and population groups (million)

Year	Total popu-lation	0-4 (factor1.2)		5-64 (factor 1)		65+ (factor 4.5)		Total OOP health exp	Total OOP health exp incl. 5% CAGR
		Popu-lation	H/care exp	Popu-lation	H/C exp	Popu-lation	H/C exp		
1	2	3	4	5	6	7	8	9 (4+6+8)	10
2006	1140	126.5	94905	956.5	598004	57.0	160364	853273	853273
2007	1160	127.6	95731	973.8	608820	58.6	164865	869416	912886
2008	1181	127.5	95656	993.2	620949	60.2	169367	885971	976783
2009	1201	127.3	95506	1011.2	632202	62.5	175838	903545	1045967
2010	1220	126.9	95205	1028.5	643018	64.7	182027	920251	1118570
2011	1237	126.2	94680	1044.0	652709	66.8	187935	935324	1193737
2012	1254	125.4	94080	1059.6	662462	69.0	194125	950667	1273984
2013	1271	124.6	93480	1075.3	672278	71.2	200314	966072	1359360
2014	1287	124.8	93630	1088.8	680718	73.4	206504	980851	1449164
2015	1303	125.1	93855	1102.3	689158	75.6	212693	995706	1544667

Source: Author estimates based on United Nations (2005); and Government of India (2007).

Appendix Table: E.7: Projected distribution of total health expenditure (Rs. million) (2006-2015)

	Current situation		Proposed programme			
Year	Total OOP health exp incl. 5% CAGR	Estimated total health exp (THE)	Public health exp (PHE)	Total OOP health exp	GDP estimates	PHE as % of GDP
	-72%	-100%	62.24%	37.76%		
2006	853273	1185101	737661	447440	39743850	1.86
2007	912886	1267898	789198	478700	45453590	1.74
2008	976783	1356643	844437	512206	50916870	1.66
2009	1045967	1452731	904247	548485	57361880	1.58
2010	1118570	1553570	967013	586557	64612270	1.50
2011	1193737	1657968	1031995	625973	72713230	1.42
2012	1273984	1769422	1101370	668053	81814440	1.35
2013	1359360	1888000	1175177	712822	92075660	1.28
2014	1449164	2012728	1252814	759914	103585118	1.21
2015	1544667	2145371	1335377	809994	116533257	1.15

Source: Author estimates based on Government of India (2005, 2007); and IMF (2008).