ACCOUNTING FOR GROWTH IN

THE PHARMACEUTICAL BENEFITS SCHEME

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# Abstract

This thesis investigates the contribution to the growth in expenditure on medicines listed on the Pharmaceutical Benefits Scheme (PBS) from three inter-related sources: (i) the addition of new medicines offering an expanding range of treatments for disease, (ii) PBS processes for determining the prices of medicines and their conditions of listing and (iii) the demand by patients for PBS medicines. In doing so it uses trend analysis presented in both tabular and graphic form, expenditure decomposition techniques based on index and indicator numbers, and econometric analysis. Using novel techniques and interpretations, it addresses some key aspects of decomposition analysis including the treatment of new and disappearing goods and the potential bias arising from changing market shares among substitutable medicines. The analysis is undertaken for the period from 1991-92 to 2005-06.

An important consequence of the cost-effectiveness and reference pricing techniques used by the PBS, is that the quantity index calculated within the decomposition of PBS expenditure can be interpreted as a measure of the quality-adjusted amount of medicines consumed by patients. This is virtually equivalent to the growth in expenditure of about 12% per annum. On average prices of medicines fell over time, modestly in nominal terms and to a greater extent in real terms. Based on the results of econometric analysis, new evidence is presented on the relative influences of copayments, safety net limits, the number of PBS medicines listed and their conditions of listing on the demand for PBS medicines by different categories of patients. Elasticities with respect to patient price are in the range -1.1 to -1.4 for General Non-Safety Net patients and in the range -0.5 to -0.9 for Concessional Non-Safety Net patients.

# Declaration

I, Kim Sweeny, declare that the PhD thesis entitled *Accounting for Growth in the Pharmaceutical Benefits Scheme* 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

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# Chapter 1

## Introduction

### 1.1 Introduction

In Australia, most of the prescription medicines used to treat disease are made available to patients under the Pharmaceutical Benefits Scheme (PBS) – a program administered by the Commonwealth Government. For most of its 60 year history, the PBS has been largely invisible to the public which may be taken as a measure of its success in providing the medicines needed by patients at a cost acceptable to them.

Reports by the Commonwealth Treasury and the Productivity Commission in recent years have raised concerns over the "sustainability" of the PBS (and other health services) based on projections that its cost as a proportion of both GDP and government revenue will increase markedly over the next 40 years. The twin factors seen as driving this are continuing strong demand arising from the growth and ageing of the population and the expected availability of and demand for expensive biotechnology-based medicines offering improved treatment for the diseases of old age such as arthritis and cancer.

Because cost is a dominant issue in considering the PBS now and in the future, the principal concern of this thesis is to understand and quantify the main determinants of the growth in expenditure on medicines made available under the PBS.

In doing so it concentrates on three interrelated factors. These are (i) the impact of the steady addition to the PBS of new medicines which expand the choices available for treating disease, (ii) the prices at which medicines are supplied to the PBS and their course over time and (iii) the strong growth in demand by patients for PBS medicines.

The first two of these factors are largely under the control of the Commonwealth Government so considerable attention is given to explaining the procedures used by the PBS for listing new medicines and determining their initial and on-going prices

and providing evidence on how these procedures determine market outcomes. The price setting procedures of the PBS combined with formal industry agreements with pharmacists influence both the cost incurred by the Government in running the PBS and the returns received by suppliers and pharmacists from PBS medicines.

Patients are largely insulated from the wholesale and retail prices set by the Government. They contribute a fixed copayment to the cost of medicines they consume and any small premium added to the Government's base cost by suppliers. In addition a safety net provision further protects patients from onerous expense.

The Government has less influence on the third factor examined in this thesis – the demand for medicines by patients. This is largely governed by the prevalence of disease, the extent to which it is diagnosed and treated with medicines. Nonetheless the Government through its controls over copayments and safety net limits can both moderate the demand for medicines and influence the distribution of the cost between itself and patients. By changing the number of copayments necessary to reach the safety net limit the Government can control the number of patients that can access medicines at cheaper prices. Its control over restrictions on listing can also be used to influence demand for medicines. Regression analysis is used to quantify the impacts of these and other factors on demand and to derive new estimates of elasticities with respect to price, income and the number of medicines.

The relative importance of the three factors influencing PBS expenditure is explored in a number of ways. Principal among these is the decomposition of PBS expenditure into its components – the steady addition of new medicines, changes in prices, and changes in the quantities of medicines consumed. Two basic decomposition techniques are used – (i) the traditional use of standard index numbers to decompose a value ratio, and (ii) the less well known use of indicators which decompose a difference in value.

The principal challenge in using index numbers is accounting for new and disappearing goods. Standard ways of dealing with this are used as well as a novel technique – the Time Product Dummy regression approach which incorporates information about all goods in the market.

In decomposing pharmaceutical expenditure there is a further problem that needs to be addressed – the potential for bias arising from shifting market shares among similar medicines. In the literature this is considered a problem when different brands are treated separately but it is argued that this potential bias also needs to considered when comparisons are made involving different medicines treating the same disease.

Related to this is the other major theme developed in this thesis – the fact that the way pharmaceutical markets are defined is important in understanding pharmaceutical market outcomes. This is true not only for assessing the degree of oligopoly in markets but also for understanding the operations of the PBS and the determinants of demand. It is argued that the PBS is best seen as a collection of disease treatment markets composed of medicines that are broadly substitutable for each other and analysis should be undertaken with this in mind. These markets can be defined in a number of ways and many of the results presented compare explanations using these different definitions.

Most studies that decompose pharmaceutical expenditure use standard index number techniques to estimate a price and quantity index. Several authors argue that within the quantity index there is a further hidden "price" effect arising from the bias due to shifting market shares. Evidence is presented for the extent of such an effect within the PBS and this effect is reinterpreted in the light of the PBS cost-effectiveness and reference pricing procedures.

The period of analysis covers the years from 1991 to 2006. This is largely dictated by the availability of data but does cover periods of significant change within the PBS, including the introduction of major policy changes such as a mandatory price cuts for some medicines in August 2005.

The thesis is organized in the following way.

Chapter 1

The next section of this chapter sets out the theoretical structure and methods used in the thesis. The following sections are taken up firstly with a description of Australian pharmaceutical markets, emphasizing the predominance of the PBS and other pharmaceutical benefit programs administered by the Commonwealth Government. This is followed by a consideration of the characteristics of medicines that are responsible for the institutional, structural and other factors that shape the markets for medicines. These include the presence of agents (doctors) acting on behalf of consumers (patients); the regulation of safety and efficacy; the ubiquity of insurance and other intermediaries and the importance of patents. This is followed by a section describing the cost and time necessary to develop new medicines and the role and impact of regulatory authorities such as the Therapeutic Goods Administration.

It is important in analyzing pharmaceutical markets to appreciate how such markets are best defined and the implications this has on the supply and consumption of medicines. The last section of this chapter argues that the overall market for PBS medicines is best considered as a collection of much smaller disease treatment markets which are largely independent of each other. This is because medicines are typically developed for a specific disease or a limited set of diseases. This means that a particular medicine can only be considered substitutable with the restricted group of medicines that have been developed for that disease. There are a number of ways of defining such treatment markets and the primary one adopted in this thesis is based on the Anatomical Therapeutic Classification (ATC) managed by the WHO.

Chapter 2

Central to market outcomes for PBS medicines are the operations of the PBS itself. Chapter 2 concentrates on PBS listing and pricing procedures. The prices of new medicines seeking PBS listing are largely determined by an economic analysis comparing the incremental cost-effectiveness of the new medicine with a comparator. The majority of new medicines are listed on a "cost-minimisation" basis, meaning that evidence is presented that they are no worse than (ie essentially equal in effectiveness with) the comparator. Medicines listed on this basis against a common comparator

form Reference Pricing Groups (RPG) which play an important role in the subsequent price histories of newly listed medicines and most other medicines listed on the PBS. Special groups such as those within Therapeutic Premium Groups (TPG) and Weighted Average Monthly Treatment Cost (WAMTC) groups are the subject of more formal pricing controls.

The chapter provides evidence of the outcomes from the operations of this approach to reference pricing. Aside from its control over the initial and on-going prices of medicines on the PBS, the Government influences the demand for medicines through other aspects of a medicine's listing. One of these is the degree of restriction placed on the diseases or conditions for which the medicine may be prescribed or the circumstances of the patient.

The chapter also provides more detail on the formulae determining the price of a PBS medicine at three stages – ex-factory, wholesale, and retail (dispensed). The dispensing fee charged by pharmacists is examined in both nominal and real terms over time. The chapter concludes with a description of recent changes in PBS policies that have arisen from perceived limitations of the PBS to deliver cost savings to the Government.

Chapter 3

This chapter looks at the other major policy settings determined by the government for the PBS. These are the criteria determining whether a patient is classified as a "General" or "Concessional" patient, and within these two categories whether they are covered by the Safety Net provisions. These criteria determine how much of the cost of a medicine is paid by the patient via a copayment (plus any price premium), the residual being paid by the Government. Data is presented on how the copayment and safety net levels have changed over time and their influence on the number of safety net cardholders.

Chapter 4

This chapter provides an introduction to the analysis of the growth in PBS expenditure by looking at the historical experience and highlighting how the relative importance of different classes of medicines has changed considerably over the past 15 years. This analysis identifies the importance of RPGs, TPGs and WAMTC groups in driving overall expenditure. The role of new medicines in PBS growth is assessed both historically and in terms of their novelty and the relationship between the number of medicines and the level of PBS expenditure is examined econometrically.

In markets such as the USA, patent expiry and the entry of competitor (generic) brands leads to significant reductions in prices. The extent of generic competition within the PBS is described and estimates are given of the extent and rate of change in the share of expenditure held by generic companies. The relationship among patent expiry, entry of new brands and prices is examined in detail for the period prior to the recent policy changes. Some conclusions are drawn about the extent to which price changes were related to patent expiry and new entry and changes in restriction levels.

Chapter 5

The analysis in Chapters 6, 7 and 8 relies in part on price and quantity indexes for PBS expenditure and its components. Chapter 5 reviews the candidate index formula against criteria suggested by the relevant literature. The performance of these candidate formulae is assessed in Chapter 6. One of the principal issues in index number theory is how to handle new and disappearing goods. Chaining is a technique to minimize any bias arising from omitting these goods from standard formulae. A technique which uses information on all goods is the Time Product Dummy approach and this is described in some detail.

Griliches and Cockburn (1994) identified a further source of bias in pharmaceutical price indexes arising from the shift in market shares among different brands of the same medicine. This bias could also arise from changes in the market shares of different medicines within the same treatment market. It is argued that the extent of these biases can be assessed by comparing indexes calculated using data defined at

increasing levels of aggregation. There are however considerable theoretical and practical obstacles to undertaking these calculations and corresponding degrees of reservation are required in interpreting the results.

An alternative approach to decomposing expenditure which has been explored recently in the literature is to employ price and quantity indicators rather than indexes. Indexes are used to decompose a value ratio into its price and quantity components, so that the percentage change in value can be expressed two components: the percentage change in prices and the percentage change in quantity. Indicators decompose a change in value into the actual amount due to changes in prices and the amount due to changes in quantities. The two approaches provide complementary evidence on changes in PBS expenditure. Candidate indicator formulae are discussed and assessed.

Chapter 6

Chapter 6 demonstrates how well the different index number formulae perform in detail at two levels of aggregation – for data defined at the unique brand level and at the PBS item level. A PBS item defines a certain combination of chemical, form and strength and there can be a number of different brands within the one item. The comparisons include both the standard formulae and the Time Product Dummy Approach. The comparisons provide evidence on the effect of omitting new and disappearing goods from PBS index calculations.

The data available for this thesis enable the price and quantity data used in index calculations to be defined in two ways. Both are used in Chapter 7. Based on these findings the Fisher index using price and quantity data defined using the derived price approach at the item level is used for the bulk of the analysis in Chapters 7 and 8.

Finally a comparison is made of indexes calculated at five different levels of aggregation to assess the bias if any arising from changing market shares described in Chapter 5. The implications of this are further discussed in Chapter 7.

Chapter 7

Chapter 7 presents a decomposition of PBS expenditure into the three components – changes in prices and quantities of common items and the addition of net new items using Fisher price and quantity indexes. Further insight into the dynamics of PBS growth is obtained using the price and quantity indicators described in Chapter 5. Results are given for the PBS as a whole and for WAMTC groups and RPGs. These results are compared with those from similar decompositions in a variety of other countries. The interpretation of the quantity index in these circumstances is contentious and a number of observers have sought a further hidden price effect arising from the substitution bias discussed in Chapter 5. It is argued that the extent of this bias in the PBS is lessened considerably by the operation of reference pricing and the quantity index is reinterpreted as a quality adjusted measure of consumption.

Chapter 7 also uses the derived quantity approach to obtain price indexes for suppliers, wholesalers and pharmacists to assess the how these supply chain participants have fared over time under the operation of the pricing formulae determined within the five-yearly Community Pharmacy Agreements.

Finally price and quantity indexes are calculated for different categories of patients. Within each category it is possible to produce a "patient price" index which combines the effect of the relevant patient copayment determined by the Government and any price premium added by the manufacturer. The "Government price" is then the difference between this and the "patient price". A  comparison of the two prices shows the extent to which the Government has been able to use its control over copayments to shift the distribution of cost between itself and patients.

Chapter 8

This chapter estimates demand equations for the four categories of patients – General and Concessional in their two safety net groups. Models of demand developed within the literature are reviewed and it is argued that a relatively simple formulation is appropriate given the nature of PBS pricing procedures. Previous studies of the demand for PBS medicines and estimates of price and income elasticities are

reviewed. The demand equations in this chapter estimate the impact of those factors identified in earlier chapters which are controlled by the Government: copayments, safety net limits, the number of medicines listed on the PBS, and restriction levels. Added to these is the overall level of real household disposable income or expenditure.

As noted above, the price to which the patient is exposed is the "patient price" incorporating both copayment and premium. Results are reported using this patient price as an explanatory variable as well as just the copayment by itself. This enables the influence of the manufacturer's premium to be evaluated. Results are reported at two levels of aggregation. The first is based on 15 annual observations for the complete PBS market. Here three different definitions of consumption of PBS medicines as the dependent variable are used, firstly the number of units of medicine consumed, secondly the estimated quantity index and thirdly total PBS expenditure deflated by this index. The second level of aggregation uses data defined at the PBS item level for each of the 15 years. The number of observations that are used at this level of aggregation is in the thousands, the exact number varying with patient category. These different estimation strategies enable the influence of all the possible factors influencing demand to be better assessed.

Chapter 9

Chapter 9 discusses the findings of the thesis in the light of the Government's policy objectives and is arranged around the three major themes of (i) the contribution of new medicines, (ii) price determination and its effects and (iii) the demand for medicines.

In describing the characteristics and operations of pharmaceutical markets in the following chapters, use is made of a number of sources of data for the PBS and other Australian and international markets. Information on sales, prices, patents, classifications and other aspects of medicines are drawn from a range of sources and these are described in Appendix A. Where necessary particular issues associated with certain sets of data are discussed in the chapters in which they occur.

Appendix B summarises the index and indicator formulae used in the decomposition analysis, while Appendix C sets out the procedure for estimating the Time Product Dummy regression equation.

## 1.2 Theoretical structure and methods

(i) Theoretical structure

The traditional neoclassic model of a market has a demand side characterised by a large number of consumers making purchasing decisions based on their incomes, the price of the product, the prices of alternative products, and a range of subjective factors such as tastes, preferences, and needs. On the supply side there are assumed to be a large number of suppliers for each product using broadly similar technologies, the result being that prices are likely to be driven down by competition to a value equal to the marginal unit cost of supply plus an average profit margin.

Pharmaceutical markets show characteristics significantly different from these assumptions.

On the supply side, the pharmaceutical industry has a technology system dominated by a long, risky and expensive product development stage and a production process usually characterised by a small marginal unit cost of production and low barriers to entry. The combination of high development costs and low manufacturing costs has meant that the only way pharmaceutical manufacturers can recover the large initial R&D costs incurred in developing new medicines, is for their products to be protected by patents which grant the patent holder a period of time during which they are the sole supplier. Patents are now granted for a period of 20 years, which usually means 8-10 years of market exclusivity before suppliers of generic equivalents are able to enter the market. Although the manufacturer of a new medicine can act as a monopolist supplier for this particular chemical compound, the new medicine will typically be competing with other established treatments in the form of medicines with varying degrees of similarity in chemical composition and action within the body.

Because a new medicine has patent protection, the supplier will seek to set a price that is significant multiples of the marginal unit cost of supply to recoup development costs. Once the patent has expired, other (generic) suppliers of chemically identical equivalents can enter the market at prices closer to marginal unit cost of supply. Because regulatory agencies ensure that these are genuinely equivalent, the originator supplier will compete with generic suppliers on the basis of brand differentiation and advertising.

On the demand side, consumer decisions are usually not made by the final consumer (the patient) but by an agent (a health professional, usually a doctor). Doctors prescribe medicines for patients based on their views about which medicine has superior therapeutic worth in treating the patient's condition. In reaching this decision, doctors draw upon a body of knowledge acquired by extensive education and training, a range of reference materials and refresher courses and their accumulated experience with conditions and treatments. General practitioners treat patients with a wider variety of conditions than do specialists who accumulate deeper knowledge and experience within a narrower range of conditions.

In most countries in most situations, the doctor's decision is only weakly influenced by the medicine's price, either in relation to the price of other medicines or in absolute terms.

The doctor and the patient can, to varying degrees, ignore the cost of the medicine in their decisions because, in most countries, an insurance intermediary, typically a government-controlled organisation, meets most of the cost. In Australia, there is effectively only one intermediary, the Pharmaceutical Benefits Scheme (PBS), a Commonwealth Government which provides universal coverage, but also uses its monopsonistic strength to determine which medicines will be available and under what conditions, and to negotiate their prices with suppliers.

The choices available to patients about purchasing PBS medicines are limited. A prescription from a doctor specifies which medicine should be dispensed although the patient usually has the option of specifying which brand to buy. In making the purchase decision the patient is expected to be influenced by the price to be paid. This

is the relevant copayment and any price premium added by the manufacturer. Income would also be expected to influence the purchase decision. Because the PBS is funded out of general revenue derived from income and other taxes and not by premiums paid by patients, there is no influence on consumer decisions from this source.

Thus the thesis does not employ a neoclassical theoretical structure, but views the market for PBS medicines as one in which suppliers face heavy sunk costs, prices are largely determined by Government regulation and consumer decisions are mostly mediated by doctors and show only limited responsiveness to market signals.

(ii) Methods

Explaining the growth in PBS expenditure fully requires two different approaches: using an accounting for growth framework and through demand analysis. In the case of the PBS, decomposition analysis based on the use of index numbers can be used to describe the course of prices of medicines, the quantity of them consumed and the impact of new medicines. The literature on decomposition of pharmaceutical expenditure has identified a number of potential biases that might arise in such an analysis. The thesis utilizes a number of techniques to minimize these biases. The new and disappearing goods problem is addressed through the use of Time Product Dummy techniques. The bias from shifts in market shares of substitutable medicines is discussed and the theoretical limitations of methods for addressing this bias are identified. Because the PBS uses cost-effectiveness analysis to determine the prices of medicines, it is shown that rather than the price and quantity indexes being biased in this way, the quantity index can be reinterpreted as a quality-adjusted measure of the consumption of PBS medicines.

While the accounting framework can provide insight into factors determining expenditure outcomes, demand analysis can be used to identify and quantify those factors determining demand for patients for PBS medicines. In this context the price and quantity indexes can be used as both dependent and explanatory factors within demand analysis.

In general the economic analysis of a market should address simultaneity in demand and supply factors. It is argued that because supply factors are controlled by the Government they do not impinge on the consumer's decision to purchase a PBS medicines.

In addition the price faced by the consumer can be regarded as exogenously determined as copayments are set by the Government and a patient price made up of the copayment and any price premium added by the supplier is highly correlated with the copayment itself.

The third element which can influence market outcomes is the supply of new medicines. Again this is essentially determined by the Government and can be regarded as exogenous, although the decision by the suppler to seek listing may be influenced by demand.

It is possible therefore to estimate demand function for PBS patient categories as a function of explanatory variables that are largely exogenous. These variables can include the patient price or copayment, safety net levels, restriction levels, income, and the number of medicines available within a pharmaceutical treatment markets.

Regression analysis suing both aggregated and quasi-panel time series data are used to estimate coefficients in these demand equations and derive associated price and other elasticities.

## 1.3 Government programs providing pharmaceutical benefits

The Commonwealth Government's objectives in its National Medicines Policy are to ensure

- "timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry" DoHAC (2000).

The second of these objectives is pursued mainly through the activities of the Therapeutic Goods Administration (described below), while the third is articulated in the National Strategy for Quality Use of Medicines (Commonwealth of Australia 2002) and programs such as the National Prescribing Service. The fourth objective has been addressed through a number of industry support programs, most recently the Pharmaceuticals Partnership Program.

The first objective is the principal concern of this thesis and is met by a range of programs administered by the Commonwealth Government that deliver pharmaceutical benefits to the Australian people. The programs which account for most of the cost are those gathered under the umbrella of the Pharmaceutical Benefits Scheme (PBS), although expenditure is also significant under some of the other programs, most notably the Repatriation Pharmaceutical Benefits Scheme (RPBS), which is the responsibility of the Department of Veterans Affairs. The State governments are responsible for public hospitals and for the costs of pharmaceutical benefits delivered in them, where these are not covered by the Commonwealth programs. In addition, there is a private market for those prescription medicines that are either not listed under the PBS or prescribed for indications outside those permitted by the PBS.

Table 1.1 provides estimates of the value of pharmaceutical markets in Australia for 2005-06 and for the various government programs.

Clearly medicines provided under the PBS predominate as they make up $7,714.3 million of the total prescription medicine market of $9,811.4 million or 78.6%. To this can be added $513.2 million (5.2%) from medicines under the RPBS and a further $383.7 million (3.9%) in other Commonwealth Government programs.

**Table 1.1      Australian pharmaceutical markets, 2005-06, $m.**

| Market | Program | Cost | Source |
|---|---|---:|---:|
| PBS - | General | 6,459.2 | 1 |
| Pharmacy | Dental | 3.8 | 1 |
| | Emergency Drug (Doctor's Bag) | 10.1 | 1 |
| | Extemporaneous | 5.1 | 1 |
| | Injectable/solvent pairs | 1.2 | 1 |
| | Palliative Care | 0.4 | 1 |
| | Special Pharmaceutical Benefits | 36.9 | 1 |
| PBS - | Highly Specialised Drugs Program | 522.0 | 1 |
| Section 100 | Botulinum Toxin Program | 6.6 | 2 |
| | Chemotherapy Scheme | 41.9 | 1 |
| | Human Growth Hormone Program | 19.7 | 2 |
| | IVF/GIFT Program | 49.7 | 2 |
| | Opiate Dependence Treatment Program | 24.8 | 2 |
| | Special Authority Program | 54.7 | 1 |
| PBS - | Colostomy and Ileostomy | 0.5 | 2 |
| Other | Safety net cards | 7.9 | 2 |
| | Aboriginal health services | 23.2 | 2 |
| | Other - Bush Nursing, Continuing Medication, Special Access Scheme | 0.1 | 2 |
| | General Non-Safety Net below copayment | 446.5 | 3 |
| | | | |
| RPBS | PBS items | 459.4 | 1 |
| | RPBS items | 42.8 | 1 |
| | Other | 11.0 | 1 |
| | | | |
| Other | Herceptin Program | 50.3 | 4 |
| Government | Lifesaving Drugs Program | 30.8 | 5 |
| | National Diabetes Services Scheme | 104.8 | 2 |
| | National Immunisation Program | 197.8 | 6 |
| | | | |
| Hospital | Public | 712.7 | 7 |
| | | | |
| Private | Private prescriptions | 487.5 | 8 |
| | | | |
| Total | | 9,811.4 | |

Sources

1. Data supplied to CSES by Medicare Australia
2. DoHA (2006c)
3. CSES estimate. In 2005-06 general non-safety net use was 26.0% of cost of all medicines with a dispensed price greater than the general copayment level. Total cost of medicines with a dispensed price less than the general copayment level was $1,375.4 million which is use by patients other than general non-safety net patients so their use is estimated as (26.0/74.0)*$1,375.4 million = $446.5 million
4. CSES estimate; 750 patients at $67,000 cost per patient, DoHA (2006a)
5. DoHA (2007c)
6. DoHA (2006b)
7. Public hospital recurrent expenditure on medicine supplies was $1,235.8 million in 2005-06 (AIHW 2007a) or $712.7 million net of public hospital HSD and other Section 100 cost ($523.1 million).
8. Private prescription medicines account for 3.9% of pharmacy sales, which are estimated as $12.5 billion in 2005-06 (Sweeny 2007b).

State Governments through public hospitals spend a further $712.7 million (7.3%) and the private prescription market is quite small at $487.5 million (5.0%). This latter figure is similar to the amount estimated to be spent by general non-safety net patients on medicines that cost less than the value of the general copayment and is not therefore picked up in official PBS data. It is interesting to note also that the bulk of cost under the RPBS is the use by RPBS cardholders of PBS items rather than use of those items that are only available on the RPBS itself.

Aside from the PBS and RPBS which are described further below, the other main Commonwealth pharmaceutical programs are the Herceptin Program, the Lifesaving Drugs Program, the National Diabetes Services Scheme and the National Immunisation Program. The Herceptin Program makes available the medicine *Herceptin* (trastuzumab) to women with HER2 positive late stage breast cancer. Since October 2006 *Herceptin* has also been listed on the PBS for women with HER2 positive early stage breast cancer. The Lifesaving Drugs Program provides 4 very expensive medicines to treat 3 rare life threatening diseases. One of these diseases is mucopolysaccharidosis type 1 and the medicine laronidase-rch will be provided to treat 8-12 patients a year at a cost of $16.4 million over 4 years (DoHA 2007c). The National Diabetes Services Scheme provides access to products and services needed for the self-management of diabetes at subsidised prices and includes syringes, insulin infusion pump consumables and glucose testing reagents. The National Immunisation Program provides funds to the States and Territories for mass immunisation against a range of communicable diseases.

The Pharmaceutical Benefits Scheme[1] is administered by the Commonwealth Department of Health and Ageing with transaction processing carried out by Medicare Australia on behalf of the Department. The operations of the PBS are governed by Part VII of the *National Health Act 1953* together with the *National Health (Pharmaceutical Benefits) Regulations 1960* made under the Act. The aim of the PBS is to provide "reliable, timely and affordable access to a wide range of medicines for all Australians". (DoHA 2007f).

The Act specifies that, in general, pharmaceutical benefits can only be paid on medicines dispensed by registered pharmacists on prescriptions written by qualified

medical practitioners (in practice doctors and dentists). The bulk of medicines consumed under the PBS are made available in this way as shown by the first section of Table 1.1. Aside from the "General" category which covers the vast bulk of PBS medicines, there is specific provision for a group of medicines (mainly anti-infectives and painkillers) which are prescribed by dentists ("Dental"), an allowance for emergency supplies of a range of medicines for doctors ("Doctor's Bag"), a group of medicines that are made up by pharmacists from basic materials ("Extemporaneous"), and a group mainly of painkillers, laxatives and other medicines to provide palliative care to dying people ("Palliative Care"). The Special Pharmaceutical Benefits section consists of those few medicines (9 at August 2007) on which the Government and supplier cannot agree on the price and a Special Patient Contribution is paid by the consumer.

Section 100 of the Act makes allowance for other conditions under which PBS medicines can be delivered. Based on this section, certain medicines are listed that can only be administered to patients in a hospital by specialist practitioners. These medicines include those listed under the Highly Specialised Drugs (HSD) program, which is by far the largest component at $522.0 million, as well as the following (at August 2007)

- Botulinum Toxin Program
- Chemotherapy Scheme
- Human Growth Hormone Program
- IVF/GIFT Program
- Opiate Addiction Treatment Program
- Special Authority Program
- Special Access Scheme

The HSD Program consists of about 72 medicines used to treat a range of conditions such as arthritis, HIV/AIDS and hepatitis while the Chemotherapy Scheme has 44 medicines used to treat cancer. The Botulinum Toxin Program and the Human Growth Hormone Program consist of one medicine each – botulinum toxin and somatropin respectively, while the IVF/GIFT Program covers 5 medicines used in in-vitro fertilisation and the Opiate Addiction Program comprises two medicines – methadone

and buprenorphine. The Special Authority Program consists of two medicines - Glivec (imatinib mesylate) and Herceptin (trastuzumab) which are both used to treat cancer.

## 1.4 The characteristics of medicines as products

Although a variety of naturally occurring substances have been used in the treatment of disease for millennia, the routine use of safe and effective medicines has mostly been a phenomenon of the past 100 years. Today there are thousands of medicines available to treat with varying degrees of effectiveness most common and many uncommon conditions and there is an increasing literature that quantifies the impact that medicines have had on extending life and decreasing the pain and suffering associated with disease (for instance Cutler et al 2007, Lichtenberg 2003, 2007, Lichtenberg and Virabhak 2007).

The literature concerned with the economics of the pharmaceutical[2] industry and pharmaceutical markets has emphasized a number of characteristics of medicines and their discovery, development, manufacture and distribution that differentiate them from most other consumer products.

Most people value health and longevity above virtually all other characteristics of life and, as economic well being increases, a greater proportion of spending is dedicated to achieving relief from suffering and to maintaining and improving health and well being. As medicines are one of the principal means for achieving these outcomes, they are hence a classical "superior" product in that their consumption rises with income and that consumption is relatively income elastic. On the other hand, most studies have found that the demand for medicines is relatively price inelastic (eg Berndt 2002, Ringel et al 2002).

*Experience versus search goods*

Consumer theory suggests that a consumer will make decisions by comparing the price and quality characteristics of competing goods and purchasing the product with the price and qualities that maximises the consumer's utility. Generally speaking price is known before the purchase is made but this is not necessarily the case with quality.

Nelson (1970) makes the distinction between "search" goods whose quality is known before purchase and "experience" goods whose quality and hence utility can only be assessed following their consumption and this often only after being consumed for a significant period of time. Examples of search goods are clothing and furniture while experience goods include financial advice and consumer electronics.

Medicines are a prime example of "experience" goods and this characteristic has often been cited in the literature to explain various aspects of the economics of pharmaceuticals.

Before purchase, the cost of acquiring information about different products is low for search goods, while for most experience goods acquiring useful information is either impossible or expensive. However this is not always the case - Nelson cites the example of deciding among differing brands of canned tuna by trying each before a final decision is made. For medicines however knowing the expected qualities and drawbacks of alternative treatments is difficult for the ordinary consumer to obtain.

Nelson draws a number of conclusions[3] about the two types of goods. There will be a greater degree of oligopoly in the supply of experience goods than for search goods because consumers will be willing to try more brands of search products and this affords more opportunity for a greater number of suppliers. The cost of trying different brands of experience goods will tend to restrict the number of competing brands. In addition if the frequency of purchase for a good is low this will also reduce the number of brands consumers will be willing to sample. In this situation, being first to market or attaining market leadership is very important. For medicines treating acute conditions such as peptic ulcers or bacterial infections, frequency of purchase is low for most consumers, while for medicines for chronic conditions, such as depression, patients are often unwilling to shift to alternative treatments once a satisfactory medicine has been found.

Consumers will seek to overcome the ignorance of the qualities of experience goods (and avoid sampling them at random) by seeking advice informally from friends or more formally from consumer reports which compare competing products across their quality characteristics. Advertising can also be a source of information about

particular brands. Advice will be sought more often the lower is the frequency of purchase. For medicines the primary source of information for patients is a medical practitioner, and hence most promotional activity by pharmaceutical companies is aimed at influencing doctors.

Retail outlets that sell search goods will tend to cluster more than stores that sell experience goods. This is because clustering cuts down the cost of comparing different brands and hence offers consumers a greater range of choice before purchase. Store location is less important for experience goods because decisions about them depend on consumption in the home. Unlike clothing or furniture stores therefore, pharmacies are not likely to cluster with other pharmacies.

Finally, the advertising for search goods is more likely to be specific to a particular retailer while advertising of experience goods is more likely to cover a wider area and not be location-specific.

The experience good nature of medicines and their perception as a particular type of superior good explains much of the other special characteristics of pharmaceuticals discussed below.

*Efficacy and side effects*

Although medicines are intended to treat a particular disease or condition by influencing the behaviour of a particular chemical pathway in the body, they often affect other parts of the body in unwanted ways leading to adverse reactions or side effects.

A particular patient's reactions to a medicine either in terms of achieving positive outcomes or experiencing side effects depend on a number of factors including the patient's genetic makeup and the particular circumstances of the illness, such as the presence of other illnesses. This variability means that some medicines will be ineffective for some groups of people, while some groups will suffer a certain range of side effects while others will not. Normally the body reacts to the presence of a foreign substance such as a medicine by changing it into another chemical and

eventually excreting it. The effectiveness of this process is governed by the extent to which a certain family of enzymes, CYP450, is expressed within the body. Individual variations in this process are determined in part by differences in particular genes. The more of this enzyme that is created, the quicker a medicine will be broken down and eliminated reducing its effectiveness as a treatment.

Because illness is common to most people at some time in their lives, and the product used to treat this illness has these characteristics, the State has increasingly intervened over time to regulate the production and sale of medicines. Initially this intervention was to ensure that medicines being offered to the public were safe and did not cause serious injury, death or other unwanted effects. The progressive tightening of the requirements to demonstrate safety was joined later by a concern to show that medicines were effective in treating the condition for which they were advertised. Most countries now require that companies wishing to sell a medicine within their jurisdiction provide evidence derived from clinical trials that the medicine is both efficacious and safe and this requirement has shaped the economics of the discovery, development, manufacture and sale of medicines.

### *Purchasing decisions*

An important determinant of outcomes in most markets is the extent of competition among the players, both on the demand side and the supply side.

The traditional neoclassic model of a market has a demand side characterised by a large number of consumers making purchasing decisions based on their incomes, the price of the product, the prices of alternative products, and a range of subjective factors such as tastes, preferences, and needs. On the supply side there are assumed to be a large number of suppliers for each product using broadly similar technologies, the result being that prices are likely to be driven down by competition to a value equal to the marginal unit cost of supply plus an average profit margin.

Pharmaceutical markets show characteristics significantly different from these assumptions. On the demand side, consumer decisions are usually not made by the final consumer (the patient) but by an agent (a health professional, usually a doctor).

Doctors prescribe medicines for patients based on their views about which medicine has superior therapeutic worth in treating the patient's condition. In reaching this decision, doctors draw upon a body of knowledge acquired by extensive education and training, a range of reference materials and refresher courses and their accumulated experience with conditions and treatments. General practitioners treat patients with a wider variety of conditions than do specialists who accumulate deeper knowledge and experience within a narrower range of conditions.

In most countries in most situations, the doctor's decision is only weakly influenced by the medicine's price, either in relation to the price of other medicines or in absolute terms.

The doctor and the patient can, to varying degrees, ignore the cost of the medicine in their decisions because, in most countries, an insurance intermediary, typically a government-controlled organisation, meets most of the cost. In Australia, there is effectively only one intermediary, the Pharmaceutical Benefits Scheme, which provides universal coverage, but also uses its monopsonistic strength to determine which medicines will be available and under what conditions, and to negotiate their prices with suppliers. Even in the USA which does not have centralized insurance intermediaries, it is estimated that only 19% of pharmaceutical expenditure in 2007 was met from out-of-pocket payments with 41% from public funds such as Medicare and 40% from private insurance (CMMS 2007).

*R&D, manufacturing costs and patents*

On the supply side, the pharmaceutical industry has a technology system dominated by a long, risky and expensive product development stage and a production process usually characterised by a small marginal unit cost of production and low barriers to entry. With the exception of a few medicines based on naturally occurring biological molecules, such as insulin and other hormones, most medicines until recent years have been small, low molecular weight compounds developed using synthetic chemistry. These have usually had low production costs. Over the past 15 to 20 years, biotechnology-derived medicines based on modifications of naturally occurring molecules in the body have begun to enter the market. These medicines are typically

much harder to manufacture in commercial quantities and to an acceptable standard of purity and safety, and are therefore considerably more expensive even without the addition of a premium to recover development costs. To date they have been used to treat mainly uncommon conditions so their overall cost to the health system has been low. This is now changing as expensive biotechnology-based medicines are becoming available to treat more common disorders such as cancer and rheumatoid arthritis.

The combination of high development costs and low manufacturing costs has meant that the only way pharmaceutical manufacturers can recover the large initial R&D costs incurred in developing new medicines, is for their products to be protected by patents which grant the patent holder a period of time during which they are the sole supplier. Patents are now granted for a period of 20 years, which usually means 8-10 years of market exclusivity before suppliers of generic equivalents are able to enter the market. Although the manufacturer of a new medicine can act as a monopolist supplier for this particular chemical compound, the new medicine will typically be competing with other established treatments in the form of medicines with varying degrees of similarity in chemical composition and action within the body.

Because a new medicine has patent protection, the supplier will seek to set a price that is significant multiples of the marginal unit cost of supply to recoup development costs. Once the patent has expired, other (generic) suppliers of chemically identical equivalents can enter the market at prices closer to marginal unit cost of supply. Because regulatory agencies ensure that these are genuinely equivalent, the originator supplier will compete with generic suppliers on the basis of brand differentiation and advertising.

A pharmaceutical company will market a new medicine if its expected revenue is sufficient to offset both the fixed and variable costs of its supply. The expected net revenue will depend on the expected level of sales and the price for the medicine. Medicines are usually manufactured at a few locations around the world to supply a multiplicity of markets. In the absence of significant barriers to trade, most countries will therefore face will face similar marginal unit costs of supply either for the active ingredient or the medicine made up into packs. The size of the market in Australia will limit the expected level of sales compared to larger economies such as the USA,

although other components of unit cost of supply such as administration and distribution could be significantly lower. In most jurisdictions the nature and extent of marketing is controlled and this component of cost is unlikely to be greatly different in Australia than for most other countries. Two countries – the USA and New Zealand - allow direct-to-consumer advertising of specific products but this form of marketing is usually restricted to a narrow range of products.

PBS price setting procedures, particularly the application of economic evaluation techniques and reference pricing, act to hold down the price of new medicines. These approaches to price setting are becoming more widespread among third-party payers (typically insurers) around the world, particularly in Europe, but even in some US markets.

It might be expected that, on balance the presence of the PBS and the smaller size of the market in Australia would deter the entry of more medicines than would be the case in larger markets such as the USA where the influence of price-negotiating intermediaries is much weaker. There should therefore be a greater degree of oligopoly in the supply of medicines in Australia, even after allowing for the patent protection given to new medicines.

The smaller size of the Australian market might also be expected to act as a deterrent to new suppliers of generic equivalents of off-patent medicines. A new supplier must compete against both the originator company and possibly established generic suppliers. The PBS sets virtually the same price for all suppliers of a particular medicine, so the ability for a new supplier to compete on price is limited. In addition it will face significant up-front costs in establishing a distribution and sales network.

The degree of market concentration in Australia compared to other countries is explored in Sweeny (2007b), which also demonstrates that assessments of market concentration within the PBS depend significantly on how pharmaceutical treatment markets are defined. This is the subject of the following section.

## 1.5 Development costs, productivity and regulatory approval

Because the process of developing a new medicine takes a long time, is characterised by a high failure rate and requires expensive testing in human clinical trials, the ratio of R&D expenditure to sales in the pharmaceutical industry is among the highest of any sector of the economy. For this reason pharmaceutical companies have invested heavily in technologies and techniques to improve success rates, increase productivity, and lower costs. Despite this, the cost of developing a new medicine has increased over time with the most recent estimates (DiMasi et al 2003, Tufts Center 2003) putting the average cost of developing a new medicine at US$897 million and the industry expects this to rise further in future (Davies 2006). The cost of developing biotechnology pharmaceutical products is even higher at US$1,241 million (Tufts Center 2006, Dimasi and Grabowski 2007). These estimates are the subject of some controversy (Public Citizen 2001, and reply by Dimasi et al 2005) because they include expenditure on successful and unsuccessful drug candidates as well as an allowance for the opportunity cost of capital over time. Similar results to those of Dimasi et al have been obtained by Adams and Brantner (2006) using publicly available data from Pharmaprojects, a company providing commercial information on the pharmaceutical industry.

It is becoming increasingly apparent that the usual approach by pharmaceutical companies to developing medicines is not as productive as it used to be.

Despite a large increase in spending on R&D, there has not been a proportionate increase in the number of new medicines reaching the market, as measured by the number of approvals by the United States Food and Drug Administration (FDA) (Figure 1.1), although this is to some extent explained by the increasing requirements of regulatory agencies and is offset by an increase in supplemental indications for already approved medicines.

**Figure 1.1 FDA approvals for new entities**
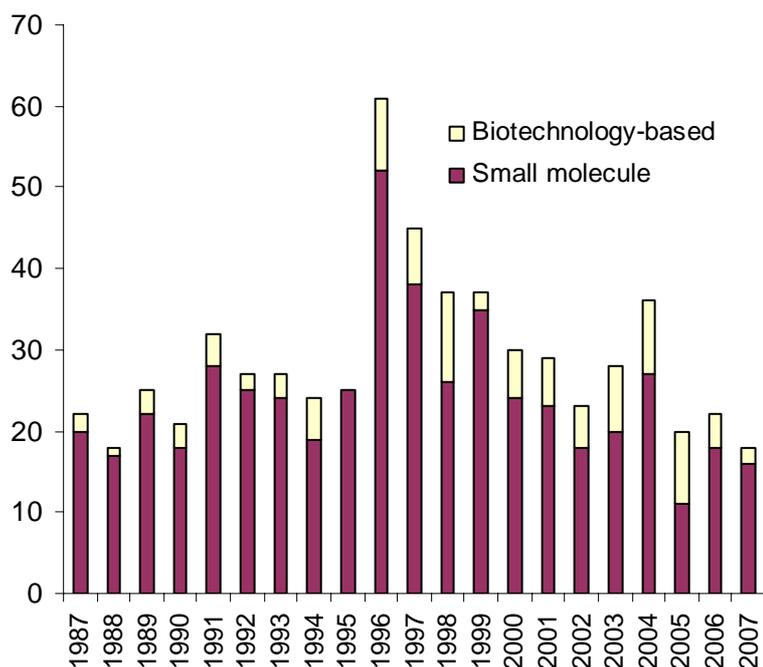


Source: FDA (2007a, 2007b), PAREXEL (2006).

In part this decreased productivity of R&D reflects the fact that the easier targets to treat have been addressed and it is inherently more difficult to treat conditions such as cancer and dementia for which existing treatments are inadequate. The switch by companies from developing traditional small molecule medicines to those based on biotechnology opens up a wider range of drug targets and potential drug candidates and promises to provide better treatments for these conditions, although there are still relatively few biotechnology medicines that treat widespread problems.

The process of bringing a new medicine to market is characterised by a number of distinct stages from initial discovery to final regulatory approval and is often referred to as the "drug pipeline". These stages are

- Discovery
- Preclinical testing
- Clinical trials (Phases I, II, and III)
- Application
- Approval

According to the FDA, only about 1 in 1,000 potential drug candidates get beyond the preclinical stage.

The outcome of the discovery phase is a handful of lead candidate compounds that have shown promising activity against a drug target. It is often at this stage that promising candidates are patented, typically for a 20-year lifespan. These candidates are subject to further testing for safety and efficacy firstly in a preclinical development stage and then in clinical trials using human patients.

The preclinical stage is really concerned with whether the compound can be made into a medicine that will treat the disease, is not toxic and has minimum unwanted side effects.

Clinical trials are used to test the efficacy and safety of new drugs in humans. In Phase I trials, the drug is administered to a small number (20-80) of healthy volunteers to test for toxicity and side effects and for correct dosage levels. In Phase II this is replicated in larger number (100-300) patients with the disease to be treated, while in Phase III trials yet larger numbers (1,000-3,000) of patients are used to verify the efficacy of the drug and to monitor adverse effects during longer-term use.

As might be expected from the number of patients involved, Phase III is the most expensive stage of developing a new medicine in terms of actual outlays, although earlier stages become more expensive if the cost of capital is taken into account. The first two columns in Table 1.2 show this based on estimates by Dimasi et al (2003). The time spent in each stage increases steadily with Dimasi et al estimating an average total time spent in clinical trials of 72.1 months, followed by a further 18.2 months in the final regulatory approval stage. The final two columns present alternative estimates from Abrantes-Metz et al (2004) of the probability of success at each stage and the mean duration in months in each stage based on an analysis of all medicines considered by the FDA between 1989 and 2002.

**Table 1.2    Drug development costs and times**

| | % of current clinical costs[1] | % of capitalised clinical costs[1] | Mean time in phase months[1] | Probability of success %[2] | Mean duration months[2] |
|---|---|---|---|---|---|
| Phase I | 12.2 | 31.3 | 12.3 | 80.7 | 19.7 |
| Phase II | 18.8 | 30.3 | 26.0 | 57.7 | 29.9 |
| Phase III | 69.0 | 38.4 | 33.8 | 56.7 | 47.0 |
| All phases | 100.0 | 100.0 | 72.1 | 26.4 | 96.6 |

Source 1: Dimasi et al (2003), 2: Abrantes-Metz et al (2004)

If a medicine successfully completes Phase III in the opinion of the company developing the medicine, the next step is to apply for regulatory approval. In Australia companies will usually also seek to obtain listing on the PBS.

Because of the size of the markets involved, most companies will seek to obtain approval for sale from the Food and Drug Administration (FDA) in the USA and from the European Medicines Agency (EMEA) in Europe. Since 1995, the approval of medicines in Europe has been carried out under the auspices of the EMEA, which makes use of national regulatory agencies for this purpose. Medicines applying for approval under the EMEA must include evidence of relative performance against a comparator medicine while in the USA the comparison may be made against a placebo only.

In Australia, companies wishing to market a medicine must apply to the Therapeutic Goods Administration (TGA, a unit of the Department of Health and Ageing) to have their product listed on the Australian Register of Therapeutic Goods (ARTG). Although medicines have been regulated in Australia by the Commonwealth Government in a systematic way since 1956, the current regulatory framework was established under the *Therapeutic Goods Act 1989* which created both the TGA (replacing the National Biological Standards Laboratory) and the ARTG from February 1991. McEwen (2007) provides a useful history of therapeutic goods regulation in Australia.

The TGA requirements for data from companies making applications are based on the European Union (EU) requirements and the TGA accepts data packages (or dossiers) in the European Union format (TGA 2007b). The guidelines for submissions are also very similar to those of the EU. For high priority medicines for important and serious

illnesses, which often include medicines to treat cancers, sponsors may, by prior agreement, submit the US dossier. In general however the TGA follows the EMEA approvals process quite closely.

The TGA has a system of priority evaluation for products that meet certain criteria. These are that 'the product should be a new chemical entity, that it is not otherwise available on the market as an approved product, and that the product is for the treatment of a serious, life-threatening illness for which other therapies are either ineffective or not available (that is, that the product should offer a significant therapeutic advance)' (TGA 2007b). Unfortunately the TGA does not indicate whether an approved medicine has been given a priority evaluation. The average evaluation time for a new chemical entity is about 300 working days or about 420 elapsed days (TGA 2007c).

Once regulatory approval has been granted, medicines may be sold within the jurisdiction of the regulatory authority. In Australia and many other countries in Europe and elsewhere, where a government insurance scheme dominates the market, there is likely to be further delay in the process of bringing the medicine to market company as companies seek inclusion in the scheme's formulary.

In the USA, once FDA approval is granted, market entry is quite quick, although the increasing scrutiny of third party payers and their agents, such as Prescription Benefit Managers (PBM), means that the situation in that country is becoming increasingly similar to that in Australia or Europe.

If a medicine is unsuccessful in obtaining a listing on the PBS, it can still be sold on the private market although this is often not a commercial proposition in Australia. Non-PBS medicines used in hospitals are not assessed by the PBAC.

The author has investigated the lags in approval for all medicines listed on the PBS for the period 1991 to 2006 (CSES 2007a, Sweeny 2007b). FDA, EMEA and ARTG approval dates were compared with PBS listing dates. The lag between the availability of medicines in the USA and their listing on the PBS is around 18 to 24 months on average although there is considerable variation among medicines. The lag between

availability in Europe and the PBS is between 12 to 18 months while the time taken from approval by the TGA to PBS listing is 9 to 12 months. In general all these lags have shown a tendency to increase over time, especially over the last few years.

## 1.6 Defining pharmaceutical treatment markets

When a pharmaceutical company develops a new medicine it is usually aiming to treat a single disease or condition or at least a very narrowly defined range of diseases and conditions. Before being able to market a new medicine, the supplier needs permission from the regulatory authority to do so, and this authority will stipulate which diseases can be treated with the medicine and under what conditions. Companies seeking to have other conditions treated by the medicine will need to go through the regulatory process again to obtain approval. Intermediaries, such as the PBS, may further restrict the range of diseases that the medicine can be used to treat and put additional conditions on their use.

There are some instances where a particular medicine will be able to treat more than one condition – painkillers and antibiotics are examples – but in most cases a medicine will be effective (or at least the first choice) only for a single disease or condition. This means that of the 680 medicines available through the PBS, for instance, only a handful will be effective against a particular disease and only this group of medicines can be regarded as competing with each other as the preferred treatment for that disease.

The limited extent of substitutability among medicines means that pharmaceutical companies can be regarded as competing within a large number of narrowly defined disease or treatment markets.

There are a number of ways in which these treatment markets can be defined. There is an increasing trend by medical practitioner groups, government agencies, insurers, and other organisations concerned with health to develop and promulgate therapeutic guidelines based on systematic reviews of the evidence available on suitable treatments for specific disease or groups of diseases. The Cochrane Collaboration founded in 1993 and responsible for the Cochrane Database of Systematic Reviews is

probably the best known of these efforts to "explore the evidence for and against the effectiveness and appropriateness of treatments (medications, surgery, education, etc) in specific circumstances" (Cochrane Collaboration 2007).

In particular areas of medicine, specialist associations are often responsible for undertaking these reviews. In the field of mental disorders, for instance, the American Psychiatric Association has produced the well known *Diagnostic and statistical manual of mental disorders* currently in its fourth edition (American Psychiatric Association 2007). The equivalent professional associations in Australia and the United Kingdom have released similar guidelines for mental health practitioners (RANZCP 2004 and Anderson et al 2004).

In Australia the campaign for evidenced-based medicines is carried out under the title of "Quality Use of Medicine" and has lead to the establishment of agencies such as the National Prescribing Service which promotes the findings to doctors and others responsible for treating ill health. Standard reference works for doctors incorporate these recommendations as do stand alone databases such as that provided by Therapeutic Guidelines Limited (2007).

One of the most widely used ways of classifying medicines in terms of their use is the Anatomical Therapeutic Classification (ATC), a classification scheme maintained by the WHO Collaborating Centre for Drug Statistics Methodology in Oslo, under which medicines are "divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties". (WHO Collaborating Centre 2007)

The table below gives the names for the five levels of classification within the ATC system as well the number of codes at each level at January 2007.

| Level | Title | Number | Code[*] |
|-------|-------|--------|---------|
| 1st | Anatomical main group | 14 | ATC1 |
| 2nd | Therapeutic subgroup | 94 | ATC3 |
| 3rd | Pharmacological subgroup | 265 | ATC4 |
| 4th | Chemical subgroup | 854 | ATC5 |
| 5th | Chemical substance | 4123 | ATC7 |

*The code ATCn is the author's and refers to the length (n) of the ATC code at that level.

The highest level - *Anatomical main group* – is a list of 14 bodily systems, such as the cardiovascular system, respiratory system, musculo-skeletal system and the nervous system. The fifth level, at the other extreme, is the particular medicine listed using its chemical name. Some of the medicines in the ATC system are listed with more than one ATC7 code because they can treat multiple conditions. There are some 252 medicines with 2 ATC7 codes, 67 with 3 codes and 53 with 4 or more codes.

To illustrate how the ATC scheme works an example of its application for PBS medicines to treat depression is given in Table 1.3 at the end of this section.

The *anatomical main group (ATC1)*, *N – Nervous system*, is made up of 7 *therapeutic subgroups (ATC3)* all of which contain medicines that act on various parts of the nervous system, namely

| ATC3 code | ATC3 name |
|-----------|-----------|
| N01 | Anaesthetics – for blocking pain and other sensations |
| N02 | Analgesics - painkillers |
| N03 | Antiepileptics – for treating epilepsy |
| N04 | Anti-Parkinson drugs – for treating Parkinson's disease |
| N05 | Psycholeptics – for treating psychosis and anxiety and for sedation |
| N06 | Psychoanaleptics – for treating depression, stimulants, dementia |
| N07 | Other nervous system drugs – for addiction, vertigo, Alzheimer's disease etc |

Each therapeutic subgroup is distinct and different in the types of illnesses that are treated by the medicines contained in the group. *Analgesics (N02)*, *antiepileptics (N03)* and *anti-Parkinson drugs (N04)*, for instance, are never used to treat depression.

Depression is sometimes accompanied by other nervous system conditions such as anxiety and *psycholeptics (N05)* could be co-prescribed in that case. One PBS medicine listed for depression, *lithium carbonate (N05AN01)* is classified within the N05 therapeutic subgroup.

The therapeutic subgroup *psychoanaleptics* (N06) is made up of 4 *pharmacological subgroups* (ATC4)

| ATC4 code | ATC4 name |
|---|---|
| N06A | Antidepressants |
| N06B | Psychostimulants, agents used for ADHD and nootropics |
| N06C | Psycholeptics and psychoanaleptics in combination |
| N06D | Anti-dementia drugs |

*Psychostimulants (N06B)* are used to treat conditions such as attention deficit hyperactivity disorder and narcolepsy and *anti-dementia drugs (N06D)* are used for dementia – in both cases these are nervous conditions quite different from depression. The pharmacological subgroup N06C consists of two antidepressants – amitriptyline and melitracen in combination with a psycholeptic but these combinations have never been available in Australia.

Within the pharmacological subgroup *Antidepressants (N06A)* there are 5 *chemical subgroups* (ATC5) which are principally differentiated by their mode of action within the nervous system, in particular which chemical pathways they attempt to modify.

| ATC5 code | ATC5 name | Mode of action |
|---|---|---|
| N06AA | Non-selective monoamine reuptake inhibitors (tricyclic antidepressants) | Nonselective uptake inhibitors of noradrenaline and serotonin |
| N06AB | Selective serotonin reuptake inhibitors | Selective inhibitors of serotonin uptake |
| N06AF | Monoamine oxidase inhibitors, non-selective | Irreversibly inhibit the enzymes MAO-A and MAO-B |
| N06AG | Monoamine oxidase type A inhibitors | Reversibly inhibit monoamine oxidase type A (MAO-A) |
| N06AX | Other antidepressants e.g. | Various |

Within each of these chemical subgroups the efficacy and side effect profiles of the individual medicines (ATC7) are quite similar. One of the drawbacks of the ATC system however is the inclusion of "residual" categories such as *N06AX – Other antidepressants* which include a more heterogeneous collection of medicines with somewhat different modes of action. Often medicines in these residual categories form the basis of new chemical subgroups on subsequent consideration by the WHO Centre.

The market for pharmacological treatments of depression using the ATC system therefore can only be considered as consisting of those medicines within the

pharmacological subgroup *N06A - Antidepressant* with the possible inclusion of *lithium carbonate* from *N05A* – a total of 23 PBS medicines at January 2007. However as Table 2.1 shows, this only represents about 40% of the 58 antidepressants within the ATC system.

At the beginning of 2007, only two of the listed PBS antidepressants – venlafaxine and reboxetine – were still protected by patents and the off-patent medicines had attracted varying number of suppliers. The most popular antidepressants, the selective serotonin reuptake inhibitors, had the most suppliers along with moclobemide. On the other hand some of the older medicines had more suppliers in earlier years, for instance amitriptyline which currently has only one supplier has had at least 3 others over the past 15 years. In total there were 29 suppliers of medicines within the pharmacological subgroup *N06A – Antidepressants*.

The example of the antidepressants suggest that markets for medicines can only be considered at their broadest at the ATC4 level and the degree of substitutability increases when moving from ATC4 to ATC5 and ATC7. At the ATC4 level the market consists of medicines that are suitable for treating a particular condition but vary significantly in their modes of action and side effect profiles. At the ATC5 level the medicines are quite similar in their action and chemical composition and usually their side effect profiles. At this level some medicines will be patent protected and some will be off-patent. Those off-patent will vary in the number of companies willing to supply that medicine. At the ATC7 level the market is for supply of the same chemical entity and products are only differentiated by their brand name, if the medicine is off-patent. Patent-protected medicines are monopolies by definition.

The ATC system is commonly used to classify medicines and is widely used in research on pharmaceutical markets. The largest supplier of data on pharmaceutical markets world-wide, IMS Health, for instance uses a modified version of the ATC system at the pharmacological subgroup level (ATC4) as a category for classifying medicines in its databases.

Despite this, the ATC system is not wholly definitive in terms of the degree of substitutability of medicines. The evidence presented by companies when seeking to

list medicines on the PBS is used by the Department of Health and Ageing as the basis for determining Reference Pricing Groups (RPG) which consist of medicines listed on a cost-minimisation basis and having a high degree of substitutability. More detail on listing procedures and RPGs are provided in Chapter 5.

In the case of antidepressants there are three such RPGs as shown in Table 1.3, the most important of which is that having the DoHA code N06(3) consisting of all the SSRIs (N06AB) plus moclobemide from ATC chemical subgroup N06AG and three medicines from the residual category N06AX. Reference Pricing Groups could therefore be used as an alternative way of classifying medicines in defining markets for treatments. The chief drawback however is that many medicines on the PBS have not been classified to an RPG. Among the antidepressants, clomipramine (N06AA04), nortriptyline (N06AA10), phenelzine (N06AF03), tranylcypromine (N06AF04), mianserin (N06AX03), and venlafaxine (N06AX16) do not belong to any of the RPGs.

Markets defined at the ATC5 level will vary in terms of the practical substitutability of medicines within that market. Although all the antidepressants have similar efficacy and side effect profiles, patients vary in their response to the different types of antidepressants and sometimes a doctor may have to try a number before a suitable one is found for a particular patient. Guidelines have been developed to advise doctors on how to undertake this experimentation to ensure patient safety and this in practice limits the degree of substitutability among antidepressants. On the other hand doctors freely switch between different versions of *proton pump inhibitors (A02BC)* a popular type of treatment for peptic ulcers, because there are no adverse consequences from doing so. Marketing efforts by pharmaceutical companies tend to be concentrated on markets like these where patients and doctors are largely indifferent to the range of medicines available and switching between medicines is common.

There were 151 different ATC4 codes, 315 different ATC5 codes and 634 individual ATC7 codes on the PBS at January 2007.

**Table 1.3    Types of antidepressants listed on PBS classified by ATC and RPG**

| ATC total | PBS total | RPG group | ATC code | ATC name | PBS suppliers at Jan 2007 |
|---|---|---|---|---|---|
| 532 | 115 | | **N** | **Nervous system** | |
| 96 | 28 | | **N06** | **Psychoanaleptics** | |
| 58 | 22 | | **N06A** | **Antidepressants** | **29** |
| 21 | 8 | | **N06AA** | **Non-selective monoamine reuptake inhibitors** | **9** |
| | | | N06AA01 | DESIPRAMINE HYDROCHLORIDE* | |
| | | N06(1) | N06AA02 | IMIPRAMINE HYDROCHLORIDE | 2 |
| | | | N06AA04 | CLOMIPRAMINE HYDROCHLORIDE | 5 |
| | | | N06AA06 | TRIMIPRAMINE MALEATE* | |
| | | N06(1) | N06AA09 | AMITRIPTYLINE HYDROCHLORIDE | 1 |
| | | | N06AA10 | NORTRIPTYLINE HYDROCHLORIDE | 1 |
| | | N06(2) | N06AA12 | DOXEPIN HYDROCHLORIDE | 2 |
| | | N06(2) | N06AA16 | DOTHIEPIN HYDROCHLORIDE | 2 |
| 9 | 6 | | **N06AB** | **Selective serotonin reuptake inhibitors** | **18** |
| | | N06(3) | N06AB03 | FLUOXETINE HYDROCHLORIDE | 10 |
| | | N06(3) | N06AB04 | CITALOPRAM HYDROBROMIDE | 9 |
| | | N06(3) | N06AB05 | PAROXETINE HYDROCHLORIDE | 8 |
| | | N06(3) | N06AB06 | SERTRALINE HYDROCHLORIDE | 9 |
| | | N06(3) | N06AB08 | FLUVOXAMINE MALEATE | 5 |
| | | N06(3) | N06AB10 | ESCITALOPRAM OXALATE | 2 |
| 6 | 2 | | **N06AF** | **Monoamine oxidase inhibitors, non-selective** | **2** |
| | | | N06AF03 | PHENELZINE SULFATE | 1 |
| | | | N06AF04 | TRANYLCYPROMINE SULFATE | 1 |
| 2 | 1 | | **N06AG** | **Monoamine oxidase type A inhibitors** | **9** |
| | | N06(3) | N06AG02 | MOCLOBEMIDE | 9 |
| 20 | 5 | | **N06AX** | **Other antidepressants** | **7** |
| | | | N06AX03 | MIANSERIN HYDROCHLORIDE | 2 |
| | | N06(3) | N06AX06 | NEFAZODONE HYDROCHLORIDE* | |
| | | N06(3) | N06AX11 | MIRTAZAPINE | 5 |
| | | | N06AX16 | VENLAFAXINE HYDROCHLORIDE | 1 |
| | | N06(3) | N06AX18 | REBOXETINE MESILATE | 1 |

* No longer listed on the PBS – trimipramine since November 1999, desipramine since February 2002 and nefazodone since May 2004.

[1] Duckett (2004) provides a useful recent summary of various aspects of the Pharmaceutical Benefits Scheme.

[2] The terms "medicine", "pharmaceutical" and "drug" are used interchangeably in the literature. Because the word "drug" can also be used in reference to the manufacture and consumption of substances that are illegal, the pharmaceutical industry in Australia favours the word "medicine" to describe its products to avoid this connotation. While "medicines" is unambiguous, "medicine" of course also refers to the more general alleviation of disease. The term "pharmaceutical" is defined as pertaining to pharmacy or pharmacists indicating that the pharmaceutical industry is based in part on the science of pharmacy and that its products are made available to the public by people qualified in this science.

[3] The following discussion is a modified version of the conclusions found in Nelson (1970)

# Chapter 2

# PBS Listing and Pricing Procedures

## 2.1 Introduction

This chapter sets out the procedures that the Government uses in determining whether and under what conditions a medicine will be listed on the PBS. Companies wishing to list their medicines on the PBS must apply in a standard format and include evidence about the performance of their medicine against a comparator in terms of efficacy, safety and cost.

Companies can argue on a cost-effectiveness basis that their medicine is superior to the comparator justifying a price premium or on a cost-minimisation basis which means their medicine is equivalent to or no worse than the comparator and is priced accordingly. Data is presented on the success rates of these types of applications. Medicines listed on a cost-minimisation basis form Reference Pricing Groups and the prices of members of RPGs are set together. This, along with other mechanisms such as WAMTC groups, provides the means for the Government to exert a large degree of control on the prices of PBS medicines.

In addition to setting the initial and subsequent prices of medicines, the Government also influences the demand for medicines through the level and nature of restrictions it sets on the conditions for which a doctor may prescribe a medicine. These restrictions have become generally tighter over time.

The PBS listing procedure determines the price which the wholesaler charges the pharmacist. The price paid by the wholesaler to the supplier is determined by the Government through a formula, as is the dispensed price charged by the pharmacist. These formulas are described in Section 2.3. Evidence is presented showing that the real value of the dispensing fee set for pharmacists under the Community Pharmacy Agreements decreased steadily for much of the past 15 years.

The chapter concludes with a description of policy changes introduced by the Government since 2005. The other major Government program providing pharmaceutical benefits – the Repatriation Pharmaceutical Benefits Scheme – is described in Sweeny (2007a).

## 2.2 PBS listing and pricing procedures

As is the case in most comparable countries, the PBS provides medicines from a formulary based on a positive list (Jacobzone 2000), requiring suppliers ("sponsors") to apply to have their medicines made available for subsidy. Negative lists, on the other hand, allow all medicines to be subsidised unless specifically excluded by the listing authority. The United Kingdom is an example of a country operating a scheme with a negative list.

The process to gain PBS listing is shown in Figure 2.1 reproduced from PBPA (2006). The two main organisations involved are the Pharmaceutical Benefits Advisory Committee (PBAC) which recommends to the Minister for Health and Ageing which medicines and medicinal preparations should be listed on the PBS and under what conditions, and the Pharmaceutical Benefits Pricing Authority (PBPA) which recommends to the Minister the price at which they should be listed. The PBAC was established as an independent statutory body in 1953 and the PBPA was formed in January 1988.

Medicines with an estimated cost to the PBS of over $5 million per year must be approved by the Department of Finance and Administration, while those expected to cost over $10 million per year must be approved by the Cabinet of the Commonwealth Government. For medicines expected to cost less than $5 million, the decision on listing is made by the Minister for Health and Ageing.

In response to a range of queries and complaints about the nature and transparency of the procedures for listing and pricing medicines, the PBPA has provided a regularly revised outline of these processes in its *Policies, Procedures and Methods Used in the Pricing of Pharmaceutical Products*, the most recent edition of which at time of writing is May 2006 (PBPA 2006).

**Figure 2.1    Process to gain PBS listing for registered medicines.**
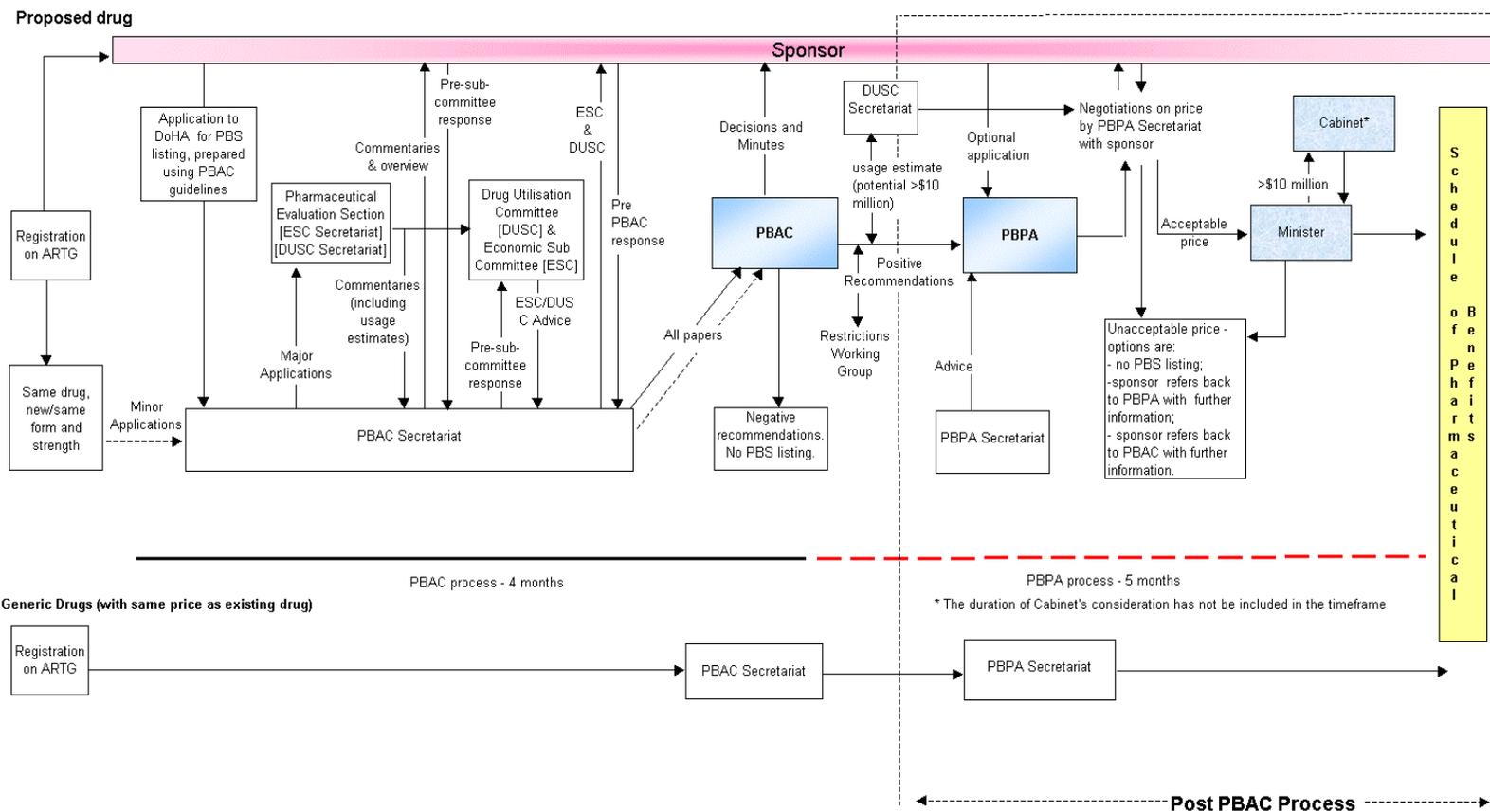


Source: reproduced from PBPA (2006)

In addition, the DoHA has prepared *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee* (*Guidelines*) (DoHA 2006d) to assist sponsors. The latest and most comprehensively revised edition of this latter document is for December 2006. These two documents are the source for much of the description of the processes of the PBS in this section.

The PBS *Guidelines* were developed based on a body of economic theory and analysis, known as pharmacoeconomics, that was developed to provide a rationale for decisions about the price to be paid for medical treatments and the conditions of their availability. The application of this literature to procedures for pricing and listing PBS medicines was proposed in an influential report to the then Department of Health, Housing, Local Government and Community Services in December 1989 (Evans et al 1993), which sets out in some detail the arguments in favour of the use of cost-minimisation, cost-effectiveness, and cost-utility analysis and against the use of cost-benefit analysis. The report draws on several sources, principally, Drummond (1987), Torrance (1987) and Torrance and Feeny (1989). A partial list of the subsequent literature on aspects of the application of economic analysis to PBAC decision making is available at DoHA (2005d).

### 2.2.1 PBAC evaluation of medicines

Prior to a decision by the PBAC, a medicine seeking a PBS listing must be approved by the Therapeutic Goods Administration (TGA), the body responsible in Australia for approving all medicines, and be registered on the Australian Register of Therapeutic Goods (ARTG) for specific therapeutic indications. Submissions to the PBAC however, can be made once a positive recommendation by officers of the TGA has been made to its Australian Drug Evaluation Committee (ADEC) and prior to final marketing approval.

An amendment to the *National Health Act* in 1987 required the PBAC to consider comparative effectiveness and cost in making its recommendations. From 1991, submissions by sponsors began to include an economic analysis and from January 1993 this was made mandatory (Birkett et al 2001).

The PBAC describes the guidelines governing its activities as follows:

> "To assess value for money, PBAC considers the clinical place, overall effectiveness, cost and cost-effectiveness of a proposed drug compared with other drugs already listed in the PBS for the same, or similar, indications. Where there is no listed alternative, PBAC considers the clinical place, overall effectiveness, cost and cost-effectiveness of the proposed drug compared with standard medical care. On the basis of its community usage, PBAC recommends maximum quantities and repeats and may also recommend restrictions as to the indications where PBS subsidy is available… For acute medical conditions, the maximum quantity is usually sufficient for a normal single course of treatment (bearing in mind the size of the manufacturer's pack). For chronic medical conditions, the maximum quantity and repeats usually provide up to six months' therapy, depending on the need for clinical review of the condition to be treated." (*Guidelines* p5)

Further,

> "A new drug may be recommended for listing if:
> - it is needed for the prevention or treatment of significant medical conditions not already covered, or inadequately covered, by drugs in the existing list and is of acceptable cost-effectiveness
> - it is more effective or less toxic (or both) than a drug already listed for the same indications and is of acceptable cost-effectiveness
> - it is at least as effective and safe as a drug already listed for the same indications and is of similar or better cost-effectiveness." (*Guidelines* p6)

### 2.2.2 Submissions to the PBAC

Suppliers proposing to have a new product listed on the PBS are required to follow a specified application procedure (as described in the *Guidelines*) and to provide a range of information including the cost of the new medicine and its proposed price, as well as an economic evaluation in order for the PBAC to 'evaluate the costs

associated with the new drug, or indication, against the benefits gained from its use, and compare that cost-outcome ratio to existing therapy. New drugs are most commonly recommended by the PBAC on the basis of either cost minimisation or an acceptable incremental cost effectiveness ratio (ICER).' (PBPA 2006, p 12).

The PBAC distinguishes between major and minor submissions. The latter do not require an economic evaluation and these cover

- listing a new form (or strength) of a currently listed drug for which a price advantage is not requested, or for which the likely volume and proportion of use is expected to be small
- changing the maximum quantity per prescription of a currently listed drug
- changing the number of repeats per prescription of a currently listed drug
- clarifying the wording of a restriction (while not altering the intended use).

New brands of listed medicines, ie generic equivalents, are dealt with by the DoHA rather than the PBAC. Suppliers to the PBS of brands of a medicine competing with an originator brand of the same medicine have the option to say in the PBS Schedule whether their brand is bioequivalent to the originator brand.

On the other hand, major submissions are required when applying to

- list a new drug (including a new fixed combination product, a new nutritional product, a new vaccine or a new orphan drug)
- substantially change the listing of a currently restricted drug (including a new indication or a change in restriction)
- enable a review of the comparative cost-effectiveness of a currently listed drug in order to change a PBAC recommendation to the PBPA on its therapeutic relativity or price advantage
- list a new form (or strength) of a currently listed drug for which a price advantage is requested.

### 2.2.3 Types of economic analysis

The guidelines for a major submission to the PBAC specify that the submission have 6 sections (A to F) of which the most important are those that compare the outcomes from clinical trials of the proposed medicine and its comparator (Section B), the translation of this evidence into the Australian PBS context (Section C) and the presentation of the economic analysis based on the evidence in these two sections (Section D). A description of the contents of a major submission is provided in Sweeny (2007a).

The evidence presented from clinical trials is used to guide the choice of which type of economic analysis is recommended to the sponsor - in particular the choice between a "cost-minimisation" analysis and a "cost-effectiveness" analysis.

After a discussion of what the clinical trial data should encompass, the guidelines present a table in Section B (p 88) which categorises the comparison of clinical trial data for the proposed medicine and its comparator in two dimensions – comparative effectiveness in treating the condition for the medicine seeking listing and the comparative safety in terms of side effects and adverse events associated with use of the medicine. For both dimensions there are four states – "Inferior", "Uncertain", "Noninferior", and "Superior". While the first and last of these categories are relatively straightforward, "Uncertain and "Noninferior" require further elaboration.

> "'**Uncertainty**' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations (eg where the toxicity profiles of the compared drugs differ, with some aspects worse for the proposed drug and some aspects better for the proposed drug)." (*Guidelines* p88)

> "**Noninferiority** means that, in terms of effectiveness, the proposed drug is no worse than its main comparator. It is used to support a claim of equivalence because it is not adequate to demonstrate the absence of a statistically significant

difference between the treatments to claim equivalence; such a lack of a significant difference might occur when the trials are too small to demonstrate a real difference in the effects of the interventions. The appropriate comparison to present is the point estimate of the difference with its 95% confidence interval. This allows PBAC to assess whether the confidence interval contains the minimal clinically important difference." (*Guidelines* p69)

The essential difference between assessing whether the proposed drug is superior or noninferior to the main comparator is that the 95% confidence interval for superiority excludes the possibility that there is no difference between the therapies, whereas the 95% confidence interval for noninferiority excludes the possibility that the proposed drug is inferior to a clinically important extent. (*Guidelines* p88)

The table is reproduced below where the text in the cells indicates the recommended form of economic analysis, namely

CMA = cost-minimisation analysis
CEA = cost-effectiveness analysis
CUA = cost-utility analysis

| Comparative safety | Comparative effectiveness | | | |
|---|---|---|---|---|
| | **Inferior** | **Uncertain\*** | **Noninferior\*\*** | **Superior** |
| **Inferior** | Health forgone: need other supportive factors | Health forgone: need other supportive factors | Health forgone: need other supportive factors | ? Likely CUA |
| **Uncertain\*** | ? | Health forgone: need other supportive factors | ? | ? Likely CEA/CUA |
| **Noninferior\*\*** | ? | Health forgone: need other supportive factors | CMA | CEA/CUA |
| **Superior** | ? Likely CEA/CUA | ? Likely CUA | CEA/CUA | CEA/CUA |

The table infers that if the comparative effectiveness is either "Inferior" or "Uncertain" the PBAC discourages any form of analysis unless superior safety is demonstrated. If the comparative effectiveness of "the proposed drug is no worse than (or noninferior or equivalent to) the main comparator, there is no basis in terms of health outcomes to justify a higher price (unless there are cost offsets due to a different method of administering the proposed drug). A cost-minimisation analysis is therefore appropriate." (p 89)

For situations where comparative effectiveness is "Superior", "a cost-effectiveness analysis or cost-utility analysis is appropriate to determine whether the increase in health outcomes (and any cost offsets) justifies the increase in drug costs (and hence increased price) in terms of being acceptably cost-effective. If there are uncertainties and/or trade-offs across health outcomes (eg both increased effectiveness and reduced safety or differing safety profiles), a cost-consequences analysis is appropriate to present these results in a disaggregated way against the costs and, if it helps to reduce the uncertainty and/or quantify the trade-offs, a cost-utility analysis would also be appropriate." (p 89)

Where noninferiority is used as the basis of the submission, the cost-minimisation analysis required is much simpler than either a cost-effectiveness or cost-utility analysis, because the problem for the sponsor becomes one of demonstrating the costs of the proposed medicine and its comparator in achieving the same level of effectiveness.

If the sponsor is claiming the proposed medicine is therapeutically superior to the main comparator, the Guidelines set out four types of economic evaluation that could be used (p 116-117), namely

> *"Cost-utility analysis (generally preferred)*
>
> A cost-utility analysis presents the health outcome in terms of the life-years gained from the start of the analysis, with each life-year adjusted by a utility weight that is society's preferences for the health outcome experiences in that life-year relative to full health. The ultimate benefit of restored health is the

restoration of health-related quality of life, for example restoration of opportunities to undertake activities of daily living. Economists have attempted to identify the value placed by individuals on different health states. The basis for this valuation is that each increment in health related quality of life gives satisfaction (measured as the strength of preference for the restored health over the pre treatment state of health and termed 'utility' by economists), which is the ultimate outcome of life. The denominator in a cost-utility analysis is most commonly the incremental QALY [quality-adjusted life year] gained, which is the difference between the two profiles following the use of the proposed drug or its main comparator, each calculated as the times spent in successive varying health states, with each period of time weighted by the strength of preference for, or the utility weight of, its respective health state…

*Cost-effectiveness analysis*

A cost-effectiveness analysis measures the incremental cost per extra unit of health outcome achieved. That is, it differs from a cost-utility analysis in that the health outcome is reported in its natural units. If the proposed drug is demonstrated to offer more of a given health outcome than its main comparator (eg it achieves the desired health outcome in a higher proportion of patients), this goes beyond cost minimisation...

*Cost-benefit analysis (supplementary option)*

A cost-benefit analysis expresses all outcomes (health and non health) valued in monetary rather than natural or utility units. This is in contrast to other forms of economic evaluation and requires a monetary valuation of these outcomes… Cost-benefit analysis can also include both health and non health outcomes.

*Cost-consequences analysis (if disaggregation of outcomes would be helpful)*

A cost-consequences analysis compares the incremental costs of the proposed drug over its main comparator with an array of outcomes measured in their natural units rather than a single representative outcome as presented in a cost-

effectiveness analysis. It can be presented if the proposed drug is demonstrated to have a different profile of effects that are not adequately captured by a single outcome measure; there might be trade-offs between the two drugs in terms of the directions of the changes in effectiveness and safety (and within effectiveness and safety). As such, it is a form of disaggregated analysis of changes in patterns of health care resource provision and changes in health outcomes and can be presented before presenting other types of aggregated economic evaluation, such as a cost-utility analysis."

From these descriptions it can be seen that CUA is the preferred form of economic analysis, a view reinforced by Evans et al (1993). In practice however, if the health outcomes being compared between the proposed medicine and its comparator are straightforward, there seems to be little difference between CEA and CUA other than that a value in utility units is given to the health outcomes in CEA. Because of this most classifications of PBS medicines, for instance in therapeutic reference groups, just distinguish between "cost-effectiveness" and "cost-minimisation".

It is also clear from a reading of the *Guidelines* that while cost-benefit analysis is listed as a possible form of economic analysis, in practice sponsors are strongly discouraged from presenting submissions based on this type of analysis. Appendix 7 of the *Guidelines* presents a list of reasons for avoiding cost-benefits analysis, including the difficulties of valuing health states and the inclusion of non-health outcome benefits. However some of the objections in terms of the subjectivity of valuation could also be made against the utility weights used in CUA to weigh health states in calculating QALYs.

In providing a rationale for the need for an economic analysis, Evans et al (1993) note that "Efficiency analysis has been applied to new medical technologies, including pharmacological agents, in an attempt to ensure that the resources allocated to them would not have produced greater benefits if used elsewhere. This involves comparing the benefits which would have been produced by the new technology with the benefits which would have been produced by the same resources in alternative uses." (p 10). Again this seems to be an argument for cost-benefit analysis which is then refuted in the rest of the report.

While the PBAC argues strongly that its terms of reference restrict it to a narrow comparative assessment of the health-related outcomes and costs associated with a proposed medicine and its comparator, Islam and Mak (2002) have made a case for an approach based on cost-benefit analysis which encompasses a broader range of outcomes (including social outcomes) and costs. This type of analysis however is best used when making decisions from a whole-of-government perspective.

All three approaches to economic analysis – CMA, CEA and CUA – are aimed at producing a metric, in the form of health outcome per dollar of cost, for both the new medicine and the comparator, to enable comparison between the two. If, for instance, a new medicine is proposed that treats hypertension (ie high blood pressure), the health outcome might be units of blood pressure reduced per dollar.

The *Guidelines* draws a distinction in measurement of health outcomes between *surrogate (*or *intermediate) outcome indicators*, which measure the change in physical outcome which is believed to be associated with an improvement in health status, and *final outcome indicators* which measure the change in health status. For example, in the treatment of hypertension, an intermediate outcome might be the change in blood pressure, while the final outcome might be the number of years of life saved by avoiding deaths from heart attack or stroke. Clinical trials can provide evidence on intermediate outcomes but it is usually harder to measure final outcomes because it may require many years and/or very large samples before the differences in outcomes become apparent.

The difference between intermediate and final outcomes becomes important when there are multiple outcomes associated with a medicine and the profile for the new medicine is different from that of the comparator. As an example, an antidepressant medicine may reduce the number of deaths from suicide and also improve the quality of life for sufferers by alleviating their depressive feelings. In this case it is necessary to combine these outcomes into a single measure, which means that the individual measures all be expressed in the same units. Typical final outcome units are deaths prevented, life-years gained or quality-adjusted life-years gained.

In cost-utility analysis, utilities are measured by QALYs and there is a substantial literature on how these should be quantified. A considerable amount of effort has gone into expressing disease states within a society in terms of their effects from years of life lost due to premature mortality (YLL) and/or from years of life lost due to disability (YLD). These can be combined to form disability-adjusted life-years which are now more commonly described as quality-adjusted life-years (QALYs). These QALYs have been used to estimate the overall burden of disease within societies (eg Mathers et al 1999) and as a method of determining priorities within health programs, such as the PBS.

In calculating the health outcome ratio, the costs measured are the same for all three methods. The Guidelines specify that only direct costs for both the new medicine and the comparator be included. These consist of

- the cost of the medicine
- the cost of all other medical resources which need to be used in conjunction with the medicine
- the cost of medical resources used in treating side effects associated with the medicine

An analysis which includes all direct costs for both the new medicine and comparator will pick up any savings in medical costs arising from using the medicine (for instance, savings in the cost of hospitalisations avoided through using the medicine). The *Guidelines* discourage the inclusion of any indirect benefits, such as those accruing to an individual patient. It argues that benefits to patients from returning to work earlier through use of the new medicine can contribute to the patient's well-being but do not provide a net benefit to society as a whole, because among other things, an unemployed worker will replace a worker absent through illness.

### 2.2.4 PBAC outcomes

When it assesses submissions by sponsors to list medicines on the PBS, the PBAC makes one of four decisions

- Positive recommendations; or
- 1st time decisions not to recommend; or
- "Subsequent decisions" not to recommend; or
- Deferrals

A sponsor has the option of resubmitting an application a number of times if it does not receive a positive recommendation, and for a few medicines this means that it can be a substantial period of time before a final outcome is known.

Publicly available information on the decisions of the PBAC on sponsors' submissions has only been available for about seven years. Since its December 1999 meeting, the PBAC has posted its positive recommendations on the DoHA web site, and since June 2003 it has included the other types of decisions (DoHA 2007e). In addition, since July 2005, it has also published Public Summary Documents (DoHA 2007g, 2007h) which summarise the information contained in company submissions to the PBAC and the PBAC's comments on the submissions. Importantly these documents include information on the medicine and its comparator, and estimates of the impact on PBS cost.

Based on this source of information it is possible to give some summary information on the PBAC processes. The consultancy firm Pretium has examined all decisions taken since June 2003 and has calculated the probability of success for the two types of submission – cost-effectiveness and cost-minimisation – for new listings, new indications and other types of listings (Lush Media 2006). Table 2.1 shows the cumulative results for the period June 2003 to July 2006.

Overall the probability of success for a submission seeking a listing for a new medicine is 53.3% while for a submission seeking a new indication for a medicine already listed it is 54.5% and for submissions for other changes for a medicine already listed it is 86.3%. While virtually all new medicines with a CM submission gain listing (94.7%), less than a third of CE submissions are successful (31.3%). The probabilities are a little higher for submissions for new indications (100.0% and 35.9%), and significantly higher (45.2%) for CE submissions seeking other changes to listing.

**Table 2.1    PBAC outcomes, June 2003 to July 2006**

|  | Type of analysis | Positive | Other | Total | Positive as % |
|---|---|---|---|---|---|
| New listing | CE | 20 | 44 | 64 | 31.3 |
|  | CM | 36 | 2 | 38 | 94.7 |
|  | Other | 0 | 3 | 3 | 0.0 |
|  | Total | 56 | 49 | 105 | 53.3 |
| New indication | CE | 14 | 25 | 39 | 35.9 |
|  | CM | 14 | 0 | 14 | 100.0 |
|  | Other | 2 | 0 | 2 | 100.0 |
|  | Total | 30 | 25 | 55 | 54.5 |
| Other | CE | 14 | 17 | 31 | 45.2 |
|  | CM | 53 | 3 | 56 | 94.6 |
|  | Other | 134 | 12 | 146 | 91.8 |
|  | Total | 201 | 32 | 233 | 86.3 |
| Total |  | 287 | 106 | 393 | 73.0 |

Source: Lush Media (2006)

Among the successful new listing submissions, 35.7% were cost-effectiveness based while 64.3% were based on cost-minimisation analyses. For successful new indication submissions the proportions were evenly divided at 46.7% with 6.7% based on other kinds of analyses.

Although the PBAC may make a positive recommendation, this does not necessarily mean that the medicine will be listed on the PBS, as it requires further consideration by the PBPA, the Minister for Health and Ageing and possibly the Department of Finance and Administration and the Cabinet.

Using the information from the published PBAC decisions, as well as descriptions contained in the Therapeutic Relativity Sheets (DoHA 2007k) described in Section 2.2.5 below, it is possible to determine the basis upon which some of the medicines were finally listed on the PBS. Of the 412 medicines listed after July 1991, there were 251 for which a listing basis could be determined. Of these there were 50 medicines with a cost-effectiveness listing, 180 with a cost-minimisation listing and 21 medicines which had cost-effectiveness listings for some indications and cost-minimisation listings for other indications. Allocating these 21 to both the other groups results in 71 cost-effectiveness listings and 201 cost-minimisation listings. The resulting estimate of 26.1% of identifiable listings being on a cost-effectiveness basis is somewhat less than the 35.7% of positive PBAC recommendations accounted for

by CE submissions, although the two numbers are based on analyses over different periods of time.

George et al. (2001) reviewed all 355 submissions to the PBAC between 1991 and 1996 and found that there 125 cost-effectiveness analyses (35%), 98 cost-minimisation analyses (28%), 3 cost-utility studies (3%), and 129 pseudo cost-effectiveness, other, or no analyses (24%). Of these only 33 (or 26% of the cost-effectiveness and cost-utility analyses) provided an analysis with final outcomes either in the form of life-years gained (26) or in QALYs (9).

For those submissions with final outcomes measured in life-years gained, the PBAC did not reject any new medicine with an incremental cost per additional life-year gained of less than $42,697 (at 1998-99 prices). On the other hand it did not unequivocally recommend any new medicine with a value above $75,286. Within this range 4 medicines were recommended and 5 rejected or deferred. Based on these findings, George et al assert that the PBAC appears to have a threshold value of between $42,000 and $65,000 for a life-year. They recognise that these estimates may include life-years of less than perfect health which may have been implicitly recognised by the PBAC in its decisions. The width of the threshold range may also indicate that the PBAC is guided by factors other than strict economic efficiency in its recommendations.

The number of analyses using QALYS as final outcomes was too small to make any meaningful estimate of an implicit threshold for an incremental cost per QALY.

Abelson (2003) has estimated the value of a life-year in Australia at $108,000. Sweeny (2003) has indirectly estimated the value of a life-year at between $100,000 and $200,000 based on a range of US and Australian studies (Viscusi 1993, Murphy and Topel 1999, Cutler et al 2000, Nordhaus 2002, Viscusi and Aldy 2003, Kniesner and Leeth 1991, Miller et al 1997). These values for a life-year suggest that the PBAC may be setting too low an implicit value and therefore rejecting medicines that might otherwise be accepted.

Birkett et al (2001) examined all submissions between 1993 and 1999 and of these 39% were cost-minimisation analyses, 36% cost-effectiveness analyses, 5% cost-utility analyses and 20% partial analyses. Over the period the proportion of cost-minimisation (50%) and cost-utility (16%) analyses increased while that of cost-effectiveness (24%) and partial (10%) analyses decreased (the numbers in brackets being for 1999).

## 2.2.5 PBPA pricing processes

The Pharmaceutical Benefits Pricing Authority (PBPA) within the Department of Health and Ageing has responsibility for determining the price of both new medicines entering the PBS and of medicines already on the PBS. In doing so it acts on the advice of the PBAC as to clinical and cost effectiveness and in making decisions considers a range of factors, the most important of which are

- The proposed price for the medicine
- The prices of other medicines in the same therapeutic group
- Cost data obtained from sponsors, and
- Overseas prices (UK and New Zealand).

While the level of activity of the company in Australia in new investment, production and research and development is still formally a factor (Factor (f)), in practice this is no longer taken into account.

### *Pricing new medicines or new indications*

For new medicines, or when new indications are requested for existing PBS medicines, the PBPA pricing procedure depends on whether the PBAC recommended the medicine on the basis of cost-effectiveness or cost-minimisation. In the case of cost minimisation, the medicine is priced at the level of the lowest price comparative medicine. Sometimes the price is adjusted if the costs of administration vary between say an orally administered tablet and an intravenous infusion. However this adjustment is not made in all cases.

For medicines recommended on the basis of cost-effectiveness, the process seems to be less straightforward. If the PBAC suggests that incremental cost effectiveness ratios are 'high' but 'acceptable', the PBPA will probably not accept the price requested by the sponsor but seek a lower price. For medicines recommended without this qualification the PBPA is not explicit about the extent to which it accepts the price nominated by the sponsor in the cost-effectiveness analysis. However it does say that if "a sponsor demonstrates to the PBAC a clinical advantage for a particular drug over alternative products (recommended on the basis of acceptable cost effectiveness) then that drug may be granted a higher subsidised price over the alternative." (PBPA 2006 p 9).

The PBPA describes three methods of determining prices, namely

- Cost Plus Method,
- Reference Pricing, and
- Weighted Average Monthly Treatment Cost (WAMTC)

but it is clear from the descriptions of each that the last two are only applied for medicines recommended on a cost-minimisation basis. The prices for cost-effectiveness medicines must therefore be determined using the *Cost Plus Method*, which aims to set the price based on a gross margin of around 30% on the cost of manufacture. Higher margins are accepted for medicines with a low volume while lower margins may be sought for high volume products. Here the cost of manufacture includes a variety of costs, such as landed costs, packaging, quality assurance, plant and equipment, manufacturing overheads and TGA fees.

There is no readily available information on how much the final price for cost-effectiveness medicines determined in this way departs from that used in the sponsor's economic analysis for calculating the incremental cost effectiveness ratio.

*Reference Pricing* occurs when medicines are recommended on the basis of cost-minimisation, and with this approach 'the lowest priced brand or drug sets the benchmark price for either the other brands of that drug or the other drugs within the same therapeutic group. Pricing within these therapeutic groups is based on

therapeutic relativities between drugs as noted on the therapeutic relativity sheets…Therapeutic relativity sheets show specific relativities and pricing comparisons between drugs with a therapeutic group and form the basis of pricing decisions made by the PBPA. The relativities are usually based on PBAC advice but may also be historically based.' (PBPA 2006 p 9, 16)

The relativity sheets are regularly updated and published (DoHA 2007k), but it is somewhat difficult to use their descriptions to identify completely the cost-minimisation therapeutic groups and their constituent medicines, because some descriptions are ambiguous. Following the publication of the August 2005 edition of the PBS Schedule, the DoHA posted on its web site a revised version of a previously unpublished list of cost-minimisation groups and their constituent medicines. Since that time the list of what are now called Reference Pricing Groups (RPG) and their constituent medicines has been revised to coincide with major editions of the PBS Schedule and to incorporate new medicines and changes in views on how RPGs should be defined (DoHA 2007i). RPGs are typically formed when a medicine listed on a cost-effectiveness basis becomes the comparator for medicines listed on a cost-minimisation basis against it. RPGs therefore consist of medicines listed on both CE and CM bases. At April 2007 there were 111 RPGs encompassing 328 medicines. There were a further 353 medicines which are not part of a group, either because they were listed on a cost-effectiveness basis and as yet have not been the seed for a RPG, or because they are not mentioned in the Therapeutic Relativity Sheets, usually because they are old medicines.

The form of reference pricing in which the prices of different brands of the same medicine, including the originator brand are set together and usually at the same level, is found in many different countries (Boston Consulting Group 2004, Davey et al 2005). The extension of reference pricing to include other medicines within the same therapeutic class was developed in Australia, and has only been adopted more broadly in other countries in recent years.

Because the comparator medicine can belong to a different ATC category and may have been on the market for a considerable time, the price of the new medicine may be linked through this form of reference pricing to the price of a medicine that has

already experienced patent expiry and the entry of generic competitors offering lower prices. Even if this is not the case, the comparator itself may have been listed based on an economic evaluation which had linked its price to that of another comparator which had experienced patent expiry.

Over time, it might be expected that there will be a growing proportion of medicines listed on the PBS that are both linked to a comparator and, through a chain of comparators, to medicines that are quite old. These are likely to be out of patent with generic competitors and possibly prices that are approaching the marginal cost of supply.

In some cases, the prices negotiated by the PBPA with the sponsor depart from those suggested by the value of incremental improvements in health outcomes. Despite statements that the PBS does not operate to achieve explicit or implicit budget targets (for instance, DoHA 2006d, p 23), sponsors are required to estimate the overall cost of the new medicine to the PBS and this is taken into consideration in the decision to list or not and at what level in Government this decision is taken.

In addition, the PBPA can negotiate 'risk-sharing agreements' with sponsors to limit the cost of the medicine to the PBS. "The two most common types of arrangements are price-volume agreements, where the sponsor of a particular drug agrees to a price reduction for any sales that exceed a pre-agreed sales volume and rebate agreements where the sponsor offers a rebate (of varying size) for the cost of increased expenditure over a set annual subsidisation cap/threshold" (DoHA 2006d p 13). Risk-sharing agreements are imposed when there is potential for significant use outside the PBS indications for the medicine and the cost could be high.

This form of agreement is the only mechanism within the PBS where demand by patients has an influence on the price received by suppliers. In all other circumstances suppliers agree to supply whatever amount of medicine is demanded at the price set by the PBS.

The Australian National Audit Office (2006) recently reviewed the operation of cost-containment measures within the PBS (principally restrictions and risk-sharing

agreements) and found that "…[the DoHA] is increasingly using restrictions, authority required restrictions and risk sharing agreements to control expenditure and decrease the risk of PBS drugs being used outside subsidy conditions…" (p 13)

With respect to restrictions, they concluded that "the complexity of restrictions, including the number of words required to define conditions, is increasing, as is the proportion of restricted and authority required items on the PBS… Generally, over time, restrictions are relaxed or conditions are added. Often when a restriction is relaxed or discontinued, [the DoHA] negotiates a price reduction with the drug's sponsor." (p 15)

For risk-sharing agreements, they found that since the first formal agreement was signed in October 2003, 14 had been entered into and at November 2005, a further nine were being negotiated. However of these agreements only 2 had been activated by November 2005, although a further 3 would be activated in 2006 (p 47-48). This suggests that the effect of risk-sharing agreements on prices has been very limited, but they are likely to become more important over time. The PBPA annual report for 2006-07 (PBPA 2007) notes that there were 55 agreements in place or in development at 30 June 2007.

Currently 3 Section 100 medicines – abacavir, bosentan and efavirenz are listed at the sponsor's desired price on the understanding that free goods will be provided to hospitals to make up the difference between this price and the cost effectiveness price.

### *Pricing of PBS medicines once listed*

All medicines listed on the PBS are reviewed annually, with all medicines in a broadly defined therapeutic class being reviewed together. Sponsors can seek variations in prices or these can be initiated by the PBPA. Changes may occur if

- the price of the benchmark brand or product within a therapeutic group changes
- the cost of supplying the medicine has changed
- a price increase results in a gross margin that is still acceptable

- the PBAC's views on relativities changes
- there are changes in listing restrictions
- additional indications are approved
- pricing agreements trigger a change
- suppliers wish to add or change a price premium

In December 1990, the Minimum Pricing Policy was introduced which set the price to be reimbursed by the PBS for a medicine as the lowest priced brand of the medicine listed on the PBS at the time. Where there are two or more brands of the same medicine, suppliers can add a *brand premium* to the benchmark price, as long as their brand is bio-equivalent or interchangeable with the benchmark brand. In this case, the patient wishing to purchase this particular brand pays both the copayment and the premium. In December 1994, brand substitution was introduced. This enabled pharmacists to offer patients cheaper brands of a particular medicine if not specifically prohibited by the prescribing doctor.

In general, if a particular medicine has brands with a premium, this does not mean that the other medicines that are members of the same therapeutic group can also have premiums. For certain groups however the other medicines in the group can add a *therapeutic premium* even though there is only one brand of that particular medicine. These types of premium were introduced in February 1998, are determined by the Minister for Health and Ageing and currently apply to four Therapeutic Premium Groups (TPG):

- H2-receptor antagonists for treating peptic ulcers
- Calcium channel blockers for treating high blood pressure
- Angiotensin converting enzyme (ACE) inhibitors for treating high blood pressure
- Certain HMG CoA reductase inhibitors (statins) for lowering cholesterol

In certain circumstances the PBS will pay the premium as well as the base price, especially if the patient has adverse effects from using the other medicines in the group, or changing medicines causes patient confusion. Pharmacists are not allowed to substitute for different medicines within these groups.

Aside from these arrangements, there are a few medicines where the Government and supplier have not been able to agree on a price but the Government allows the supplier to add a Special Patient Contribution (SPC) to the Government's base price. The patient pays the SPC and any copayment applicable.

Until recently only two medicines had ever added an SPC – bleomycin and polygeline – but a further 8 have been agreed since the introduction of the recent mandatory 12.5% price reduction discussed in Section 2.4 below. For most of these medicines, there are provisions (in the form of separate PBS item codes) for the Government to pay the SPC on behalf of the patient, usually if other alternative treatments are not suitable.

For certain groups of medicines, once they are listed on the PBS, their prices are determined by the Weighted Average Monthly Treatment Cost (WAMTC) methodology which was introduced in 1988. This is a further refinement of reference pricing where the aim is to equalise the cost of a month's treatment among the medicines in the group.

The methodology is described in DoHA (2004) as follows

"Reference pricing is usually based on the therapeutic relativities of drugs, from clinical trials, as presented to the Pharmaceutical Benefits Advisory Committee (PBAC) at the time of submission ie 20 mg of drug X was deemed equivalent to 30 mg of drug Y. Price is then generally determined on this basis.

The WAMTC methodology is intended to account for different usage practices in the market place compared to the formal clinical trial situation. Using sample data on prescribing behaviours and data on script volumes, a weighted average daily (and thus monthly) cost of treatment can be obtained.

…The WAMTC methodology is intended to account for different usage practices in the market place compared to the formal clinical trial situation. As an example, if drug A is listed on a cost minimisation basis versus drug B with

45 mg = 60 mg, but as used in clinical practice the average daily doses are 47 mg and 59 mg then the price for drug A should be lower and for drug B higher than based on the 45 mg = 60 mg comparison."

Current WAMTC groups are

- Angiotensin converting enzyme (ACE) inhibitors*.
- Angiotensin II receptor antagonists (ATRAs).
- Calcium channel blockers (CCBs)*.
- H2-receptor antagonists (H2RAs)*.
- HMG Coenzyme A reductase inhibitors (statins)*.
- Proton pump inhibitors (PPIs).
- SSRIs plus. A subgroup of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) and other antidepressants that have been listed on a cost minimisation basis with the SSRIs.

The four Therapeutic Premium Groups indicated by the asterisk are necessarily WAMTC groups. Since its introduction there have been significant revisions to the WAMTC methodology in 1992 and in 2003 following a review by Ernst & Young (2001).

### 2.2.6 Restrictions, Cautions and Notes

As noted above, when the PBAC makes a recommendation about a submission for a new medicine to be listed on the PBS, it can specify the level and nature of any restrictions that may be applied to the indications for which it is listed and the conditions under which it can be prescribed.

There are three levels of restriction

- "Authority required",
- "Restricted", and
- "Unrestricted".

Before "Authority required" items can be prescribed, the doctor must obtain permission by contacting Medicare Australia by mail or phone prior to prescribing the medicine according to the wording within the PBS Schedule. For "Restricted" items, the doctor must only prescribe the medicine for the indications given in the Schedule, while for "Unrestricted" items there is no restriction on how the medicine can be prescribed.

The report by the Audit National Audit Office (2006) mentioned earlier provides examples of medicines where the length and complexity of restrictions has increased over time and the PBPA acknowledges that the level of restriction is set high on initial listing of the medicine in order to judge the extent of usage before being relaxed after some time has passed. When restriction levels change, the PBPA also often seeks a price cut to compensate in part for any increased usage that may occur, in a manner similar to the risk-sharing agreements discussed earlier.

This use of the restrictions at first listing of a new medicine is demonstrated in Table 2.2 and Figure 2.2 which show that in most years, over 50% of new listings have an "Authority required" restriction, with most of the other listings being on a "Restricted" basis.

**Table 2.2    Restriction listings for new PBS medicines.**

|  | Authority required | Restricted | Unrestricted | Total | % Authority required |
|---|---|---|---|---|---|
| 1991-92 | 7 | 11 | 11 | 29 | 24.1 |
| 1992-93 | 8 | 9 | 7 | 24 | 33.3 |
| 1993-94 | 7 | 10 | 7 | 24 | 29.2 |
| 1994-95 | 13 | 8 | 5 | 26 | 50.0 |
| 1995-96 | 8 | 7 | 5 | 20 | 40.0 |
| 1996-97 | 16 | 15 | 8 | 39 | 41.0 |
| 1997-98 | 13 | 15 | 6 | 34 | 38.2 |
| 1998-99 | 10 | 9 | 1 | 20 | 50.0 |
| 1999-00 | 14 | 12 | 2 | 28 | 50.0 |
| 2000-01 | 9 | 11 | 7 | 27 | 33.3 |
| 2001-02 | 10 | 8 | 1 | 19 | 52.6 |
| 2002-03 | 10 | 9 | 3 | 22 | 45.5 |
| 2003-04 | 17 | 5 | 0 | 22 | 77.3 |
| 2004-05 | 18 | 1 | 3 | 22 | 81.8 |
| 2005-06 | 12 | 5 | 2 | 19 | 63.2 |
| 2006-07 | 13 | 11 | 3 | 27 | 48.1 |
| 2007-08* | 17 | 4 | 7 | 28 | 60.7 |

*first 9 months only

**Figure 2.2    Restriction listings for new PBS medicines**
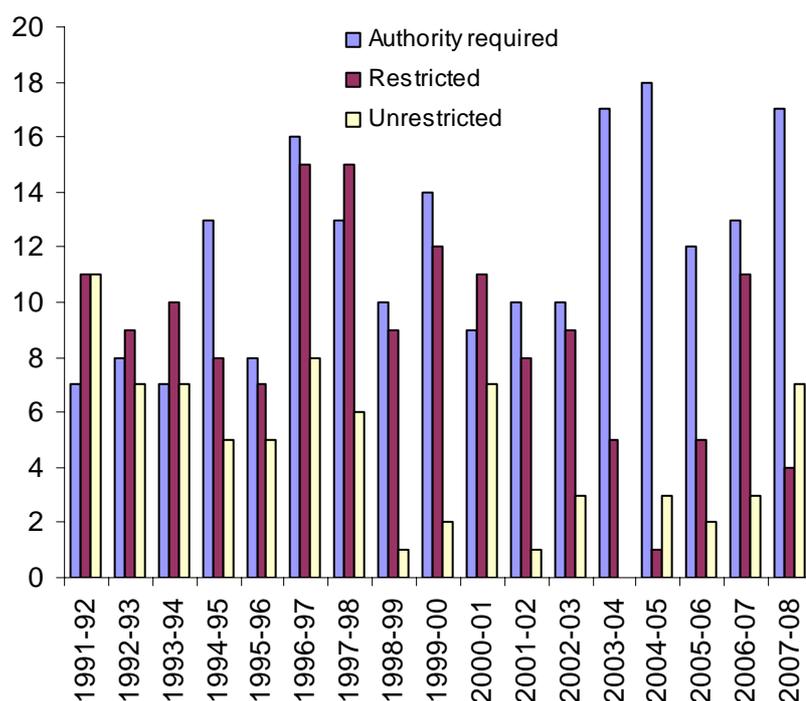


There has been a tendency for the proportion of "Authority required" listings to increase – from an average of 38.2% in the first half of the period to 56.5% in the second half with high percentages in recent years.

At March 2008, the PBS had 2431 items with the following restriction levels.

|  | Number | % |
|---|---|---|
| Authority required | 879 | 36.2 |
| Restricted | 696 | 28.6 |
| Unrestricted | 856 | 35.2 |
|  |  |  |
| Total | 2431 | 100.0 |

Each PBS item can also be accompanied by an explanatory "Note" to clarify how the item can be prescribed and a "Caution" to warn of known adverse reactions from, or precautions to be taken with, a particular medicine.

It is an offence under the *National Health Act 1953* for a prescriber to prescribe a subsidised PBS medicine outside its restriction indications. Nevertheless "leakage" does occur and some insight into the attitude of prescribers is given in research

commissioned by Medicare Australia in 2003 and reported in Audit National Audit Office (2006, p 43).

This found inter alia, that

- "48 per cent [of prescribers] were not aware that prescribing outside the restrictions was breaking the law
- 40 per cent agreed or strongly agreed, and a further 19 per cent neither agreed nor disagreed, that prescribing outside the restriction was against the law but everyone does it
- 51 per cent agreed or strongly agreed that criteria for prescribing restricted benefit items often did not reflect the best clinical practice, but 33 per cent disagreed or strongly disagreed"

## 2.3 Pricing relationships within the PBS

If a medicine is recommended for listing on the PBS, the price agreed with the supplier is the price to the pharmacist (PTP), namely the price at which the wholesaler will supply a standard pack of the medicine to the pharmacist. Until July 2006, the supplier of the medicine received 90% of this price, with the wholesaler receiving 10%. From July 2006, the shares are 93% to the supplier and 7% to the wholesaler. Section 100 medicines are usually provided direct from the supplier to the pharmacist, so there is no wholesaler margin.

The PBS Schedule (DoHA 2007j) specifies among other things, the maximum amount that may be prescribed and dispensed of a particular form and strength of a medicine listed on the PBS. This maximum amount is usually the same amount of medicine included in the standard pack supplied by the manufacturer, but can often be a multiple of this amount (and, for a few medicines, a fraction of this amount).

The dispensed price, ie the retail price of the medicine, is calculated by a formula negotiated within the context of the 5 yearly Community Pharmacy Agreements between the Commonwealth Government and the Pharmacy Guild. The formula is shown in Table 2.3 below for the period January 1991 to the present.

**Table 2.3    Formula for calculating dispensed price**

| Price to pharmacist for maximum quantity | Dispensed price for maximum quantity |
|---|---|
| **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 |

For most medicines listed on the PBS, the dispensing fee is the "Ready Prepared" dispensing fee ($5.44 at August 2007). For opiates such as morphine and oxycodone, a "Dangerous Drug" fee is added to this for some 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. The dispensed price for Section 100 medicines is the same as the price to pharmacist for maximum quantity (ie there is no margin or dispensing fee). Figure 2.3 shows the value of the ready prepared dispensing fee since January 1991 as well as this value deflated by the Consumer Price Index adjusted so that both series have the same value in January 1991.

**Figure 2.3    Ready prepared dispensing fee, $**
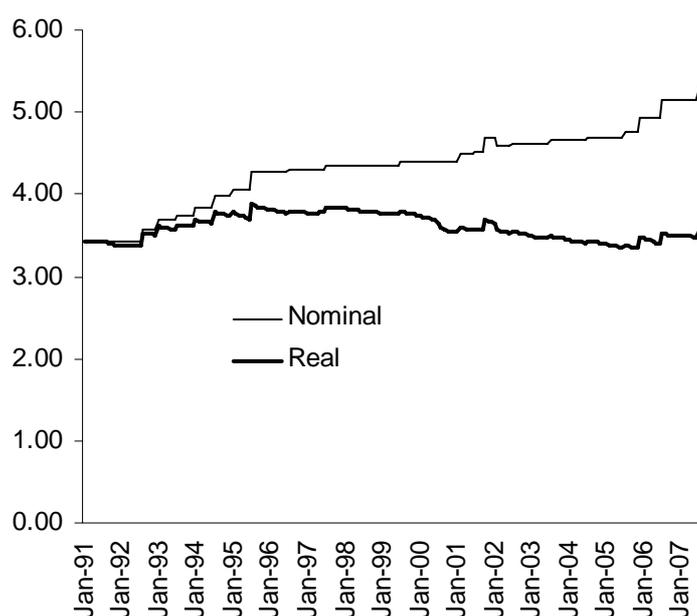
The data supporting Figure 2.3 is provided in Sweeny (2007a). While the nominal value of the fee increased from $3.43 to $5.44 there have been extended periods when it has remained virtually unchanged. This has meant that the real value of the fee increased only slightly. After increasing steadily to 1996, the fee fell in real terms thereafter until a revival once the Fourth Community Pharmacy Agreement came into effect and inflation indexation was re-established.

## 2.4 PBS policy changes since 2004

Most of the policy instruments used by the Commonwealth Government to influence the level of usage of PBS medicines have been described in the earlier part of this chapter. In 2004 and 2006 however the Government introduced a range of measures aimed at reducing price paid for PBS medicines.

On October 1, 2004, in the lead up to the Federal Election, the Coalition parties announced, as part of the funding of their *Recognising Senior Australians – Their Needs and Their Carers* policy, that if re-elected they would apply a 12.5% reduction in the price of certain PBS medicines. Under the *Charter of Budget Honesty*, the Department of Finance and Administration estimated that this measure would achieve savings of $701.8 million over the four years from 2004-05 to 2007-08. These savings were later revised to $740 million, and the papers accompanying the Commonwealth Budget for 2005-06 was further revised to be $1,036 million over the period to 2008-09.

Administrative guidelines for the new policy are given at DoHA (2005a) and as Attachment D to the PBPA Guidelines (PBPA 2006). These state that

> "A 12.5 % price reduction will only be triggered by an application to list a new generic brand of a medicine. This includes:
>
> - New generic medicines - these are new versions of medicines where the patent for the original medicine has expired. The new version of medicine has the same active ingredient as the original medicine.
> - New pseudo generic medicines - these are new versions of medicines which are still on-patent. These may be marketed by the patent holder, or by

another sponsor under an arrangement with the patent holder. The new version of medicine has the same active ingredient as the original medicine.

As the PBS is based on a reference pricing system (the prices of medicines are linked if they work in the same way or have the same health outcome), the reduction will:

- Flow on to all brands of that medicine.
- Flow on to all forms and strengths of that medicine which are administered in the same way.
- Flow on to all other medicines in the same reference pricing group, which are administered in the same way.
- Be applied to combination medicines (when one medicine is combined with another medicine in the one formulation) on a pro-rata basis.
- Be applied on a pro-rata basis, based upon the PBS listed indication(s) in common between the new generic brand and the other medicines in the same reference pricing group. The pro-rata reduction will be determined by the listing recommendations of the Pharmaceutical Benefits Advisory Committee and the utilisation of the medicine in the relevant indication(s). Where there is disagreement about the pro rata reductions to apply, an assessment will be made by the Pharmaceutical Benefits Pricing Authority."

The new policy commenced on 1 August 2005 and applied only once for each medicine, including for medicines in a reference pricing group where the reduction occurred as a flow-on from another medicine.

Estimates by the author in CSES (2005) prior to the introduction of the policy indicated that savings to the Government would be substantially larger than estimated by the Government. This was confirmed by outcomes for the first four rounds of price cuts between August 2005 and August 2006 which will save the Government an estimated $842 million on conservative assumptions over the four years from 2005-06 to 2008-09 (CSES 2006b).

The mandatory 12.5% price reduction policy was introduced because it was known that several popular medicines would be subject to patent expiry over the following five to ten years and suppliers would therefore seek to list new brands of these medicines. In addition there would be further new brands being offered for medicines already off-patent. However experience with reference pricing and the Minimum Pricing Policy had shown that there was little if any incentive for suppliers introducing a new brand to offer a price significantly lower than the base price for that medicine. Such a supplier would gain no real competitive price advantage firstly because the base price of all other brands of the medicine would be set to the price being offered, and secondly any brand premium added by another supplier in part compensation for this would only be a small addition to the base price. In these circumstances the only way to achieve price cuts was to make them mandatory.

A more complex package of changes focussing on further price cuts was discussed with the industry in May 2006 and finalised as policy in early 2007 (DoHA 2006e, DoHA 2007b). Some of these changes required amendments to the *National Health Act 1953* so the policy was designed to be implemented from 1 August 2007.

The initiatives within this latest package concentrate on new mechanisms for reducing prices but also include measures to compensate wholesalers and pharmacists, to streamline the "Authority required" procedure and to consult with industry. The key to the new pricing arrangements is the establishment of two formularies within the PBS from 1 August 2007.

Formulary 1 (F1) will consist of a number of single brand medicines, but will not include single brand medicines which are interchangeable at the patient level with multiple brand medicines. These medicines are those within the current WAMTC groups except for the SSRIs and only simvastatin and pravastatin within the statin group.

Formulary 2 (F2) will consist of multiple brand medicines and those single brand medicines not included in F1. If there are multiple brands for some forms and strengths of a particular medicine but only a single brand for other forms and strengths all forms and strengths will belong to F2.

Although reference pricing will be retained for the determination of prices of new medicines on the PBS, this policy seriously compromises reference pricing as a means of determining prices for medicines already listed, as argued by some of the architects of reference pricing (Searles et al 2007). Thus some Reference Pricing Groups will be split into those medicines on F1 and those on F2, and there will be no link between price changes for those on F2 and those on F1. While DoHA (2007b) asserts that reference pricing will continue among medicines within RPGs on F1, in practice the only way for medicines on F1 to experience a price change (other than outside the reference pricing mechanism) is if a new brand of the medicine is listed on the PBS (possibly following patent expiry) at which time the medicine will shift to F2 and also be subject to the mandatory 12.5% pricing policy. Reference pricing among medicines on F2 will only apply to those within TPG groups and across different brands of the same medicine. Thus a change in the price of a medicine on F2 will not flow through to other members of the RPG on F2, other than for the 4 TPGs.

For a transition period of three years from 1 August 2007, F2 will be split into two sub-formularies.

Formulary F2T will comprise medicines attracting significant treading terms to pharmacy at 1 October 2006. This means those medicines for which some suppliers will offer 25% or more in the way of discounts from the official PBS price to pharmacist (or equivalent inducements). Medicines offering discounts were identified as such by the Pharmacy Guild.

Formulary F2A will comprise medicines not attracting significant trading terms to pharmacy discounts.

All medicines on F2A will be subject to a mandatory price cut of 2% per year for three years beginning on 1 August 2008. In addition suppliers of a new brand of a F2A medicine will be required to disclose the actual price to pharmacist. Staged price reductions in the base price will then occur for all brands of that medicine until the weighted average disclosed price is reached. Price reductions from disclosure will

commence on 1 August 2009. In general medicines leaving F1 for F2 will be subject to the same conditions as F2A medicines.

Medicines on F2T will be subject to a mandatory 25% price cut on 1 August 2008, except for a defined list of patent protected medicines within the TGPs, for which the price cut will be phased in over the remaining patent life. Suppliers offering a new brand of an F2T medicine from 1 January 2001 will be required to disclose the actual price to pharmacist and price cuts based on these disclosed prices will commence from 1 August 2012.

In addition to these changes to pricing policy, an incentive of $1.50 will be paid to pharmacists each time they dispense a substitutable premium-free brand to encourage greater dispensing of generic brands rather than originator brands.

The Government claimed that the package of initiatives would lead to savings of $3 billion over 10 years and savings of $580 million in the four years from 2007-08 to 2010-11 (DoHA 2006e). Estimates by the author in CSES (2006a) indicated that savings to the Government would be around $480 million over four years although the modelling did not include savings due to the incentive for pharmacists and other changes in pharmacy and wholesaling arrangements, or before some changes to and elaborations of the new policy were made as reflected in DoHA (2007b) and the composition of the formularies was finalised.

The other major initiative by the Government in recent years which could influence the PBS was the conclusion of a Free Trade Agreement (FTA) between Australia and the United States in May 2004. This agreement contained a number of commitments relating to the PBS which were clarified by an exchange of letters in November 2004. The PBS had been placed on the agenda for the FTA negotiations by the US government at the prompting of US research-based pharmaceutical companies, but despite this pressure the commitments made by the Australian Government in the final agreement are likely to have little if any impact on the operations of the PBS. The main outcome from the FTA is the establishment of an independent review mechanism which "shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to

list" (Independent Review (PBS) 2005). The Convenor of the Independent Review (PBS) was appointed in May 2006 and her task is to manage the independent review by a qualified expert. This is equivalent to obtaining a second opinion because new evidence cannot be presented to this reviewer. The recommendations of the review are made public and considered by both the PBAC and the Minister but neither are obliged to accept any recommendations contrary to the original PBAC decision.

Sponsors also have the opportunity for a hearing before the PBAC while its application is being processed by the PBAC. The FTA also requires that details of PBAC recommendations be made publicly available and this has been implemented.

# Chapter 3
## PBS Patients, Copayments and Safety Nets

### 3.1 Introduction

The purpose of this chapter is to describe how the categories of beneficiaries (ie patients) within the PBS are defined by the Government, and the differences among them in terms of the contributions they make to the cost of the PBS medicines they consume. The two basic categories of general and concessional patient each have a safety net provision and how the Government sets the value of copayment and safety net limits is important in determining the shares of PBS cost borne by patients and the Government.

Evidence is presented that the level of both copayments and safety net limits has increased over time in both nominal and real terms. This has had the effect of progressively shifting a greater proportion of the cost of the PBS from the Government to the patient.

Estimates based on regression analysis suggest that an increase of 10% in the number of general copayments necessary to reach the general safety net limit will reduce the number of general safety net cardholders by 24.4%. For concessional patients, an increase of 10% in the number of copayments necessary to reach the safety net limit will reduce the number of cardholders by 55.6%

### 3.2 Categories of patients

PBS benefits are available to all Australian residents and eligible foreign visitors, i.e., people from countries which have Reciprocal Health Care Agreements with Australia, namely Finland, Ireland, Italy, Malta, the Netherlands, New Zealand, Norway, Sweden, and the United Kingdom. Since 1 July 2001, all Australian citizens must produce a Medicare card when benefits are dispensed, as proof of eligibility.

The PBS distinguishes between general patients who contribute a higher copayment when purchasing PBS medicines and concessional patients who contribute a lesser

copayment. Concessional patients must have one of the following cards from Centrelink or the Department of Veterans Affairs (DVA):

- Pensioner Concession Card;
- Commonwealth Seniors Health Card;
- Health Care Card; or
- Repatriation Health Card or Repatriation Pharmaceutical Benefits Card

Pensioner Concession Cards are available to a range of social security beneficiaries, including aged pensioners, unemployment beneficiaries, and single parents.

To qualify for the Seniors Health Card, a person must:
- be an Australian resident, living in Australia, and
- have reached age pension age but not qualify for the Age Pension, and
- have an annual income of less than
  - $50,000 (singles)
  - $80,000 (couples combined), or
  - $100,000 (couples combined who are separated due to ill health)

These latter limits are increased by $639.60 for each dependent child cared for (Centrelink 2007).

In addition to subsidising the cost of medicines for both general and concessional patients, the PBS also provides for Safety Nets which allow for a lesser copayment once the annual cost of medicines incurred by a patient exceeds the amount specified as the Safety Net limit. For general patients once the safety net limit is reached the copayment is the same as the concessional copayment, while for concessional patients, there is no copayment once the safety net limit has been reached. At the beginning of a new year, safety net patients revert to their previous patient category until the safety net limit is reached again.

To estimate the number of patients in each of these categories, information was obtained from the Information Management Branch of Centrelink on the number of concessional cardholders by card type for the period January 2001 to June 2007.

Information prior to 2001 was not readily available. There were some 4,973,689 concessional cardholders in December 2006 made up of 301,575 Seniors Health Cardholders (6.1%), 1,495,083 Health Care Cardholders (30.1%) and 3,177,031 Pensioner Concessional Cardholders (63.8%). At the same time there were about 315,000 Repatriation (Gold, White and Orange) Benefits cardholders (DVA 2007b).

This implies that of a total Australian population of 20,851,997 in December 2006, there were some 15,563,308 people who would be classified as general patients, or 74.6% of the total population. Of these there were 392,923 safety net cardholders or about 2.5% of general patients. As these figures are for December this represents the largest proportion of general patients that are safety net cardholders during the course of the year. In June 2006, for instance they were about 0.2% of general patients.

By contrast, the 1,375,097 concessional safety net cardholders represented 27.6% of concessional patients in December 2006 (and 4.9% in June 2006).

Over the period from June 2001 to June 2007, the overall Australian population grew by 8.2% but the number of general patients grew by 11.0% while the number of concessional patients fell by 0.1%. During this time however the number of Seniors Health Cardholders grew by 40.7%, the number of Health Care Cardholders fell by 16.2% and the number of Pensioner Cardholders increased by 6.1%.

### 3.3 Copayments and safety net limits

Table 3.1 sets out the history of copayments and safety net thresholds based on data compiled from a number of sources including DoHA (2007d, 2007l), various issues of the Schedule (DoHA 2007j), private communications from the DoHA, and Sloan (1995).

Since the introduction of a $0.50 copayment for general patients on 1 March 1960, the copayment remained at this level until November 1971 when it was increased to $1.00. From 1960 to 1982 there were two categories of patients - "General" and "Pensioner".

**Table 3.1    History of PBS copayments and safety net thresholds, $**

| Change Date | Copay Pensioners | Copay Concessional | Copay General | Safety net Concessional | Safety net General | Safety net General 2 |
|---|---|---|---|---|---|---|
| 01.03.1960 | | | 0.50 | | | |
| 01.11.1971 | | | 1.00 | | | |
| 01.09.1975 | | | 1.50 | | | |
| 01.03.1976 | | | 2.00 | | | |
| 01.07.1978 | | | 2.50 | | | |
| 01.09.1979 | | | 2.75 | | | |
| 01.12.1981 | | | 3.20 | | | |
| 01.01.1983 | | 2.00 | 4.00 | | | |
| 01.07.1985 | | 2.00 | 5.00 | | | |
| 01.11.1986 | | 2.50 | 10.00 | 25 scripts | 25 scripts | |
| 01.07.1988 | | 2.50 | 11.00 | 25 scripts | 25 scripts | |
| 01.11.1990 | 2.50 | 2.50 | 15.00 | 130.00 | 25 scripts | |
| 01.01.1991 | 2.50 | 2.50 | 15.00 | 130.00 | 300.00 | 50.00 |
| 01.08.1991 | 2.50 | 2.50 | 15.70 | 130.00 | 300.00 | 50.00 |
| 01.10.1991 | 2.60 | 2.60 | 15.70 | 130.00 | 300.00 | 50.00 |
| 01.01.1992 | | 2.60 | 15.70 | 135.20 | 309.90 | 51.60 |
| 01.01.1993 | | 2.60 | 15.70 | 135.20 | 312.30 | 52.00 |
| 01.08.1993 | | 2.60 | 16.00 | 135.20 | 312.30 | 52.00 |
| 01.01.1994 | | 2.60 | 16.00 | 135.20 | 400.00 | |
| 01.08.1994 | | 2.60 | 16.20 | 135.20 | 400.00 | |
| 01.01.1995 | | 2.60 | 16.20 | 135.20 | 407.60 | |
| 01.08.1995 | | 2.60 | 16.80 | 135.20 | 407.60 | |
| 01.01.1996 | | 2.70 | 16.80 | 140.40 | 600.00 | |
| 01.08.1996 | | 2.70 | 17.40 | 140.40 | 600.00 | |
| 01.01.1997 | | 3.20 | 20.00 | 166.40 | 612.60 | |
| 01.01.1999 | | 3.20 | 20.30 | 166.40 | 620.30 | |
| 01.01.2000 | | 3.30 | 20.60 | 171.60 | 631.20 | |
| 01.01.2001 | | 3.50 | 21.90 | 182.00 | 669.70 | |
| 01.01.2002 | | 3.60 | 22.40 | 187.20 | 686.40 | |
| 01.01.2003 | | 3.70 | 23.10 | 192.40 | 708.40 | |
| 01.01.2004 | | 3.80 | 23.70 | 197.60 | 726.80 | |
| 01.01.2005 | | 4.60 | 28.60 | 239.20 | 874.90 | |
| 01.01.2006 | | 4.70 | 29.50 | 253.80 | 960.10 | |
| 01.01.2007 | | 4.90 | 30.70 | 274.40 | 1059.00 | |

Sources: DoHA (2007d), various issues; DoHA (2007j); Sloan (1995)

A further "Concessional" category for other concessional patients besides pensioners was introduced on 1 January 1983 with an associated copayment of $2.00 (or half the General copayment). The distinction between these other concessional patients and pensioners continued until 1 January 1992 when the current classification of patients into "Concessional" and "General" began. Pensioners began contributing a copayment of $2.50 in November 1990.

Safety net categories began in November 1986 when a numerical limit of 25 scripts was introduced. This was replaced by a monetary limit of $130.00 for pensioners/concessional patients in November 1990 and by $300.00 for general patients in January 1992. From 1 January 1992 until 31 December 1993, there was an

additional safety net category for general patients. Once the additional expenditure limit for this category had been reached, further benefits were free.

Initially the concessional safety net limit was set as the cost of 52 scripts times the concessional copayment and this formula continued to operate until the end of 2005. From 2006 to 2009 the safety net limit increases by 2 copayments per year so that in 2009 it will be equivalent to 60 copayments. The general safety net limit was never set in the same way but at the end of 2005 was equivalent to about 30 copayments. From 2006 to 2009 it will also increase by an additional two copayments per year (Table 3.2).

**Table 3.2    Number of copayments to reach safety net limit**

| Date | Concessional | General |
|---|---|---|
| 01.01.1991 | 52 | 20.0 |
| 01.01.1992 | 52 | 19.7 |
| 01.01.1993 | 52 | 19.9 |
| 01.01.1994 | 52 | 25.0 |
| 01.01.1995 | 52 | 25.2 |
| 01.01.1996 | 52 | 35.7 |
| 01.01.1997 | 52 | 30.6 |
| 01.01.1998 | 52 | 30.6 |
| 01.01.1999 | 52 | 30.6 |
| 01.01.2000 | 52 | 30.6 |
| 01.01.2001 | 52 | 30.6 |
| 01.01.2002 | 52 | 30.6 |
| 01.01.2003 | 52 | 30.7 |
| 01.01.2004 | 52 | 30.7 |
| 01.01.2005 | 52 | 30.6 |
| 01.01.2006 | 54 | 32.5 |
| 01.01.2007 | 56 | 34.5 |

Since their introduction, the nominal and real values of both copayments and safety net limits have increased, and while these increases have generally been modest, large changes have occurred from time to time as the Government has sought to limit its exposure to the growth in the cost of the PBS by shifting more of the cost to patients. Usually changes in copayments and safety net limits have taken effect from 1 January by an amount in line with inflation. However, as Table 3.1 shows, much larger increases occurred in November 1986, November 1990, January 1997, and January 2005.

Figures 3.1 and 3.2 graph the ratios of the general and concessional copayments to average weekly earnings (AWE) over the same period. Monthly values for AWE were

calculated by interpolating the quarterly data for the ABS series *Average Weekly Earnings, All Employees* (RBA2007d). Deflating the copayments by the Consumer Price Index (CPI) (RBA 2007a) gives broadly similar results.

**Figure 3.1    Ratio of general copayment to AWE, September 1969 to June 2007**
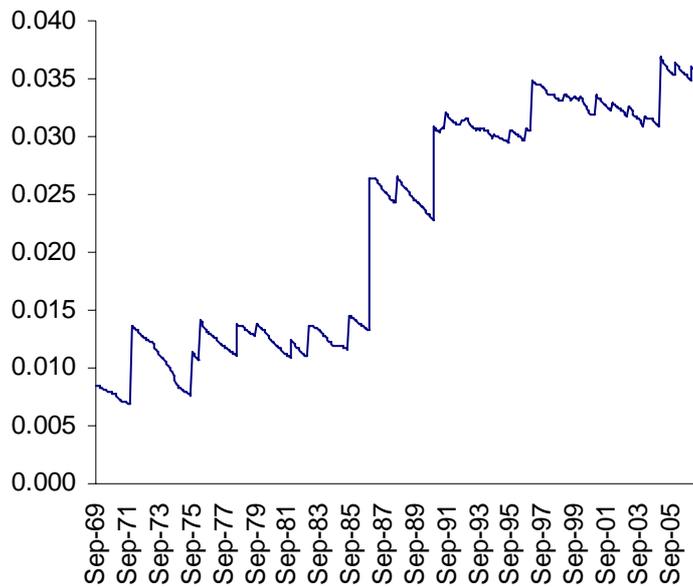


Sources: Table 3.1 and RBA (2007d)

**Figure 3.2    Ratio of concessional copayment to AWE, January 1983 to June 2007**
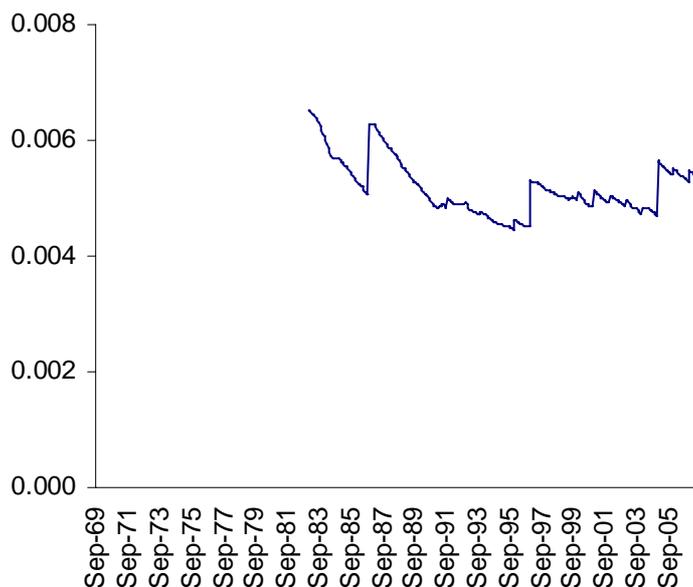


Sources: Table 3.1 and RBA (2007d)

While the general copayment has increased in nominal terms over the past 35 years, the effect of the intermittent large rises has been to increase it substantially in real

terms as well, although the usual pattern has been one of a sharp rise followed by a steady decline until the next rise. The most recent large increase occurred in January 2005 with the general copayment rising from 3.1% to 3.7% of average weekly earnings. In contrast, the concessional copayment fell or remained steady in real terms over longer periods of time since its introduction in 1983, except for significant increases in November 1986, January 1997 and January 2005. The most recent rise may however be a sign of an increasing real concessional copayment in the future.

To provide a better picture of the course of the general and concessional copayments over the period for which most of the analysis in this thesis is conducted, Figures 3.3 and 3.4 reproduce Figures 3.1 and 3.2 for the period July 1991 to June 2007. The overall increase in real terms in the copayments is affected mainly by the large increases in January 1997 and January 2005 so that the ratio of the general copayment to AWE rose from 3.1% to 3.5% from July 1991 to June 2007 while the concessional copayment increased from 0.51% to 0.57%.

**Figure 3.3    Ratio of general copayment to AWE, July 1991 to June 2007**
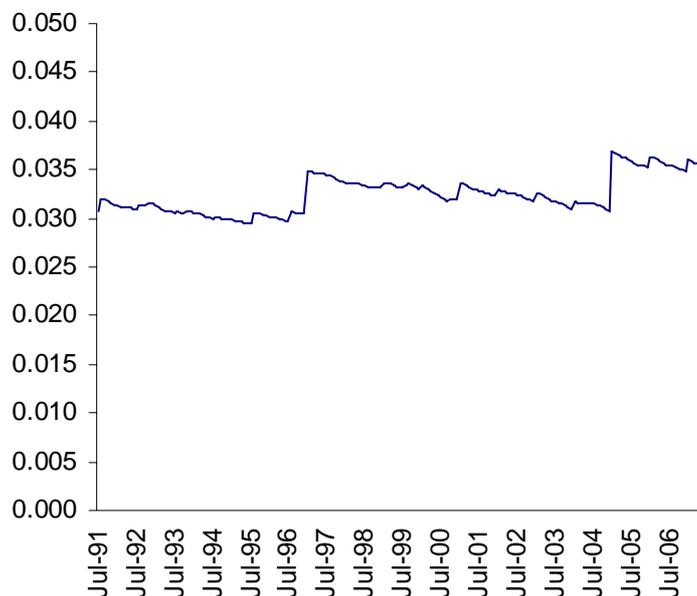


Sources: Table 3.1 and RBA (2007d)

**Figure 3.4    Ratio of concessional copayment to AWE, July 1991 to June 2007**
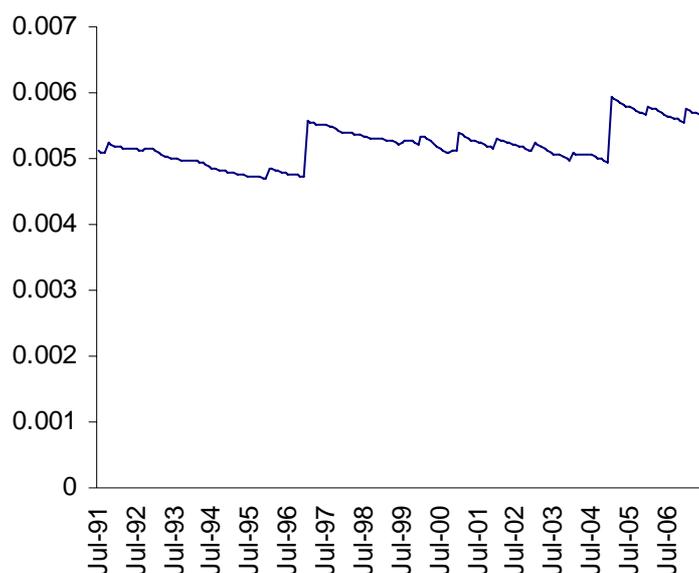


Sources: Table 3.1 and RBA (2007d)

While there have been some real increases in the copayments, there have been larger rises in the real safety net limits. From July 1991 the general safety net limit rose from 61.2% of AWE to 123.5% while the concessional safety net limit increased from 26.6% to 32.0% (Figures 3.5 and 3.6).

The timings for the large increases in safety net limits were somewhat different for the two patient categories – being January 1994, 1996 and 2005 for general patients and January 1997 and 2005 for concessional patients.

The picture that emerges from this analysis is a progressive increase in real terms for the copayment and especially the safety net limit for general patients, and a lesser real increase for concessional patients. As will be seen in Chapter 6 below, this must be seen against steadily falling prices for PBS medicines and hence reflects a deliberate policy over an extended period of time by the Commonwealth Government to shift an increasing proportion of the cost of the PBS from itself to patients.

**Figure 3.5    Ratio of general safety net limit to AWE, July 1991 to June 2007**
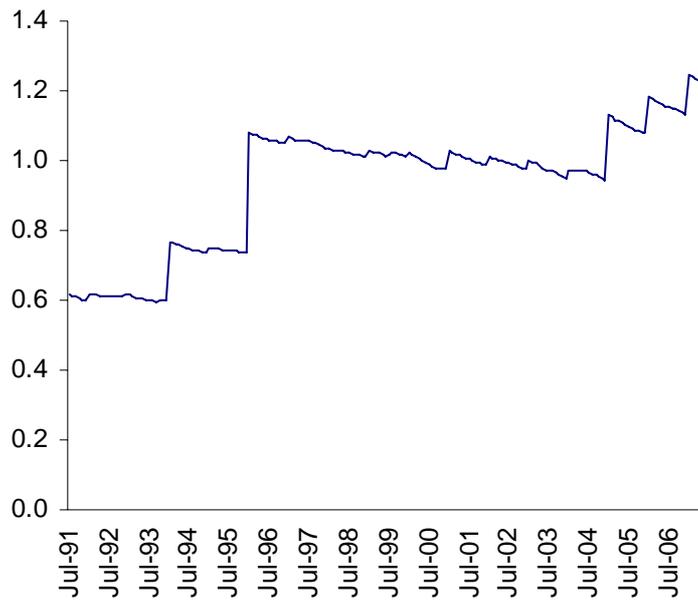


Sources: Table 3.1 and RBA (2007d)

**Figure 3.6    Ratio of concessional safety net limit to AWE, July 1991 to June 2007**
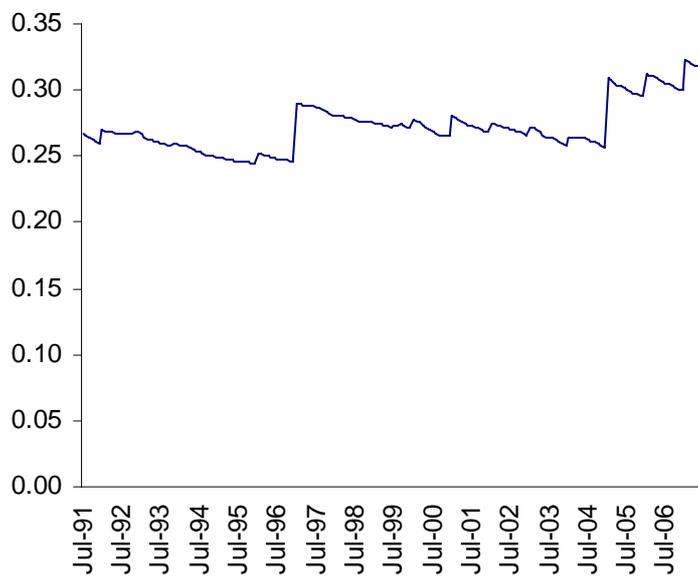


Sources: Table 3.1 and RBA (2007d)

## 3.4 Safety net cardholders

A different way of seeing this is to look at the number of people holding safety net cards over this period (DoHA 2006c, various issues). As noted earlier the number of cardholders increases rapidly throughout the year as more people reach the expenditure limit. In 2005 for instance there were 46 cardholders in January, 375,020 in June and 1,969,200 in December. To see the trend in cardholders therefore the number at June each year is shown in Figures 3.7 and 3.8 for general and concessional patients.

**Figure 3.7**     **General safety net cardholders in June**
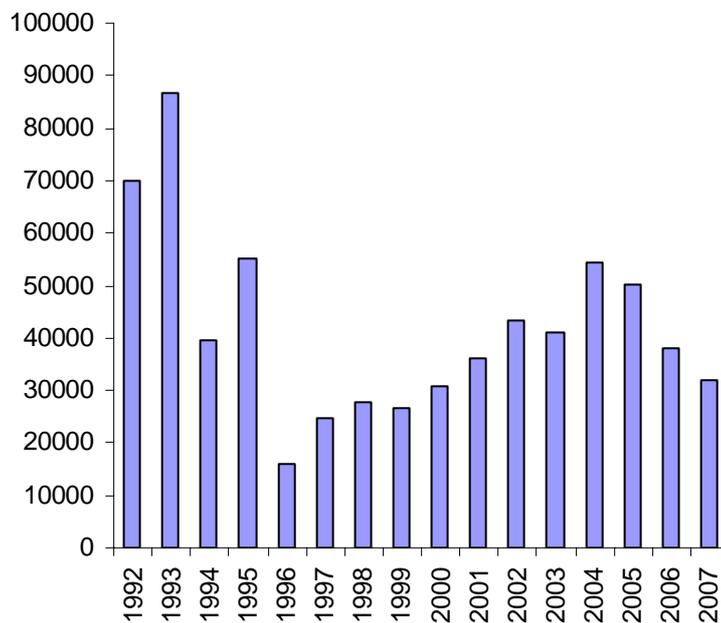


Source: DoHA (2006c)

This shows clearly the impact of the increased limits for general patients as the number of cardholders fell substantially in 1994 and 1996 and again in 2006 and 2007. The number of concessional cardholders rose strongly through the period and especially in 2004 but fell significantly in both 2006 and 2007. A comparison with Table 3.2 indicates that these falls coincided with an increase in the number of copayments necessary to make the safety net limit. The flagged increases in the number of copayments to the year 2009 will further reduce the number of safety net cardholders.

To influence the number of safety net cardholders, the Government has two instruments – the value of the safety net limit and the value of the copayment. As described above and shown in Table 3.2, until recently the Government's policy for concessional cardholders has been to set these together to ensure that the number of copayments to reach the safety net limit has been constant. From 1997 to 2004 this was also the case for general patients, but at other times the safety net limit and the copayment have been set somewhat independently of each other.

**Figure 3.8    Concessional safety net cardholders in June**
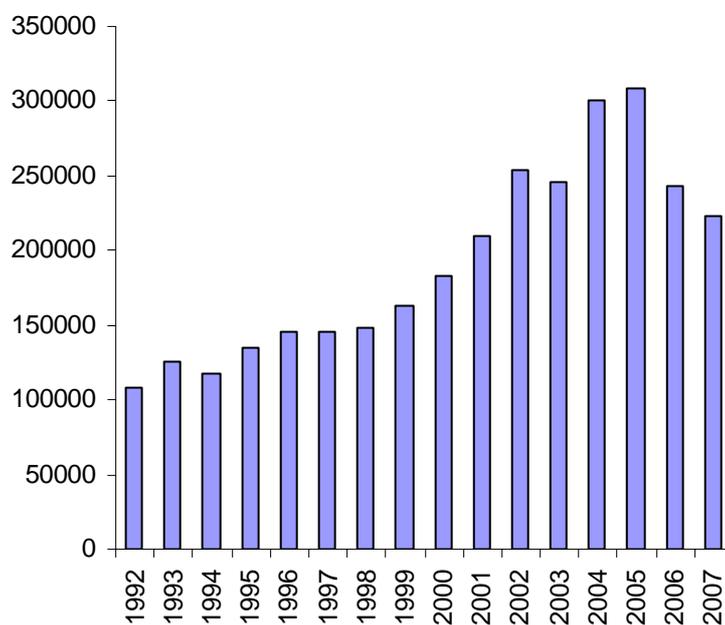


Source: DoHA (2006c)

The relative impact of the two policy instruments can be determined econometrically by regressing the number of safety net cardholders on the safety net limit and the copayment. The estimation period is from January 1992 to June 2007 with a total of 186 monthly observations. The variables are defined as follows

| | |
|---|---|
| *constant* | Constant |
| $year_t$ | time trend = t for year t, 1992 = 1 |
| $d_i$ | Dummy variable for month i, January = 1 |
| $gcard_{it}$ | Number of general safety net cardholders in month i of year t |
| $ccard_{it}$ | Number of concessional safety net cardholders in month i of year t |
| $gcop_{it}$ | The value of the general copayment in month i of year t, $ |

| | |
|---|---|
| *ccop$_{it}$* | The value of the concessional copayment in month i of year t, $ |
| *glimit$_t$* | The general safety net limit in year t, $ |
| *climit$_t$* | The concessional safety net limit in year t, $ |
| *gclm$_{it}$* | The number of general copayments to reach the safety net limit |
| | = *glimit$_t$* / *gcop$_{it}$* |
| *cclm$_{it}$* | The number of concessional copayments to reach the safety net limit |
| | = *climit$_t$* / *ccop$_{it}$* |

An '*l*' before the variable name in the results reported below indicates the natural logarithm of the variable.

Tables 3.3 and 3.4 show results for alternative specifications of the equation for the number of safety net cardholders. The first two results are for equations using untransformed variables while the second two results have variables expressed as natural logarithms except for the time trend and monthly seasonal dummy variables which are untransformed. The time trend is used to account for any general increase in the number of general or concessional patients over time while the monthly dummy variables are used to control for the large differentials in monthly values across the year. Replacing the time trend with either the number of concessional cardholders or the number of general patients as relevant and re-estimating over the shorter time period from January 2001 to June 2007 for which the concessional cardholder data is available gives somewhat poorer results with the coefficients on these variables generally insignificant.

To ensure that regression results were not spurious, they were tested for cointegration among the variables by calculating the Augmented Dickey-Fuller statistics on the residuals from the equation (as suggested in Gujarati 2003). The values of these statistics all indicate acceptance of the null hypothesis of cointegration at the 5% probability level. The ADF statistic and probability level are reported for all regression results.

In Table 3.3 for the number of general safety net cardholders, all equations have coefficients for explanatory variables that have the expected sign and are generally significant at the 5% level. The logarithmic specification performs better than the one using variables that are untransformed, with all variables having very significant

coefficients, and the fit statistics being better. In general there is no difference in fit between the equation that contains both the safety net limit and the value of the copayment as explanatory variables (*glimit* and *gcop*) and the equation which only has the number of copayments to reach the safety net limit (*gclm* = *glimit/gcop*).

The logarithmic specification equation 3 in Table 3.3 evaluated using values for 2007 suggests that a 10% increase in the general safety net limit will reduce the number of general safety net cardholders by around 25.3% all other things being equal, while a 10% increase in the general copayment will increase the number of cardholders by 19.8%. If equation 4 is evaluated using values for 2007, an increase of 10% in the number of copayments necessary to reach the safety net limit will reduce the number of cardholders by 24.4%.

The equations for concessional safety net cardholders in Table 3.4 produce similar results. Again the logarithmic specification is superior in terms of overall fit and significance of the coefficients, and there is little to choose between the version that contains both the safety net limit and the value of the copayment as explanatory variables (*climit* and *ccop*) and the equation which only has the number of copayments to reach the safety net limit (*cclm*). Evaluating equation 3 using values for 2007 suggests that a 10% increase in the concessional safety net limit will reduce the number of concessional safety net cardholders by around 53.7% all other things being equal, while a 10% increase in the concessional copayment will increase the number of cardholders by 109%. From equation 4, an increase of 10% in the number of copayments necessary to reach the safety net limit will reduce the number of cardholders by 55.6%.

In interpreting these results however it should be remembered that there were only two increases in the number of copayments necessary to reach the safety net limit (in January 2006 and January 2007) so the effect of this change may not be fully reflected in the regression results.

**Table 3.3     Regression results – General safety net cardholders, n= 186**

| Equation | 1 | | 2 | | 3 | | 4 | |
|---|---|---|---|---|---|---|---|---|
| Dependent variable | gcard | | gcard | | lgcard | | lgcard | |
| | Coefficient | t-statistic | Coefficient | t-statistic | Coefficient | t-statistic | Coefficient | t-statistic |
| constant | -102135 | -3.2 | 258834 | 10.7 | 15.187 | 11.3 | 11.714 | 22.5 |
| year | 1591 | 0.6 | 5003 | 5.5 | 0.100 | 4.8 | 0.045 | 7.2 |
| d2 | 147 | 0.0 | 147 | 0.0 | 2.640 | 28.8 | 2.640 | 28.3 |
| d3 | 1149 | 0.1 | 1149 | 0.1 | 4.655 | 50.8 | 4.655 | 49.8 |
| d4 | 5257 | 0.4 | 5257 | 0.4 | 6.228 | 68.0 | 6.228 | 66.7 |
| d5 | 18267 | 1.3 | 18267 | 1.3 | 7.515 | 82.0 | 7.515 | 80.5 |
| d6 | 42029 | 3.0 | 42029 | 3.0 | 8.358 | 91.2 | 8.358 | 89.5 |
| d7 | 78574 | 5.5 | 79692 | 5.7 | 9.009 | 96.7 | 9.013 | 94.9 |
| d8 | 126612 | 8.8 | 128268 | 9.1 | 9.491 | 101.9 | 9.488 | 99.9 |
| d9 | 183760 | 12.8 | 185416 | 13.2 | 9.860 | 105.8 | 9.857 | 103.8 |
| d10 | 244261 | 17.1 | 245918 | 17.5 | 10.145 | 108.9 | 10.142 | 106.8 |
| d11 | 306015 | 21.4 | 307672 | 21.9 | 10.371 | 111.3 | 10.368 | 109.2 |
| d12 | 380617 | 26.6 | 382274 | 27.2 | 10.592 | 113.7 | 10.589 | 111.5 |
| glimit | -591 | -10.1 | | | | | | |
| gcop | 21786 | 8.4 | | | | | | |
| gclm | | | -10305 | -11.2 | | | | |
| lglimit | | | | | -3.060 | -18.4 | | |
| lgcop | | | | | 1.894 | 4.6 | | |
| lgclm | | | | | | | -2.942 | -17.9 |
| | | | | | | | | |
| Adjusted $R^2$ | 0.918 | | 0.921 | | 0.994 | | 0.994 | |
| Durbin-Watson | 0.522 | | 0.541 | | 1.238 | | 1.190 | |
| ADF | -4.393 | | -4.612 | | -9.302 | | -9.003 | |
| Prob | 0.000 | | 0.000 | | 0.000 | | 0.000 | |

**Table 3.4  Regression results – Concessional safety net cardholders, n= 186**

| Equation | 1 | | 2 | | 3 | | 4 | |
|---|---|---|---|---|---|---|---|---|
| Dependent variable | ccard | | ccard | | lccard | | lccard | |
| | Coefficient | t-statistic | Coefficient | t-statistic | Coefficient | t-statistic | Coefficient | t-statistic |
| constant | -4330 | 0.0 | 3204388 | 6.0 | 35.022 | 6.2 | 36.499 | 6.9 |
| year | 1934* | 4.6 | 1542* | 13.6 | 0.060 | 3.6 | 0.048 | 10.4 |
| d2 | 662 | 0.0 | 662 | 0.0 | 3.275 | 37.5 | 3.275 | 37.6 |
| d3 | 6435 | 0.2 | 6435 | 0.2 | 5.529 | 63.4 | 5.529 | 63.4 |
| d4 | 29622 | 0.9 | 29622 | 0.9 | 7.031 | 80.6 | 7.031 | 80.7 |
| d5 | 94496 | 2.9 | 94496 | 2.9 | 8.170 | 93.6 | 8.170 | 93.7 |
| d6 | 191035 | 5.8 | 191035 | 5.8 | 8.871 | 101.7 | 8.871 | 101.8 |
| d7 | 318952 | 9.5 | 318997 | 9.5 | 9.367 | 105.4 | 9.367 | 105.5 |
| d8 | 465052 | 13.8 | 465097 | 13.8 | 9.752 | 109.7 | 9.752 | 109.9 |
| d9 | 612438 | 18.2 | 612483 | 18.2 | 10.035 | 112.9 | 10.034 | 113.1 |
| d10 | 760211 | 22.6 | 760256 | 22.6 | 10.256 | 115.4 | 10.256 | 115.6 |
| d11 | 900844 | 26.8 | 900889 | 26.8 | 10.431 | 117.4 | 10.430 | 117.5 |
| d12 | 1068011 | 31.8 | 1068056 | 31.8 | 10.607 | 119.4 | 10.607 | 119.5 |
| climit | -12948 | -6.0 | | | | | | |
| ccop | 628624 | 5.0 | | | | | | |
| cclm | | | -63933 | -6.2 | | | | |
| lclimit | | | | | -8.071 | -5.5 | | |
| lccop | | | | | 7.780 | 4.7 | | |
| lcclm | | | | | | | -8.508 | -6.3 |
| | | | | | | | | |
| Adjusted $R^2$ | 0.943 | | 0.943 | | 0.994 | | 0.994 | |
| Durbin-Watson | 0.596 | | 0.592 | | 1.000 | | 0.999 | |
| ADF | -2.192 | | -2.283 | | -7.957 | | -7.930 | |
| Prob | 0.028 | | 0.022 | | 0.000 | | 0.000 | |

*explanatory variable is square of year

To see the effect of the new policy from 2006 to 2009 equations 3 and 4 for both types of cardholders were evaluated using known values for June 2006 and 2007 and assuming the copayments increase by 2% per annum in the next two years. Given the announced policy of increasing the number of copayments necessary to reach the safety net limit by 2 per annum to 2009, the value of the safety net limit can also be estimated. Substituting these values in equation 3 gives a decrease of 26.4% and 58.3% in the number of general and concessional safety net cardholders between 2006 and 2009 due to the impact of the new policy. Using equation 4 gives reductions of 30.2% and 52.8% respectively.

The policy of increasing the safety net limit by the value of two copayments per year will therefore have a very significant impact on the numbers of patients eligible to obtain PBS medicines at reduced cost and represents a major shift in the proportion of PBS cost borne by patients rather than the Government.

## 3.5 Government and patient shares in the cost of the PBS

Tables 3.5 to 3.7 show how much of the cost of PBS medicines incurred by each patient category is paid for by the Government and the patient. Compound average annual growth rates from 1991-92 to 2005-06 are given in the last row of each table. It should be remembered when considering these tables that the values reported for General Non-Safety Net patients are just for medicines with a dispensed price higher than the value of the general copayment. This means that the values in this category understate the true amount paid by these patients for the medicines they consume (the Patient Cost) and the overall cost of these medicines (the Total Cost), but not the amount paid by the Government (the Government Cost). The "Other" category in these tables includes medicines consumed in hospitals under the Section 100 provisions and other PBS programs as listed earlier. The expenditure in this category is for medicines that involve no charge to the patient.

General patients accounted for 23.4% of total cost in 2005-06, with concessional patients at 66.1% and "Other" at 10.5%. Concessional and general safety net patients represented 16.1% and 3.3% respectively. As the tables show, the growth rate for general safety net patients has been more varied and lower overall than other categories because of the impact of the safety net limits. By contrast, the growth of

concessional safety net patients has been the largest of all categories, except for the "other" category. General patients meet well over half of the costs of the PBS medicines they consume because of the higher copayments, meaning that concessional patients figure more prominently in the costs paid by the Government, being 70.2% of the total.

The Government paid for 58.3%, 88.8%, and 86.5% of the costs of medicines for general non-safety net patients, general safety net patients and concessional non-safety net patients in 2005-06. As Table 3.8 demonstrates, for general non-safety net patients these percentages reached an historical high in 2000-01 and have been falling consistently since then. The percentage for general safety net patients in recent years was highest in 2004-05 but fell substantially in 2005-06. For concessional patients the percentage was highest in 2003-04 but fell consistently thereafter.

**Table 3.5    Government share of PBS expenditure by patient category, $m**

|  | General | | Concessional | | Other** | Total |
|---|---|---|---|---|---|---|
|  | **Non-SN** | **SN*** | **Non-SN** | **SN** |  |  |
| 1991-92 | 160.8 | 55.3 | 708.4 | 195.0 | 100.9 | 1,220.4 |
| 1992-93 | 188.3 | 118.9 | 845.0 | 251.2 | 101.6 | 1,505.0 |
| 1993-94 | 224.7 | 142.7 | 1,019.7 | 297.6 | 116.7 | 1,801.3 |
| 1994-95 | 290.8 | 93.4 | 1,195.0 | 302.5 | 109.6 | 1,991.3 |
| 1995-96 | 343.0 | 118.7 | 1,369.4 | 360.1 | 135.5 | 2,326.7 |
| 1996-97 | 392.2 | 72.8 | 1,465.7 | 401.8 | 205.5 | 2,538.1 |
| 1997-98 | 411.9 | 98.6 | 1,576.1 | 440.0 | 259.0 | 2,785.5 |
| 1998-99 | 469.0 | 106.6 | 1,739.5 | 467.1 | 287.5 | 3,069.7 |
| 1999-00 | 521.0 | 107.0 | 2,000.6 | 547.8 | 311.7 | 3,488.2 |
| 2000-01 | 662.1 | 128.2 | 2,359.7 | 660.3 | 347.9 | 4,158.1 |
| 2001-02 | 691.2 | 148.5 | 2,569.6 | 778.4 | 396.4 | 4,584.1 |
| 2002-03 | 750.5 | 169.8 | 2,747.3 | 907.5 | 477.4 | 5,052.6 |
| 2003-04 | 824.1 | 190.7 | 2,972.3 | 1,004.5 | 570.5 | 5,562.2 |
| 2004-05 | 850.7 | 222.7 | 3,077.0 | 1,145.5 | 660.0 | 5,955.9 |
| 2005-06 | 850.1 | 216.2 | 3,145.5 | 1,172.5 | 764.7 | 6,149.0 |
|  |  |  |  |  |  |  |
| AAGR, % | 11.7 | 9.5 | 10.4 | 12.7 | 14.5 | 11.4 |

Source DoHA (2006c)

* From 1991-92 to 1995-96 includes General Free Safety Net.

** Includes Doctor's Bag, HSD and miscellaneous

**Table 3.6    Patient share of PBS expenditure by patient category, $m**

|  | General | | Concessional | | Other** | Total |
|---|---|---|---|---|---|---|
|  | **Non-SN** | **SN** | **Non-SN** | **SN** |  |  |
| 1991-92 | 129.0 | 6.0 | 173.2 | 0.0 | 0.0 | 308.2 |
| 1992-93 | 163.0 | 10.2 | 186.7 | 0.0 | 0.0 | 359.9 |
| 1993-94 | 183.0 | 11.1 | 201.6 | 0.0 | 0.0 | 395.7 |
| 1994-95 | 218.1 | 12.2 | 214.2 | 0.0 | 0.0 | 444.5 |
| 1995-96 | 237.2 | 14.3 | 226.6 | 0.0 | 0.0 | 478.1 |
| 1996-97 | 269.7 | 8.4 | 252.1 | 0.0 | 0.0 | 530.2 |
| 1997-98 | 281.7 | 12.6 | 276.4 | 0.0 | 0.0 | 570.8 |
| 1998-99 | 305.1 | 13.2 | 283.1 | 0.0 | 0.0 | 601.3 |
| 1999-00 | 333.0 | 12.6 | 306.2 | 0.0 | 0.0 | 651.8 |
| 2000-01 | 392.4 | 14.4 | 337.4 | 0.0 | 0.0 | 744.2 |
| 2001-02 | 427.0 | 16.9 | 362.2 | 0.0 | 0.0 | 806.1 |
| 2002-03 | 470.6 | 18.7 | 370.5 | 0.0 | 0.0 | 859.7 |
| 2003-04 | 524.8 | 20.5 | 392.5 | 0.0 | 0.0 | 937.8 |
| 2004-05 | 573.0 | 23.7 | 443.9 | 0.0 | 0.0 | 1,040.6 |
| 2005-06 | 606.9 | 27.2 | 489.2 | 0.0 | 0.0 | 1,123.3 |
|  |  |  |  |  |  |  |
| AAGR, % | 10.9 | 10.5 | 7.2 |  |  | 9.0 |

Source DoHA (2006c)

** Includes Doctor's Bag, HSD and miscellaneous

**Table 3.7    Total PBS expenditure by patient category, $m**

|  | General | | Concessional | | Other** | Total |
|---|---|---|---|---|---|---|
|  | **Non-SN** | **SN*** | **Non-SN** | **SN** |  |  |
| 1991-92 | 289.8 | 61.4 | 881.6 | 195.0 | 100.9 | 1,528.6 |
| 1992-93 | 351.2 | 129.1 | 1,031.7 | 251.2 | 101.6 | 1,864.9 |
| 1993-94 | 407.7 | 153.8 | 1,221.2 | 297.6 | 116.7 | 2,197.0 |
| 1994-95 | 508.9 | 105.7 | 1,409.2 | 302.5 | 109.6 | 2,435.9 |
| 1995-96 | 580.3 | 132.9 | 1,596.0 | 360.1 | 135.5 | 2,804.8 |
| 1996-97 | 662.0 | 81.2 | 1,717.8 | 401.8 | 205.5 | 3,068.3 |
| 1997-98 | 693.6 | 111.2 | 1,852.5 | 440.0 | 259.0 | 3,356.3 |
| 1998-99 | 774.1 | 119.8 | 2,022.7 | 467.1 | 287.5 | 3,671.1 |
| 1999-00 | 854.0 | 119.6 | 2,306.8 | 547.8 | 311.7 | 4,140.0 |
| 2000-01 | 1,054.5 | 142.5 | 2,697.0 | 660.3 | 347.9 | 4,902.3 |
| 2001-02 | 1,118.2 | 165.4 | 2,931.8 | 778.4 | 396.4 | 5,390.1 |
| 2002-03 | 1,221.1 | 188.5 | 3,117.8 | 907.5 | 477.4 | 5,912.3 |
| 2003-04 | 1,348.9 | 211.2 | 3,364.8 | 1,004.5 | 570.5 | 6,500.0 |
| 2004-05 | 1,423.7 | 246.4 | 3,521.0 | 1,145.5 | 660.0 | 6,996.5 |
| 2005-06 | 1,457.0 | 243.4 | 3,634.7 | 1,172.5 | 764.7 | 7,272.3 |
|  |  |  |  |  |  |  |
| AAGR, % | 11.4 | 9.6 | 9.9 | 12.7 | 14.5 | 11.0 |

Source DoHA (2006c)

* From 1991-92 to 1995-96 includes General Free Safety Net.

** Includes Doctor's Bag, HSD and miscellaneous

**Table 3.8     Proportion of PBS expenditure paid by Government, %**

|  | General | | Concessional | | Other** | Total |
|---|---|---|---|---|---|---|
|  | **Non-SN** | **SN*** | **Non-SN** | **SN** |  |  |
| 1991-92 | 55.5 | 90.2 | 80.4 | 100.0 | 100.0 | 79.8 |
| 1992-93 | 53.6 | 92.1 | 81.9 | 100.0 | 100.0 | 80.7 |
| 1993-94 | 55.1 | 92.8 | 83.5 | 100.0 | 100.0 | 82.0 |
| 1994-95 | 57.1 | 88.4 | 84.8 | 100.0 | 100.0 | 81.8 |
| 1995-96 | 59.1 | 89.3 | 85.8 | 100.0 | 100.0 | 83.0 |
| 1996-97 | 59.3 | 89.7 | 85.3 | 100.0 | 100.0 | 82.7 |
| 1997-98 | 59.4 | 88.7 | 85.1 | 100.0 | 100.0 | 83.0 |
| 1998-99 | 60.6 | 89.0 | 86.0 | 100.0 | 100.0 | 83.6 |
| 1999-00 | 61.0 | 89.5 | 86.7 | 100.0 | 100.0 | 84.3 |
| 2000-01 | 62.8 | 89.9 | 87.5 | 100.0 | 100.0 | 84.8 |
| 2001-02 | 61.8 | 89.8 | 87.6 | 100.0 | 100.0 | 85.0 |
| 2002-03 | 61.5 | 90.1 | 88.1 | 100.0 | 100.0 | 85.5 |
| 2003-04 | 61.1 | 90.3 | 88.3 | 100.0 | 100.0 | 85.6 |
| 2004-05 | 59.8 | 90.4 | 87.4 | 100.0 | 100.0 | 85.1 |
| 2005-06 | 58.3 | 88.8 | 86.5 | 100.0 | 100.0 | 84.6 |

Source DoHA (2006c)

* From 1991-92 to 1995-96 includes General Free Safety Net.

** Includes Doctor's Bag, HSD and miscellaneous

# Chapter 4

## PBS Expenditure Growth, New Medicines and Patent Expiry

### 4.1 Introduction

The cost of the Pharmaceutical Benefits Scheme (PBS) to the Government has been the subject of regular controversy and policy responses for a number of years. Recent changes to Government policy described in Chapter 2 are principally aimed at cutting the price of medicines once competitors appear but are also driven in part by a concern about the difficulty of giving patients access in the future to those innovative medicines currently in the pipeline that will be more effective in treating disease but could also be more costly. This recognises that the share of biotechnology-based medicines in new listings has become more significant in recent years and these types of medicines are inherently more expensive than traditional small-molecule based medicines. Industry acceptance of these most recent policy changes has been gained by the argument that they are needed to give more "headroom" to allow for more new medicines to be listed and to insulate newer medicines from price cuts.

From time to time the impact of individual new medicines coming onto the PBS has been highlighted, particularly when the demand for some of these medicines exceeds the estimates of their net cost made by both companies and Government. This was the case in 2000-01 when medicines for treating pain (*Celebrex* - celecoxib and *Vioxx* - rofecoxib) and for smoking cessation (*Zyban* – bupropion) were responsible for expenditure of over $270 million.

Over the past few years, long-term projections about the cost of health services caused by an ageing population have been made by the Department of the Treasury (2002, 2007) and more recently and comprehensively by the Productivity Commission firstly in a report about the economic implications of an ageing Australia and secondly in an analysis of the impact of medical technology on healthcare expenditure (Productivity Commission 2005a, 2005b). In the first of these reports the Productivity Commission estimates that the share of the PBS in GDP will rise from 0.68% in 2003-04 to 2.59%

over a forty year period to 2044-45 – a faster increase than either Medicare or hospital expenditure. In a recent report for Medicines Australia however, Access Economics (2006) argues that if growth rates in the PBS return to more historical rates, the share of GDP is likely to be at least 0.9 % lower in forty years than the Productivity Commission's estimates.

Against this background, this chapter is concerned with describing aspects of the growth in PBS expenditure and how this growth has been affected by the operations of PBS pricing and listing policies. The next section highlights the increase in PBS expenditure as a percentage of GDP driven by the continual introduction of new medicines. This expansion of choice has lead to a major shift in the relative importance of the various categories of disease treatments available through the PBS. Within overall PBS expenditure, the dominance of those groups subject to greater Government control – principally WMATC groups, RPGs and TPGs is illustrated.

The contribution to growth from the increase of medicines on the PBS formulary is described both in terms of the numbers involved and their average cost. The contribution to expenditure from new medicines is explored econometrically and suggests that each new medicine adds about $15 million to overall expenditure on average.

In pharmaceutical markets such as those in the United States, patent expiry on the originator brand followed by entry of competitor (generic) brands often results in major decrease in prices. The price setting procedures of the PBS discourage significant price differences among brands and this is illustrated by looking at the shares of both single supplier and multiple supplier medicines in PBS markets, the extent of price differences arising from premiums added by some suppliers (usually originators), and the time taken by generic brands to acquire market share.

The limited influence of patent expiry and generic entry on PBS prices is examined in some detail for all 103 instances of patent expiry in the period from July 1991 to August 2005 (ie prior to the recent changes in PBS policy). Most price changes appear unrelated to either patent expiry or new entry and change in restriction status appears more important.

## 4.2 Expenditure growth in the PBS and its composition

Over the period from 1991-92 to 2005-06, the average rate of growth in the PBS expenditure was 11.8% although this growth has moderated in recent years (Table 4.1 and Figure 4.1).

**Table 4.1     PBS expenditure, 1991-92 to 2005-06**

|         | Expenditure $m | Growth % |
|---------|---------------:|---------:|
| 1991-92 | 1,528.6        | 10.5     |
| 1992-93 | 1,864.9        | 22.0     |
| 1993-94 | 2,197.0        | 17.8     |
| 1994-95 | 2,435.9        | 10.9     |
| 1995-96 | 2,804.8        | 15.1     |
| 1996-97 | 3,068.3        | 9.4      |
| 1997-98 | 3,356.3        | 9.4      |
| 1998-99 | 3,671.1        | 9.4      |
| 1999-00 | 4,140.0        | 12.8     |
| 2000-01 | 4,902.3        | 18.4     |
| 2001-02 | 5,390.1        | 10.0     |
| 2002-03 | 5,912.3        | 9.7      |
| 2003-04 | 6,500.0        | 9.9      |
| 2004-05 | 6,996.5        | 7.6      |
| 2005-06 | 7,272.3        | 3.9      |

Source: DoHA (2006c)

**Figure 4.1     Annual growth rate of PBS expenditure, 1991-92 to 2005-06, %**



Source: DoHA (2006c)

93
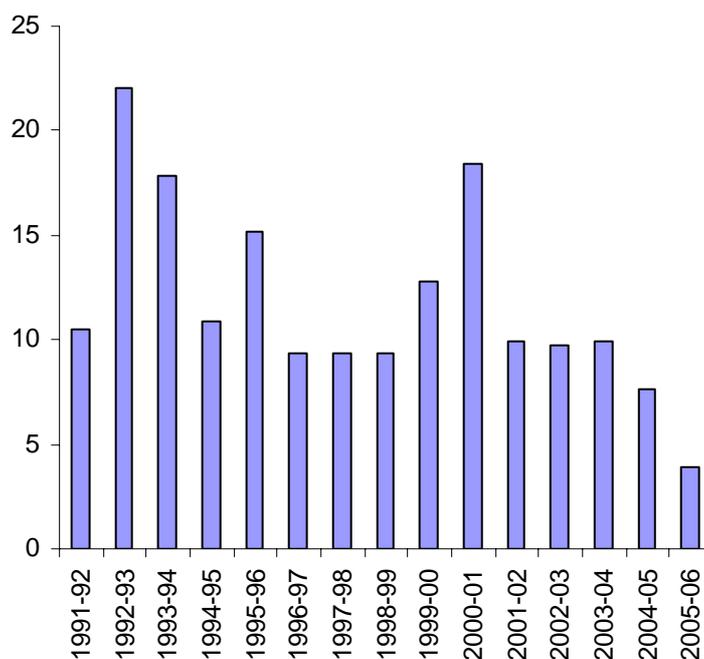
Historically however, this expenditure has been relatively constant as a proportion of GDP for extended periods of time (Figure 4.2), particularly through the 1960s, 1970s, and 1980s. It is only since the beginning of the 1990s that PBS growth has been consistently higher than the growth in overall economic activity. In 1991-92 PBS expenditure was 0.37% of GDP while it reached 0.78% in 2004-05 before falling slightly to 0.75% in 2005-06.

**Figure 4.2    PBS expenditure as percentage of GDP, %**
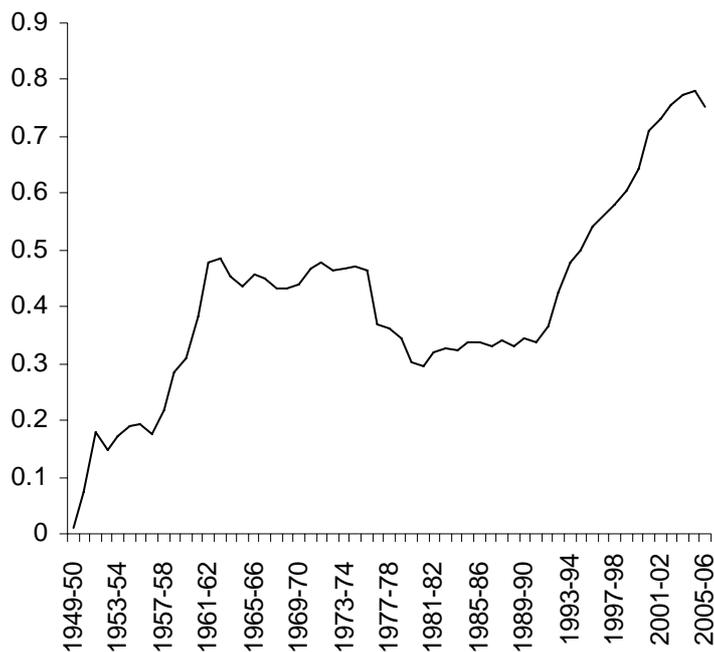


Sources: DoHA (2006c) Table 16a, 16b; ABS (2007a) 5402.0 Table 5; RBA (2007b), Table 5.1a

In part the growth in cost has been driven by the increasing availability of new medicines for treating conditions that were previously either not treated or inadequately treated. This has resulted in a shift in the importance of classes of medicines over time as reflected in Figure 4.3 which compares the shares of medicines in PBS expenditure at the Anatomical main group level (ie the ATC1 level) in 1991-92 with that in 2005-06.

In the more recent year, three ATC1 groups have dominated PBS expenditure.

**Figure 4.3   Shares of PBS expenditure by ATC main group, 1991-92 and 2005-06, %**
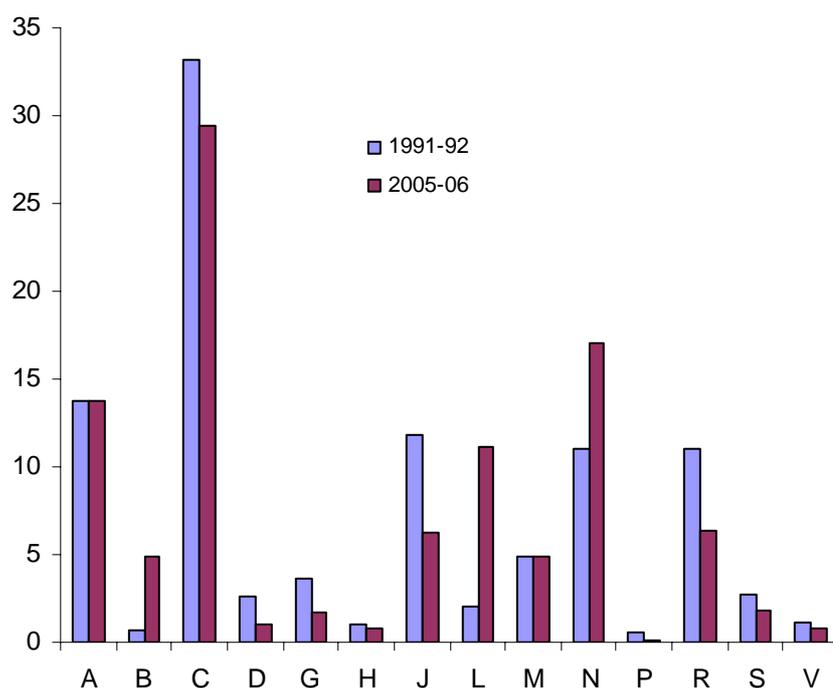


Medicines classified to *Cardiovascular system (C)* accounted for 29.4% of expenditure in 2005-06 and within this group the main contributors are medicines to treat high blood pressure (ACE inhibitors, A2RAs, betas blockers, calcium channel blockers – 12.2%) and to lower cholesterol (statins – 15.6%). The share of PBS expenditure due to cardiovascular medicines has fallen a little since 1991-92 and part of this fall is because of the impact of reduced prices arising from the operation of the PBS pricing system. The second most important ATC group is *Nervous system (N)* which took 17.0% of the PBS market in 2005-06. This group is dominated by medicines for treating psychosis (5.4%) and depression (6.4%). The third most important group in terms of expenditure is *Alimentary tract and metabolism (A)* - 13.7% in which the two most important classes are treatments for peptic ulcers (8.8%) and diabetes (3.3%).

Aside from the antidepressants, the groups that have increased most in importance have been *Antineoplastic and immunomodulating agents (L)* to 11.2% of PBS expenditure due mainly to growth in medicines to treat cancer but also because of medicines working on the immune system, and *Blood and blood forming organs (B)* although this latter group still remains small in its share of expenditure (4.8%).

By way of contrast the two significant groups that have seen their shares fall are the *Antiinfectives for systemic use (J)* and *Respiratory system (R)* medicines although for the first of these a dramatic fall in the shares of antibiotics has been offset to some extent by an increase in antiviral medicines for treating hepatitis, AIDS and other viruses. Within the respiratory group, medicines for treating asthma and other obstructive airways disease are still a significant component of PBS expenditure (6.2%).

In Chapter 2 it was shown that medicines listed on the PBS on a cost-minimisation basis become members of Reference Pricing Groups (RPGs) in which the prices of the group members are set together. About half of all PBS medicines can be classified into these 111 RPGs. In addition 7 of these RPGs are also Weighted Average Monthly Treatment Cost (WAMTC) groups whose prices are reviewed and set on the basis of equalising the cost of a month's treatment among the medicines in the group. Further there are 4 WAMTC groups that are also Therapeutic Premium Groups (TPG). The importance of each of these groups within the PBS is illustrated in Figure 4.4.

**Figure 4.4     WAMTC, TPG and RPG group shares of PBS expenditure.**
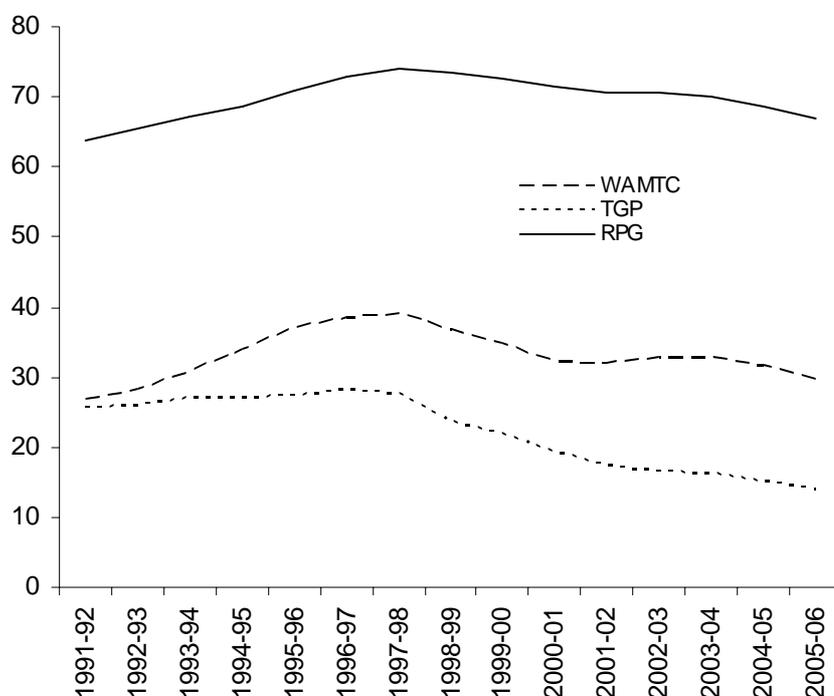


While RPGs accounted for over two thirds of PBS expenditure in 2005-06, the peak of their importance was in the late 1990s and their share of the PBS has declined

steadily since then, in part due to market saturation for some of the main RPGs and through the influence of falling prices. Similar declines in importance are evident for both WAMTC and TPG groups for the same reasons. The relative influences on overall PBS expenditure of changes in consumption and prices of medicines within RPGs and WAMTC groups are explored in more detail in Chapter 7.

## 4.3 Contribution of new medicines

Associated with this changing mix of medicines in different therapeutic areas has been a steady increase in the number of medicines listed. Table 4.2 gives for each year from 1991-92 to 2006-07, the number of new medicines listed, the number of medicines that were in their last year of listing and the overall numbers of medicines on the PBS at June.

**Table 4.2    Numbers of newly listed and exiting PBS medicines.**

| Year | Number of new listings | Number in last year of listing | Total number of medicines at June |
|---|---|---|---|
| 1991-92 | 29 | 9 | 535 |
| 1992-93 | 24 | 6 | 553 |
| 1993-94 | 24 | 29 | 548 |
| 1994-95 | 26 | 15 | 559 |
| 1995-96 | 20 | 23 | 556 |
| 1996-97 | 39 | 10 | 582 |
| 1997-98 | 34 | 23 | 592 |
| 1998-99 | 20 | 13 | 600 |
| 1999-00 | 28 | 7 | 620 |
| 2000-01 | 27 | 14 | 634 |
| 2001-02 | 19 | 14 | 638 |
| 2002-03 | 22 | 16 | 645 |
| 2003-04 | 22 | 7 | 660 |
| 2004-05 | 22 | 16 | 665 |
| 2005-06 | 19 | 16 | 668 |
| 2006-07 | 27 | 13 | 687 |
| 2007-08* | 23 | 5 | 712** |
| Total | 425 | 236 | |
| Average 1991-92 to 2006-07 | 25.1 | 14.4 | |

* first ten months only, ** at April

This latter number increased from 535 in June 1992 to 687 in June 2007 an increase of 152 or 28%. This increase however understates the 402 new medicines listed over the period which were offset by 231 medicines which exited the PBS formulary for a variety of reasons. Table 4.2 and Figure 4.5 demonstrate that the number of new

medicines listed on the PBS has usually been in the range of 20 to 25 per year despite some larger numbers in years such as 1996-97 and 1997-98.

**Figure 4.5    Numbers of newly listed and exiting PBS medicines.**
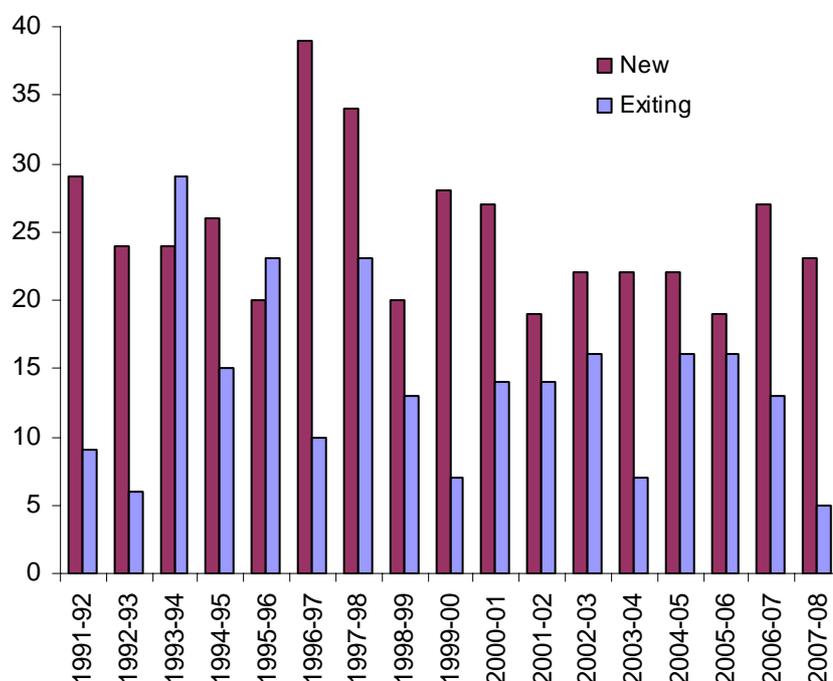


The average number listed per year over the period was 25.1. The number of exiting medicines has shown more variation from year to year but averaged 14.4 per year. It is interesting to note that over the five year period to 2005-06 the number of new medicines per year was in the range 19-22 but there was a significant jump in both 2006-07 to 27 and the first 10 months of 2007-08 to 23. This may reflect an increasing willingness to accommodate more new medicines given the "headroom" created by the price reduction policies that began to take effect in late 2005.

The contribution to the increase in PBS expenditure from new medicines can be examined in a number of ways but two are undertaken here. Firstly the average annual expenditure per new medicine is calculated based on PBS expenditure data from 1991-92 to 2005-06. Following that the relationship is explored econometrically.

The average cost to the PBS for each medicine can be calculated by adding the costs from the year of entry to 2005-06 (or the year the medicine exited the PBS) and dividing by the number of years. This average gives an indication of the typical

contribution to the annual cost of the PBS from that medicine. For the period 1991-92 to 2005-06 the average cost calculated in this way was $9.9 million (Sweeny 2007c). For medicines listed in recent years this measure must be treated with some caution because, as demonstrated below, it takes a number of years for a medicine to reach its typical annual PBS cost. In addition, this only measures the gross addition to the cost of the PBS from listing the new medicine, and does not take account of reductions in the cost of medicines from which the new medicine may take market share.

A profile of cost over time was developed for each of the medicines on the PBS and on the basis of this a profile for the average new medicine was calculated (Sweeny 2007c). Table 4.3 shows the cost for this average new medicine in the first to seventh year of life on the PBS. The first column shows the profile for all medicines since 1991-92 while the second column gives the calculations for a more recent cohort – all medicines listed since 1996-97. As might be expected the cost to the PBS rises steadily over time to reach a steady state level in about the sixth year. The most recent cohort has a somewhat higher cost profile than that for all medicines.

**Table 4.3     Average cost of a new medicine by year following listing on PBS, $m**

|        | All medicines since 1991-92 | All medicines since 1996-97 |
|--------|:---------------------------:|:---------------------------:|
| First  | 2.5  | 3.1  |
| Second | 6.7  | 8.0  |
| Third  | 9.9  | 12.2 |
| Fourth | 12.2 | 15.0 |
| Fifth  | 13.0 | 15.6 |
| Sixth  | 13.9 | 16.9 |
| Seventh| 14.0 | 16.8 |

While the average annual cost provides some idea of the impact of new medicines, most new medicines cost considerably less than this amount. About three quarters of new medicines listed (75.8%) cost less than $10 million per year, about two thirds (64.3%) end up costing less than $5 million per year, with about a third (36.1%) costing less than $1 million. As discussed in Chapter 2, PBS medicines expected to cost more than $5 million per year require approval by the Department of Finance and Administration, while those with an expected cost greater than $10 million require Cabinet approval. There are a handful of medicines (4.5%) that cost more than $50

million per year, with the rest (19.7%) falling between $10 and $50 million (Sweeny 2007c).

It was shown in Chapter 2, that when suppliers apply to have a new medicine listed on the PBS, the usual (and most successful) type of economic analysis presented is a cost-minimisation one. This accepts that the new medicine is similar in efficacy and side effects to one or more medicines already available on the PBS and the degree of innovation or novelty in the new medicine is small compared to these other medicines. Researchers have sought to characterise medicines by their degree of novelty and used this to explain their varying degrees of success in the market, either in terms of prices or sales. A common method is to follow the practice of the FDA in the United States which classifies medicines being presented for approval into either "Priority" or "Standard" according to an assessment by the FDA. For "Priority" medicines the FDA believes that the candidate medicine offers a "significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease" while a "Standard" medicine "appears to have therapeutic qualities similar to those of one or more already marketed drugs" (FDA 2004). Lu and Comanor (1998) have explained differential prices in US pharmaceutical markets using this classification. The age of medicines has also been used a proxy for degree of novelty (for example Lichtenberg 2003, 2007).

An alternative to these approaches is to assess the novelty of a new medicine by whether it is assigned a new ATC code within the ATC system. Any new medicine is assigned a unique seven digit ATC code but this is usually as an addition within an existing ATC5 level code. Occasionally a new medicine initiates a new code at ATC5 level or higher because it has a sufficiently new mode of action to warrant separate classification. Simvastatin (C10AA01) for instance initiated a new class of cholesterol lowering agents at the ATC5 level, namely *C10AA - HMG CoA reductase inhibitors*, while losartan (C09CA01) began both new ATC4 and ATC5 codes for blood pressure lowering medicines, namely *C09C* and *C09CA* both of which are called *Angiotensin II antagonists, plain*.

From June 1991 to July 2007 there were 93 medicines that were novel in the sense that they introduced a new ATC5 code. These additions amount to about 6 per year on

average and account for about 25% of all current ATC5 codes. Medicines introducing a new ATC3 or ATC4 code were much rarer at 21 and 5 over the 16 year period. Their distribution over the period is shown in Table 4.4 and Figure 4.6.

**Table 4.4    Novel medicines listed on the PBS**

|  | ATC5 | ATC4 | ATC3 |
|---|---|---|---|
| Pre 1991-92 | 285 | 146 | 74 |
| 1991-92 | 12 | 4 | 2 |
| 1992-93 | 9 | 2 | 1 |
| 1993-94 | 4 | 0 | 0 |
| 1994-95 | 9 | 2 | 0 |
| 1995-96 | 3 | 0 | 0 |
| 1996-97 | 8 | 0 | 0 |
| 1997-98 | 8 | 1 | 0 |
| 1998-99 | 4 | 1 | 0 |
| 1999-00 | 7 | 2 | 0 |
| 2000-01 | 6 | 2 | 1 |
| 2001-02 | 1 | 0 | 0 |
| 2002-03 | 3 | 1 | 0 |
| 2003-04 | 3 | 2 | 0 |
| 2004-05 | 7 | 2 | 1 |
| 2005-06 | 4 | 1 | 0 |
| 2006-07 | 5 | 1 | 0 |
| 1991-92 to 2006-07 | 93 | 21 | 5 |
| Total | 378 | 167 | 79 |
| % since 1991-92 | 24.6 | 12.6 | 6.3 |

**Figure 4.6    Novel medicines listed on the PBS, ATC5 level**
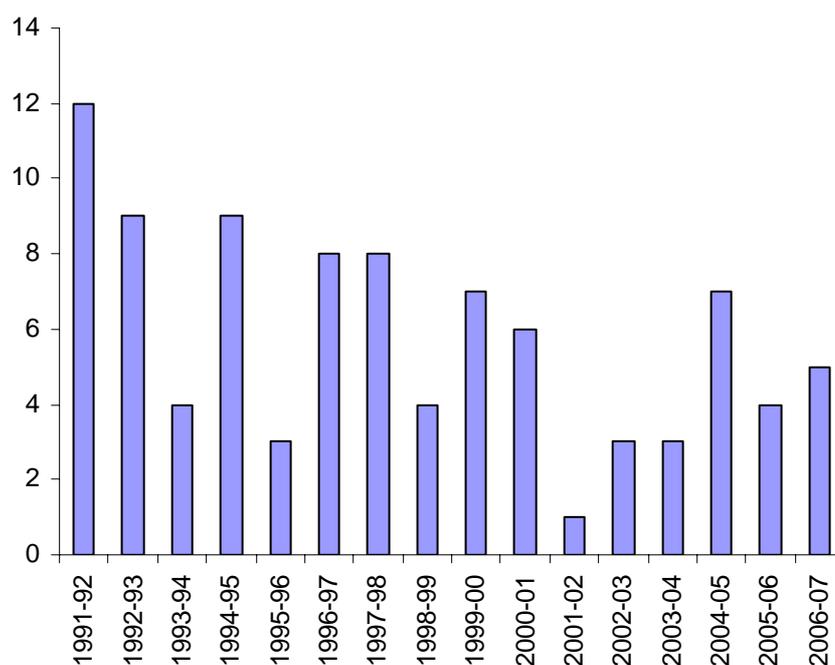
While there is considerable year to year variation, the number of novel medicines listed per year has fallen, particularly when compared to the levels of the first half of the 1990s. Over the eight years to 2006-07, the average number of medicines introducing a new ATC5 code per year was 4.5, while over the previous eight years the average was 7.1.

The determinants of PBS expenditure are likely to be complex and vary considerably among the different treatment markets. Expenditure has both a price and a volume or quantity component and the decomposition of expenditure into these components is described in the following chapters. Demand equations typically are based on a volume or quantity measure as the dependent variable and relate the amount and type of medicines demanded by patients to the influence of a number of factors, such as the incidence and prevalence of the disease being treated, the degree of restriction placed on prescribing for particular medicines, and the cost to the patient as measured by the levels of copayments, safety net levels and price premiums. Demand equations of this type are explored in Chapter 8. These equations have as the dependent variable a measure of the quantity consumed measured in physical units such as doses or defined daily doses.

When estimated at an aggregate level, these demand equations can include the number of molecules as an explanatory variable to ascertain how the expansion in demand is related to the increasing availability of medicines to treat disease. The impact of the number of molecules on the level of expenditure, rather than the quantity demanded can also be explored econometrically by a simple equation relating expenditure to a trend variable and the number of molecules.

Tables 4.5 to 4.7 set out the results of estimating equations using PBS expenditure as the dependent variable and the number of medicines and a population trend as explanatory variables. Equations are estimated using data defined at ATC1, ATC3, ATC4 and ATC5 levels and for both linear and logarithmic specifications. ATC dummy variables are used to control for market specific conditions. The variables are

| | |
|---|---|
| *constant* | Constant |
| $ccop_t$ | Average level of concessional copayment in year t |

| | | |
|---|---|---|
| $ATC_a$ | Dummy variable with value 1 for ATC code a, 0 otherwise | |
| $mol_{at}$ | Number of molecules in ATC code a in year t | |
| $pbsexp_{at}$ | PBS expenditure in ATC code a in year t | |
| $pop_t$ | Australian population at June in year t | |

An '*l*' preceding the variable name indicates the natural logarithm of the variable.

**Table 4.5    Regression results for PBS expenditure, linear**

| ATC level | ATC1 | | ATC3 | | ATC4 | | ATC5 | |
|---|---|---|---|---|---|---|---|---|
| Dep. variable | pbsexp | | pbsexp | | pbsexp | | pbsexp | |
| | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat |
| constant | -1885.9 | -9.4 | -385.0 | -11.5 | -204.4 | -11.4 | -99.1 | -10.0 |
| pop | 89.2 | 8.0 | 18.3 | 11.0 | 8.9 | 10.7 | 3.6 | 8.9 |
| mol | 15.4 | 8.5 | 12.7 | 16.4 | 12.5 | 20.6 | 16.4 | 25.6 |
| | | | | | | | | |
| Adjusted $R^2$ | 0.871 | | 0.803 | | 0.765 | | 0.718 | |
| D-W | 0.111 | | 0.119 | | 0.114 | | 0.117 | |
| Pedroni tests | 1/11 | | 7/11 | | 8/11 | | 9/11 | |
| n | 210 | | 1111 | | 2245 | | 4620 | |

**Table 4.6    Regression results for PBS expenditure, logarithmic**

| ATC level | ATC1 | | ATC3 | | ATC4 | | ATC5 | |
|---|---|---|---|---|---|---|---|---|
| Dep. variable | lpbsexp | | lpbsexp | | lpbsexp | | lpbsexp | |
| | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat |
| constant | -22.890 | -21.5 | -11.826 | -5.7 | -8.949 | -6.4 | -19.565 | -3.2 |
| lpop | 7.935 | 21.0 | 3.444 | 4.9 | 2.459 | 5.3 | 1.129 | 3.1 |
| lmol | 1.335 | 9.7 | 2.034 | 16.4 | 2.050 | 24.1 | 1.737 | 23.4 |
| | | | | | | | | |
| Adjusted $R^2$ | 0.962 | | 0.828 | | 0.821 | | 0.810 | |
| D-W | 0.320 | | 0.463 | | 0.514 | | 0.495 | |
| Pedroni tests | 3/11 | | 8/11 | | 8/11 | | 9/11 | |

**Table 4.7    Regression results for PBS expenditure including copayment**

| ATC level | ATC1 | | ATC3 | | ATC4 | | ATC5 | |
|---|---|---|---|---|---|---|---|---|
| Dep. variable | lpbsexp | | lpbsexp | | lpbsexp | | lpbsexp | |
| | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat |
| constant | -36.272 | -9.0 | -25.928 | -3.3 | -22.152 | -4.2 | -93.734 | -3.8 |
| lpop | 13.075 | 8.5 | 8.857 | 3.0 | 7.525 | 3.8 | 5.645 | 3.8 |
| lmol | 1.330 | 10.0 | 2.034 | 16.4 | 2.054 | 24.1 | 1.738 | 23.5 |
| lccop | -1.482 | -3.4 | -1.567 | -1.9 | -1.464 | -2.6 | -1.300 | -3.1 |
| | | | | | | | | |
| Adjusted $R^2$ | 0.964 | | 0.829 | | 0.822 | | 0.810 | |
| D-W | 0.308 | | 0.459 | | 0.511 | | 0.494 | |
| Pedroni tests | 4/11 | | 7/11 | | 8/11 | | 9/11 | |

Population data was obtained from ABS (2007c). Equations were estimated using a time trend and the size of the population in age categories such as "55 and over" and "65 and over" as alternatives to using the total population as an explanatory variable. However all these alternatives are highly correlated and produce virtually identical results, so only results using total population are reported. In addition equations were estimated including the average level for the concessional copayment to capture the impact of this on expenditure. Because the general and concessional copayment levels over the period 1991-92 to 2005-06 are highly correlated (r = 0.999), the concessional copayment is used as a proxy for both. In most equations however the copayment is insignificant so results are only reported including it for the logarithmic specification including ATC dummy variables (Table 4.7).

In general the logarithmic specification performs better than the linear. However, as the adjusted coefficient of determination indicates, the amount of variance explained by the independent variables declines steadily as the ATC level increases, indicating the increasing predominance of ATC-specific factors. The fit statistics for results excluding the ATC dummy variables are much inferior to those including them.

In all cases the population trend and the number of molecules have significant coefficients with the expected signs but the contribution from population becomes less as the ATC level rises, while the contribution from the number of molecules remains relatively constant. The linear specification with ATC dummy variables suggest that every additional molecule will add between $13 million and $15 million to PBS expenditure. At the ATC4 level an increase of 1 million to population adds a further $9 million to PBS expenditure. The logarithmic version implies that expenditure will increase by about twice the increase in the number of molecules and 2.5 times the increase in population (at the ATC4 level).

The results including the concessional copayment show that the coefficient on this variable has the expected sign although its significance is not as great as for the other variables. The results in Table 4.6 imply that a 1% increase in the copayment will lead to a fall in expenditure of about 1.5%. It should be noted that the inclusion of this variable does not significantly change the coefficient on the number of molecules but increases the size of the coefficient on the population variable while reducing its

significance somewhat. This latter result is probably because the two variables are highly correlated (r = 0.963). Omitting the population variable results in a positive (and significant) coefficient for the copayment variable.

All equations were tested for cointegration using the Pedroni residual cointegration test using panel data within EViews. This provides 11 test statistics for cointegration and the number of tests which indicate cointegration at the 5% level of significance are reported for each regression result in Tables 4.5 to 4.7. This test indicates no cointegration at the ATC1 level but the high scores at higher ATC levels indicate cointegrating relationships among the variables for these specifications.

In summary, the regression results show that as the number of medicines available on the PBS increases, this leads to a more than proportionate increase in expenditure on PBS medicines as the choice of medicines expands and as new medicines become available to improve the treatment of disease.

## 4.4 The extent of competition in the PBS

Once patents protecting medicines have expired, new brands competing with the originator brand are able to enter the market if they have demonstrated bioequivalence to the satisfaction of the regulatory authority. As described in Chapter 2, it is a relatively straightforward process for the supplier of a competing brand to have that brand listed on the PBS once approved by the TGA.

These competing brands are often referred to as "generic" brands and the suppliers "generic" suppliers. It is important to note however that it is not possible to draw a hard and fast line between originator and generic brands or suppliers.

"Generic" brands are often taken to be those medicines where the supplier provides them under the molecular or chemical name. For instance "Zocor" is the name of the brand of the medicine simvastatin provided by the originator company Merck, Sharp & Dohme (Australia) while the competing brand from Winthrop Pharmaceuticals is called "Simvastatin Winthrop" and the version from Genepharm Australasia Limited is simply called "Simvastatin". However the brand from Alphapharm Pty Limited has

the distinctive name of "Zimstat". A distinction can be drawn therefore between branded and unbranded generics.

While Alphapharm Pty Limited is usually described as a "generic" supplier because it does not develop its own medicines, it also acts as the single supplier of some patent-protected medicines licensed from other companies, as is the case with other "generic" suppliers. Often these are brands licensed from the originator company once that company has decided it no longer wants to supply that particular medicine any more. Aspen Pharmacare Australia Pty Ltd is another example of such a company.

Some "originator" companies also produce "generic" brands that compete with other "originator" companies once their medicines are no longer patent-protected. For instance Winthrop Pharmaceuticals only supplies off-patent medicines but is a subsidiary of Sanofi-Aventis, the second largest research-based pharmaceutical company in the world. Similarly Real-RL supplies a generic version of simvastatin ("Simvastatin-RL") but is a subsidiary of GlaxoSmithKline Australia Pty Ltd, the third largest research-based pharmaceutical company.

The picture is further complicated by the practice of originator companies licensing a "generic" company to list a "friendly" generic brand before patent expiry to protect market share and price once patent expiry has occurred.

The operation of the minimum pricing policy within the PBS means that competing suppliers have relatively little incentive to offer a lower price for their brand to the PBS because all other brands of the same medicine will have their price reduced to this level, although there is an opportunity for suppliers to add a brand premium to the price. This lack of incentive to lower prices has been the main reason why the Government introduced the changes to PBS policy in 2004 and 2006 described in Chapter 2.

Assessing the shares of "generics" in the PBS is therefore not straightforward and is best approached by establishing whether a medicine is provided on a single or multiple supplier basis. Where a medicine has multiple brands indicating competing suppliers, these brands are classified as either the "Originator" brand or as a

"Competing" brand. The procedure for determining single and multiple supplier status and classifying brands in this way is set out in Appendix A. Classifying PBS medicines in this way is a significant task and has only been undertaken completely for the year 2005-06.

Table 4.8 provides a break-down of the PBS expenditure in 2005-06 according to the supplier status and patent status of each medicine listed. Medicines are either provided by a single supplier (which can include multiple brands from the same one supplier) or by multiple suppliers, which are classified as either the "originator brand" or as a "competing brand". Medicines are "patented" if their patent expiry date is given as after 30 June 2006 or "off-patent" if expiry date is up to 30 June 2006 or is unpatented. There is a small unclassified component of expenditure – mainly extemporaneously prepared medicines, where the supplier is unknown and are assumed to be off-patent. The procedure for assigning patent expiry dates is also described in Appendix A.

**Table 4.8    PBS expenditure by supplier and patent status, 2005-06**

|  | Off-patent | Patented | Total | Off-patent | Patented | Total |
|---|---|---|---|---|---|---|
|  | $m | $m | $m | % | % | % |
| Single supplier | 828.0 | 3,895.0 | 4,723.0 | 26.8 | 96.2 | 66.2 |
| Multiple supplier | 2,254.6 | 152.7 | 2,407.3 | 73.0 | 3.8 | 33.7 |
|   Originator brand | 1,247.2 | 134.5 | 1,381.7 | 40.4 | 3.3 | 19.4 |
|   Competing brand | 1,007.4 | 18.2 | 1,025.6 | 32.6 | 0.4 | 14.4 |
| Other | 5.1 | 0.0 | 5.1 | 0.2 | 0.0 | 0.1 |
|  |  |  |  |  |  |  |
| All medicines | 3,087.7 | 4,047.7 | 7,135.4 | 100.0 | 100.0 | 100.0 |

In 2005-06, just under two thirds of PBS expenditure was for single supplier medicines, with the remaining third made up of medicines from multiple suppliers. Of these multiple brands, 57.4% of the expenditure was on originator brands with 42.6% on brands competing with the originator. As Table 4.8 shows however, even within the off-patent section of the PBS where competition among brands predominantly occurs, there is still a sizable share taken by single supplier medicines (26.8%). For the whole of the off-patent market, the share of competing brands is 32.6%, while for the whole of the PBS their share is 14.4%. This latter value then can be taken as the "generics" share within the PBS.

Not surprisingly the patented section of the PBS is dominated by single supplier medicines, although the small presence of originator and competing brands indicates that originators may have licensed competing brands for some medicines with patent expiries after 30 June 2006.

Despite the caveats discussed earlier it is possible to classify PBS suppliers as either predominantly "Research-based" in that they usually supply medicines based on their own research and development (or in alliance with other researchers) or as "Generic" companies principally supplying generic brands. Table 4.9 shows expenditure classified in this way with a small residual category of "Other" companies which supply other products such as diagnostics or act as suppliers of off-patent medicines but not in competition with other suppliers.

**Table 4.9    PBS expenditure by supplier status and type of company, 2005-06**

|  | Research-based $m | Generic $m | Other $m |
|---|---|---|---|
| Single supplier | 4,583.0 | 125.5 | 14.4 |
| Originator | 1,176.9 | 201.6 | 3.3 |
| Competing brand | 71.2 | 953.7 | 0.7 |
| Other | 0.0 | 0.0 | 5.1 |
| | | | |
| Total | 5,831.1 | 1,280.8 | 23.5 |

The "generic" companies account for about 17.9% of PBS expenditure and although their medicines are predominantly "competing" brands, medicines provided by them as single suppliers and as suppliers of "originator" brands under license account for about 25% of their contribution to PBS cost. The "research-based" companies on the other hand are overwhelmingly suppliers of either single supplier medicines or of "originator" brands.

The opportunities open to competing brands are mainly in the off-patent market which represents about 43.3% of the PBS. Within this segment competing brands have 44.7% of the markets in which they compete and 32.6% of all off-patent markets. While these shares are significant, they are much less than those in markets such as the USA were generics take up to 80% of the market once patent expiry has occurred.

There are a number of factors responsible for this such as the size of off-patent markets and barriers to entry, but an important reason is likely to be the absence of significant price competition among originator and competing brands. Patients consuming PBS medicines pay a fixed copayment plus any premium added by the supplier to the base price determined by the PBS. The incentive to switch between originator and competing brands therefore will be influenced by the size of this premium.

This relationship is explored in some detail in Chapter 8 so the discussion below presents evidence on how significant this effect might be.

There are three kinds of premium that can apply to brands listed on the PBS. The most common is the *brand premium* which is the addition made by a supplier to the base price of a particular PBS item where there are other suppliers of that item. Where they occur, brand premiums are almost always added by originator companies rather than generic companies. In recent years about 12% of all brands have had a brand premium.

*Therapeutic premiums* can be added by a manufacturer to the base price even if there are no direct competitor brands. This only applies to medicines within the four Therapeutic Premium Groups discussed in Chapter 2 and has only ever been applied to 42 brands. The third premium is a *Special Patient Contribution* (SPC) which arises when the Government and manufacturer are unable to agree on a price and the SPC is the difference between the Government base price and the manufacturer's price. Historically SPCs have applied only to one or two medicines but have become more widely used since the introduction of the 12.5% price reduction policy.

All brands with a brand premium for all items listed on the PBS from July 1991 to April 2007 were extracted from the PBS Schedule database described in Appendix A. The size of the premium was calculated by subtracting the Commonwealth dispensed price for maximum quantity (CDPMQ) from the manufacturer's dispensed price for maximum quantity (MDPMQ). Annual premiums were taken as averages of the relevant 12 monthly premiums. The premium margin was obtained by dividing the premium by CDPMQ.

The importance of premiums can be looked at in a number of ways. Firstly the number of brands with premiums can be compared to the number of brands overall. The number of brands with premiums increased from 7.3% of all brands on average in 1991-92 to 12.1% in 2005-06 (Table 4.10).

**Table 4.10    PBS brand premium margins**

|         | Brands with premium | All brands | % | Unweighted average margin, % | Weighted average margin, % |
|---------|--------------------|------------|------|-----------------------------|----------------------------|
| 1991-92 | 132 | 1800 | 7.3  | 9.2  | 6.3 |
| 1992-93 | 169 | 1842 | 9.2  | 9.8  | 6.8 |
| 1993-94 | 186 | 1866 | 10.0 | 13.3 | 8.5 |
| 1994-95 | 223 | 2129 | 10.5 | 13.6 | 8.3 |
| 1995-96 | 230 | 2174 | 10.6 | 12.7 | 8.6 |
| 1996-97 | 252 | 2352 | 10.7 | 13.0 | 7.2 |
| 1997-98 | 288 | 2661 | 10.8 | 12.5 | 7.6 |
| 1998-99 | 336 | 2794 | 12.0 | 12.7 | 8.0 |
| 1999-00 | 359 | 2927 | 12.3 | 13.8 | 7.3 |
| 2000-01 | 429 | 3182 | 13.5 | 13.2 | 7.4 |
| 2001-02 | 417 | 3592 | 11.6 | 14.5 | 7.6 |
| 2002-03 | 413 | 3759 | 11.0 | 15.9 | 9.2 |
| 2003-04 | 413 | 3871 | 10.7 | 16.4 | 9.4 |
| 2004-05 | 414 | 3594 | 11.5 | 15.2 | 6.4 |
| 2005-06 | 455 | 3750 | 12.1 | 15.2 | 6.0 |

The (unweighted) average margin for those brands with premiums has also risen steadily over the period from 9.2% of the base price in 1991-92 to 15.2% in 2005-06. However if the average is calculated by weighting the margin on a brand by its importance (its share of PBS expenditure on brands with premiums) the weighted average margin is significantly less than the unweighted average margin and shows no real increase over the period although there is substantial variation from year to year. This suggests that while the practice of adding a premium has become more common as more originator medicines face competition from generic suppliers, the size of the margin sought by originators is proportionally smaller the larger is the market for that brand. This may be due to the greater intensity of competition from generic suppliers in the market for more popular medicines.

The size of the differential between the prices sought by originator and generic suppliers is quite small compared to the usual experience in markets such as the USA

where the originator brand maintains its price and generic prices are of the order of 20% or less of the originator price (Berndt 2002, Lu and Comanor 1998). It should be recognised however that the patients generally will not pay the dispensed price but a combination of the relevant copayment and the premium if any. The comparison that matters to patients is therefore the size of the margin with respect to the copayment not the dispensed price.

Inspection of the premiums in comparison to the base dispensed price suggests that originators initially seek a premium that will simply maintain the dispensed price at its previous level, even though this means an increase in the amount paid by the patient. Originators are therefore relying on brand loyalty to maintain market share. Similarly, if the base dispensed price falls in periods thereafter the premium will be kept constant so that there is no change in the price paid by the patient (assuming there has been no change in the copayment).

The relatively small margins added by suppliers to the base price account in part for the fact that competing brands have only a minority share on average in markets in which they compete. As part of the work undertaken by the author modeling the impact of the recent changes to PBS policy (CSES 2006b), the rate at which originators lose market share was calculated using PBS expenditure data from 1991-2 to 2004-05. Table 4.11 reports this share both as an unweighted average of all PBS medicines for which this occurred during the period and as an average where the medicine is weighted by its importance as measured by its PBS expenditure.

**Table 4.11    Average market share of originator brand after entry of competitors**

| Year after competitive entry | Unweighted % | Weighted % |
|---|---|---|
| 0 | 100.0 | 100.0 |
| 1 | 94.2 | 94.4 |
| 2 | 85.6 | 87.0 |
| 3 | 79.3 | 78.1 |
| 4 | 75.3 | 71.5 |
| 5 | 73.0 | 67.7 |
| 6 | 68.5 | 62.2 |
| 7 | 66.6 | 61.3 |
| 8 | 63.0 | 61.6 |
| 9 | 56.9 | 56.8 |

Both profiles show that loss of market share is gradual so that by the fourth year after entry of competing brands, the originator still retains about 70-75% of the market and over half the market after 9 years. The reduction in share is slightly faster for the weighted average suggesting that competitors strive more aggressively for market share within larger markets.

## 4.5 Price changes after patent expiry and new entry

In the study conducted prior to the introduction of the mandatory 12.5% price reduction policy (CSES 2005), the author examined the extent to which patent expiry and any subsequent entry by competing brands led to changes in the prices paid by the PBS for these medicines. The analysis for that study covered the period from August 1994 to August 2004 but the results reported below extend this to cover a longer range from August 1991 to July 2005, ie until just before the introduction of the new policy.

During this period some 103 medicines experienced patent expiry but some had more than one expiry because of different patents for different forms. Because of this there were 112 patent expiries in total. Of these only 46 attracted competing brands for at least one of the formulations of the medicine. For each of these medicines the most popular item was identified and the price per unit was charted and examined. The price chosen was the Commonwealth price to pharmacist divided by the manufacturer's pack size because it provides the clearest picture of trends in prices. It is preferable to the dispensed price because changes in the latter will include changes made to the dispensing fee. In addition the Commonwealth price to pharmacist does not include any changes due to premiums added by the manufacturer.

Visual examination of the price data indicated that 17 of the medicines experienced either price increases, or no change in prices, or only very minor decreases (less than 5%) across the period even though there were competing brands present. The remaining 29 medicines which are listed in Table 4.12 were considered in two broad groups. The first consists of 14 medicines that are either not members of a Reference Pricing Group (RPG) or are the only member of the group which experienced patent expiry. The second group consists of 15 medicines within 6 RPGs of which 5 are

WAMTC groups. By and large these groups are more important in terms of overall PBS sales than the medicines in the first group.

**Table 4.12    Patent expiries and new entry with price falls, 1991 to 2005**

| RPG/Name | ATC code | Item | PBS cost 2005-06 | PBS cost 1991-92 to 2005-06 | Patent expiry date |
|---|---|---|---|---|---|
| Aciclovir | J05AB01 | 1007B | 8.5 | 291.4 | 2/09/1995 |
| Carboplatin | L01XA02 | 1161D | 7.0 | 39.8 | 6/06/1993 |
| Clarithromycin | J01FA09 | 6152T | 5.0 | 36.8 | 26/03/2005 |
| Cyclosporin | L04AA01 | 6114T | 24.3 | 394.6 | 5/03/1999 |
| Flecainide acetate | C01BC04 | 1090J | 5.6 | 53.2 | 27/03/1995 |
| Flutamide | L02BB01 | 1417N | 0.8 | 34.2 | 19/09/2000 |
| Gabapentin | N03AX12 | 1835N | 9.2 | 81.4 | 19/12/1991 |
| Ipratropium bromide | R03BB01 | 1542E | 21.0 | 685.6 | 4/07/1999 |
| Irinotecan hydrochloride | L01XX19 | 8415X | 14.1 | 61.1 | 13/07/2004 |
| Isotretinoin | D10BA01 | 2592K | 18.4 | 340.8 | 20/06/1991 |
| Naproxen | M01AE02 | 1659H | 4.8 | 126.1 | 12/01/1992 |
| Norfloxacin | J01MA06 | 3010K | 2.6 | 46.1 | 24/01/1998 |
| Paclitaxel | L01CD01 | 3026G | 33.0 | 183.6 | 29/01/1999 |
| Timolol maleate | S01ED01 | 1279H | 8.1 | 136.9 | 13/09/1996 |
| **Third-generation cephalosporins** | | | | | |
| Cefotaxime | J01DD01 | 1085D | 0.2 | 9.4 | 15/08/1998 |
| Ceftriaxone | J01DD04 | 1784X | 3.9 | 56.5 | 23/05/1999 |
| **Calcium channel blockers** | | | | | |
| Felodipine | C08CA02 | 2367N | 31.7 | 575.7 | 21/06/1999 |
| Nifedipine | C08CA05 | 1695F | 21.0 | 411.9 | 21/08/1988 |
| **ACE inhibitors** | | | | | |
| Captopril | C09AA01 | 1149L | 5.2 | 546.3 | 13/01/1997 |
| Enalapril maleate | C09AA02 | 1369C | 18.2 | 968.3 | 3/12/1999 |
| Lisinopril | C09AA03 | 2458J | 16.9 | 430.1 | 16/04/2001 |
| **H2-receptor antagonists** | | | | | |
| Cimetidine | A02BA01 | 1158Y | 0.9 | 167.8 | 14/09/1993 |
| Famotidine | A02BA03 | 2487X | 3.2 | 337.3 | 1/07/2003 |
| Ranitidine hydrochloride | A02BA02 | 1978D | 25.0 | 1,045.7 | 1/08/1993 |
| **Proton pump inhibitors** | | | | | |
| Omeprazole | A02BC01 | 1327W | 170.2 | 2,081.4 | 11/04/1999 |
| **Antidepressants** | | | | | |
| Citalopram hydrobromide | N06AB04 | 8220P | 41.0 | 344.2 | 5/01/1993 |
| Fluoxetine hydrochloride | N06AB03 | 1434L | 27.3 | 458.8 | 24/12/1994 |
| Moclobemide | N06AG02 | 1900B | 7.3 | 268.5 | 6/01/1997 |
| Paroxetine hydrochloride | N06AB05 | 2242B | 41.9 | 503.2 | uncertain |

The experience of the medicines in the first group is as follows.

*Aciclovir* experienced patent expiry in September 1995 although Arrow Pharmaceuticals and Alphapharm had brands listed prior to this in December 1994 and February 1995 respectively. Two price decreases of about 3% each occurred in August 1999 and February 2003 possibly due to new brands from Douglas Pharmaceuticals, Genepharm and Hexal Australia in May 1999 and Biochemie Australia in August 2002. However there were other entrants between these two dates that were not associated with price falls. There were no changes in the "Authority required" restriction level during the period. Aciclovir belongs to an RPG but the other two members – *famciclovir* and *valaciclovir* were patent protected during the period.

The patent on *carboplatin* expired in June 1993 but the only significant change in prices occurred in August 1998 when the price fell by about 25%. David Bull Laboratories already had a brand on the PBS in July 1991 and Pfizer introduced a brand in December 1992. At that time the restriction level change from "R" to "U". True generic entry from InterPharma only occurred in December 2006.

For *cyclosporin* the patent expired in March 1999 but significant price falls totalling around 9% occurred earlier in May 1997 and May 1998. New entry commenced in May 2002. The restriction level changed from "R" to "A" in November 2000.

*Clarithromycin* also had a major price fall of 55% in May 1999 well before patent expiry in March 2005 and entry of competing brands in December 2004. In May 1999 a new item for *clarithromycin* with a "U" restriction level was introduced and the other item went from "R" to "A".

*Flecainide acetate* experienced patent expiry in March 1995 and new entry in November 1999. Its price rose steadily until a fall of about 7% in February 2000. While this may be associated with the new entrant, subsequent small falls of 1-2% were not. It changed from "A" to "R" in December 1994.

The first new entrant for *flutamide* occurred in August 1999 about a year before patent expiry in September 2000. This new entry coincided with a price fall of about 15% followed by smaller falls over the next few years. Its restriction level remained unchanged at "A".

The patent on *gabapentin* expired in December 1991 but the first new entry by Arrow only occurred in August 2001 followed by other brands in August 2002. The price fell by 10% in February 2003. There was no change in the "A" restriction level. The other member of the RPG – *lamotrigine* only had new entry in May 2005.

For *ipratropium bromide* patent expiry happened in July 1999 although new brands from Alphapharm were listed in May 1997 and May 1998. Other brands entered in February 1999 and November 2000. A price drop of 10% occurred in November 1998 followed by another 10% drop in May 1999. Surprisingly the restriction level changed from "U" to "R" in May 1998.

Patent expiry for *irinotecan* occurred in July 2004 with new entry in April 2005. A price fall of about 9% has preceded this in December 2004. Restriction levels remained unchanged at "A" while new entry for the other member of the RPB – *oxaliplatin* only happened in December 2006.

The patent on *isotretinoin* expired in June 1991 but the first new brand was from Alphapharm in August 1995 followed by Douglas in August 1999. A price fall of 18% occurred three months later in November 1999. Restriction levels remained unchanged at "A".

The only significant price fall for *naproxen* was 6% and this happened in April 1992. The patent expired in January 1992 but Alphapharm already had a brand listed prior to July 1991 and no new brands were listed thereafter.

For *norfloxacin* the patent expired in January 1998 with first new entry in February 2001 from Hexal followed by an 8% price fall in May 2001. Restriction levels were "A" throughout.

For *paclitaxel* patent expiry occurred in January 1999 but the first true generic from InterPharma was listed in April 2005. Paclitaxel had a number of price reductions from June 1995 to February 2001 none of which can be linked to new entry. The other member of the RPG – *vinorelbine* only had new entry in August 2006. Restriction levels were "A" throughout.

The patent on *timolol maleate* expired in September 1996 and this was followed by new entry from Alphapharm in February 1998 coinciding with a 10% price fall.

Of these 14 medicines with patent expiry, price reductions due to new entry can only be reasonably associated with 7 of them – *flecainide* (7%), *flutamide* (15%), *gabapentin* (10%), *ipratropium* (10%), *isotretinoin* (18%) , *norfloxacin* (8%), and *timolol* (10%). For only two of these did the price fall coincide with new entry – *flutamide* and *timolol*. The large falls for *clarithromycin* were associated with a change in restriction level.

The experience of members of the second group of medicines is discussed in terms of the dynamics of the RPGs of which they are members.

One of the largest price falls in the period was felt by the two antibiotics which make up the RPG of third generation cephalosporins. This occurred in February 2003 when the prices of *cefotaxime* and *ceftriaxone* both fell by about 53%. Patent expiry for the two medicines was in August 1998 and May 1999 respectively and the first new entrant was listed in November 2001 followed by further entrants in February 2002. Restriction status changed from "A" to "R" in December 1994. The price fall appears unrelated to either new entry or restriction status.

The patent expiry on *felodipine* in June 1999 was preceded by the listing of a brand from a subsidiary of the originator company in February 1998 which was accompanied by a fall of 8% in the price. No other new entrants have been listed. Another member of the same RPG (calcium channel blockers) *nifedipine* experienced patent expiry on a particular form of the medicine in September 2001 with new entry in May 2003. Although this medicine had experienced a number of price falls since 1995 none had any relationship with these events. Patent expiry and new entry had

occurred for other members of the RPG (*dilitazem* and the other forms of *nifedipine*) well before 1991 while two were patent protected during the period (*amlodipine* and *lercanidipine*).

From 1991 to 2005 patents expired on three ACE inhibitors – *captopril* in January 1997, *enalapril* in December 1999 and *lisinopril* in April 2001. These were the first expiries within the RPG. In June 1992 the price of *enalapril* fell by 9% which coincided with a shift from "A" to "R" for the ACE inhibitors. There was no change when it changed from "R" to "U" in April 1995. In February 1998 the price of both *captopril* and *enalapril* fell by about 15%. Prior to this, there had been new entries for *captopril* in May 1996 (ie before patent expiry), and in May, August and November 1997. There were a further 6 new entries for *captopril* before the next major price drop of 12% in August 2001 which was the same for all the ACE inhibitors. While this coincided with a new entrant for *lisinopril* there had been an earlier one in May 2001 and new entrants for *enalapril* in February and May 2001.

There are two broad classes of medicines for treating peptic ulcers and patent expiry occurred in both during the period. In the older H2-receptor antagonists group these were *ranitidine* in August 1993, *cimetidine* in September 1993, and *famotidine* in July 2003. The switch from "A" to "U" for these medicines in October 1992 caused a price fall of about 18%, although there was no price change when it moved to "R" in December 1994. The first new entrant for the group was for *cimetidine* in June 1994 preceding a price fall of 8-12% in August 1994 for all three medicines. *Ranitidine* and *famotidine* suffered falls of about 25% in February 1998 although this did not coincide with a new entry and 4 other brands of *cimetidine* or *ranitidine* had been listed in the previous 2 years. There was no fall for *cimetidine* at this time. New entrants for *famotidine* beginning in August 2003 had no effect on prices.

The more recent class of peptic ulcer treatments is the proton pump inhibitors and the patent on one of these *omeprazole* expired in April 1999. The first new entries for *omeprazole* were in February and May 1999 and these were followed by a 35% price fall in August 1999 for *omeprazole*, *lansoprazole* and *pantoprazole*. This also coincided with the release of a tablet form of *omeprazole* following entry of *pantoprazole* in tablet form in November 1995. A further fall of about 20% in August

2001 for all medicines in the group is unrelated to patent expiry or new entry although *rabeprazole* was first listed in May 2001.

The final group to be considered is the newer types of antidepressants including the selective serotonin reuptake inhibitors. The patents expired on *citalopram* in January 1993, on *fluoxetine* in December 1994, and on *moclobemide* in January 1997. The patent expiry date for *paroxetine* is the subject of some dispute but new entry occurred for this medicine in August 2001. Curiously *citalopram* was only first listed on the PBS in February 1998 or 5 years after patent expiry. With the exception of *sertraline*, the other medicines within this group had no significant price changes. The major price fall for this group of medicines occurred between August and December 1996 when prices fell by 30-35% for *fluoxetine, paroxetine* and *sertraline*. The first new entrant in the group was a new brand from Alphapharm for *fluoxetine* in February 1996 followed by a brand from Douglas in November 1996. The first new brand for *moclobemide* also entered in August 1996. However these reductions in price cannot be ascribed to these new entries because of a change in restriction status from "A" to "R". For *fluoxetine* this happened in August 1996 and for *paroxetine* and *sertraline* in November 1996 at the same times as the price changes. The price of *moclobemide* did not change at this time because it moved from "A" to "R" in April 1995 at which time its price fell by 12%. It is difficult to find a link between a series of further price reductions for *moclobemide* in February 1998, November 1998 and February 2002 and either patent expiry or new entry.

Summarising this somewhat complicated picture of patent expiry, new entry and restriction change for these groups, it is difficult to find unambiguous instances where the listing of new brands for a medicine resulted in a price reduction in the absence of any change in restriction status. For the ACE inhibitors captopril and enalapril the price reductions may have come about after the cumulative listings of new brands and this may also have been the case for the peptic ulcer treatments ranitidine and cimetidine. The large falls for omeprazole after new entry present a stronger case for an association but the price reductions for the antidepressants are clearly linked to a change in restriction status.

The evidence from a close examination of those 46 cases of patent expiry followed by new entry over the period 1991 to 2005 therefore shows only a handful of medicines where the new entrant may have offered a lower price than the prevailing price at the time and for most of these the price reduction was less than 15%. Furthermore, in the majority of cases the price reduction did not coincide with the time of listing and it is difficult to think of reasons why a new entrant should subsequently offer a lower price than the one offered and accepted at listing.

Price reductions are most likely to have arisen from the operation of annual price reviews within the PBS, especially for those medicines that fall within the WAMTC and RPG groups. In addition it should be recognised that price reductions may have been negotiated when other changes were made to listing conditions aside from changes in restriction status. For instance a medicine may be made available for a larger range of conditions even though its restriction status remains unchanged.

In summary the operation of reference pricing within the PBS means that there is little incentive for a new entrant to offer a lower price knowing that this will set the base price for all other brands and that the premium added by originator brands when this occurs is traditionally quite small. The scope for price competition for a new entrant is thus very restricted which in turn is responsible for the rather slow gain in market share by brands competing against the originator. The recognition of this by the Government is largely responsible for the introduction in August 2005 of the mandatory 12.5% price reduction on entry of a new brand described in Chapter 2.

# Chapter 5

## Expenditure Decomposition Techniques and Issues

### 5.1 Introduction

Chapters 6 and 7 are mainly concerned with accounting for the growth in expenditure on PBS medicines by describing from a variety of perspectives how their prices and quantities have changed over time. The principal means of decomposing expenditure into price and quantity components is through the use of techniques derived from the theory of index numbers. This chapter therefore concentrates on describing the approaches developed in the index number literature and in discussing one of the major issues that has arisen in the application of these techniques to pharmaceutical markets. This is the potential bias caused when market shares change among medicines with different prices used to treat the same disease.

The predominant approach in the literature has been to decompose a value ratio into price and quantity indexes and the most commonly used formulae based on this approach are described Section 5.2. Section 5.3 describes the three ways which researchers have proposed to select an ideal index while Section 5.4 describes the alternative approach off decomposing the change in value rather than the value ratio. The chief difficulty faced in calculating price and quantity indexes is the "new and disappearing good" problem and the various ways of addressing this are set out in Section 5.5, including the Time Product Dummy variant of hedonic regression techniques. Section 5.6 discusses the issue raised by Griliches and Cockburn (1994) about the most appropriate way to include generic brands in pharmaceutical price indexes. Although this issue principally revolves around substitutability among brands, Section 5.6 discusses how applicable this is to substitutability among medicines more generally.

The index number literature has a long history and is large both in terms of its theoretical exposition and the application of index number techniques ranging from the macro level in the construction of systems of national accounts to micro

applications to specific industries and product markets. A number of authors have attempted to review and systematize the index number literature from time to time and Professor Erwin Diewert has been prolific in this respect (for instance Diewert 1993).

The major revisions to the manuals on the Consumer Price Index (ILO/IMF/OECD/UNECE/Eurostat/The World Bank 2004, hereafter *CPI Manual*) and the Producer Price Index (ILO/IMF/OECD/UNECE/The World Bank 2004, hereafter *PPI Manual*) have provided the most recent large-scale opportunity for these efforts. The manuals are available on-line at ILO (2004) and IMF (2004).

The two manuals are very similar in content and address most aspects of the definition, construction and use of the price indexes, predominantly from the point of view of statistical agencies responsible for their compilation. When relating index number formulae to economic theory, the CPI Manual draws upon the standard microeconomic theory of consumer behaviour and the PPI Manual relies on the theory of the firm. As the introduction to the CPI Manual notes, however, the two approaches lead to the same kinds of conclusions with regard to index numbers.

Because of its prominence, comprehensive coverage, the involvement of senior figures in the index number community and its recent publication, the *CPI Manual* provides the basis for the exposition of index number theory in a temporal situation within this chapter. The description draws also upon the PPI Manual and makes reference to original source material as required. The discussions of hedonic techniques and other topics are based on the literature in these areas.

## 5.2 Common index number formulae

At its most general, index numbers seek to explain the change in an entity from one situation to another. In economic applications the *entity* is usually a price, quantity or expenditure but can also encompass other concepts such as productivities. The *situation* is typically either *temporal* such as a year, month or quarter or *spatial* such as a country or region. However situations can include categories which are neither temporal nor spatial such as groups defined by demographic or socioeconomic

criteria. On the other hand, some analyses combine both spatial and temporal situations.

Price indexes are fundamental to economic analysis as they enable an expenditure series to be decomposed into a price component and a real component, which is necessary if such fundamental concepts as the cost of living and productivity are to be estimated. Many applications in economics require that the variables being studied are expressed in real terms and that the determination of these variables be estimated from equations that include, within their explanatory variables, prices and other variables expressed in real terms. Above a certain level of aggregation, both real and price terms can usually only be derived by the application of index number formulae to the expenditure series.

Because the chief interest in this thesis is the decomposition of PBS expenditure over time, the exposition of index numbers in this chapter is presented primarily in temporal terms.

A value (or expenditure) aggregate for a given set of $n$ items in period $t$ can be defined as

$$V^t = \sum_{i=1}^{n} v_i^t = \sum_{i=1}^{n} p_i^t q_i^t = p^t q^t \;\; ; i = 1,...,n \qquad (5.1)$$

where $v_i^t = p_i^t q_i^t$ is the value of transactions in the $i$'th item in currency units, $p_i^t$ is the price of the $i$'th item in currency units, and $q_i^t$ is the quantity (or volume) transacted of item $i$, and

$\quad p^t q^t$ is the inner product of

$\quad p^t = \left[ p_0^t, p_1^t,,, p_N^t \right]$, a 1xn vector of the prices in period t, and

$\quad q^t = \left[ q_0^t, q_1^t,,, q_N^t \right]$, a nx1 vector of the quantities in period t.

In theory it might be possible to find *unilateral* scalar indexes $P^t$ and $Q^t$ for period t such that

$$V^t = P^t Q^t \qquad (5.2)$$

meaning that the value aggregate can be separated into purely price and quantity components only using data for the current period, but this has not proven to be the case, except for the trivial case where n = 1 (*CPI Manual* 16.11-16.29). Because of this, the index number literature has been developed in terms of *bilateral* indexes comparing two situations.

Here the challenge is to decompose the change in the value aggregate from one period to another into components reflecting the changes in prices and quantities respectively. The approach that has dominated the index number literature has been to decompose the ratio of value in the current period (period *t*) to that in the base period (period *0*) into a price index $P^t$ and quantity index $Q^t$, ie

$$\frac{V^t}{V^0} = \frac{\sum_{i=1}^{n} p_i^t q_i^t}{\sum_{i=1}^{n} p_i^0 q_i^0} = P^t Q^t \tag{5.3}$$

where

$$P^t = f\left(\frac{p_i^t}{p_i^0}\right) \tag{5.4}$$

and

$$Q^t = g\left(\frac{q_i^t}{q_i^0}\right) \tag{5.5}$$

and the ratios

$$\frac{p_i^t}{p_i^0} \text{ and } \frac{q_i^t}{q_i^0} \tag{5.6}$$

are called price and quantity *relatives* respectively.

An alternative decomposition based on value differences is presented in Section 5.4 below.

Note that the number of items, *n*, is the same in both periods. In general this is not the case due to the presence of new items appearing after period *0* and some items available in period *0* disappearing by period *t*. This problem of new and disappearing items is addressed further in the chapter.

Finding appropriate formulae for $P^t$ and $Q^t$ has a long history and has exercised the minds of many economists. The simplest approach to constructing a price index is to take the arithmetic mean of the price relatives in either unweighted or weighted form

$$P^t = \sum_{i=1}^{n} \left( \frac{p_i^t}{p_i^0} \right) \qquad \text{(unweighted)} \qquad (5.7)$$

$$P^t = \sum_{i=1}^{n} \left( w_i \frac{p_i^t}{p_i^0} \right) \qquad \text{(weighted)} \qquad (5.8)$$

where $w_i$ is the weight for item $i$. The construction of quantity indexes follows that for price indexes unless otherwise noted.

Generally the weighted form of the index is preferred to the unweighted form because it gives greater influence in the calculation of the index to those items that are more important in terms of their contribution to overall value. Nonetheless unweighted indexes are of interest because weights are often unavailable to statistical agencies in practice and because of their history in the development of the stochastic approach discussed in Section 5.3 below.

The main forms of unweighted indexes are the Dutot, Carli, and Jevons indexes[i] as follows

$$P^t = \frac{\sum_{i=1}^{n} p_i^t}{\sum_{i=1}^{n} p_i^0} \qquad \text{(Dutot)} \qquad (5.9)$$

$$P^t = \frac{1}{n} \sum_{i=1}^{n} \left( \frac{p_i^t}{p_i^0} \right) \qquad \text{(Carli)} \qquad (5.10)$$

$$P^t = \sqrt[n]{\prod_{i=1}^{n} \frac{p_i^t}{p_i^0}} \quad \text{or} \quad \ln P^t = \frac{1}{n} \sum_{i=1}^{n} \left( \ln \frac{p_i^t}{p_i^0} \right) \qquad \text{(Jevons)} \qquad (5.11)$$

and the Carli and Jevons indexes are the unweighted arithmetic and geometric means of the price relatives respectively.

The most famous form of the *weighted* price index is that due to Laspeyres, namely

$$P^t = \sum_{i=1}^{n} \left( s_i^0 \frac{p_i^t}{p_i^0} \right) \qquad (5.12)$$

where

$$s_i^0 = \frac{v_i^0}{V^0} = \frac{p_i^0 q_i^0}{\sum_{i=1}^{n} p_i^0 q_i^0} \qquad (5.13)$$

In the Laspeyres index the price relatives are weighted by $s_i^0$, the share of the $i$'th item in total value in period $0$, $V^0$. Substituting from equation (5.13) into equation (5.12) gives the familiar form for this index, namely

$$P^t = \frac{\sum_{i=1}^{n} p_i^t q_i^0}{\sum_{i=1}^{n} p_i^0 q_i^0} \qquad \text{(Laspeyres)} \qquad (5.14)$$

The Laspeyres index can be interpreted as the change in the cost of a fixed basket of goods between two periods. In both periods the basket contains the same $n$ items in the quantities prevailing in the base period $0$.

The Paasche index has a similar formula to the Laspeyres index except that the fixed basket of goods is defined for the quantities in the current period t.

$$P^t = \frac{\sum_{i=1}^{n} p_i^t q_i^t}{\sum_{i=1}^{n} p_i^0 q_i^t} \qquad \text{(Paasche)} \qquad (5.15)$$

While the Laspeyres index has a straightforward interpretation as an average of price relatives weighted by value share in period 0 (as shown by equation (5.12)), the Paasche index is not the same as an average of price relatives weighted by current value shares[ii]. It can be shown however (eg in Allen 1975) that the Paasche index can be expressed as such a form, namely

$$P^t = \frac{1}{\sum_{i=1}^{n} \left( s_i^1 \frac{p_i^0}{p_i^1} \right)} \qquad (5.16)$$

so that the Paasche price index is the harmonic average of the price relatives, weighted by current period value shares.

In general there appears to be no reason to favour either the Laspeyres or the Paasche index over the other, although it would be expected that they will give different results when used.

Standard microeconomic theory suggest that if the price of a good rises between period *0* and period *t* at a faster rate than other goods, the quantity consumed in the period *t* will be less than in period *0* relative to those other goods. Because the Laspeyres price index uses the quantity weights from period *0*, it will give greater importance than is warranted in the calculation of the index to those goods that have had price increases greater than the average. Similarly, the Paasche index does not given sufficient weight to this *substitution effect*, because it gives a disproportionate weight to those goods whose price has increased at a rate lower than average, and whose quantities consumed would therefore have risen relative to others.

In a decomposition due to Bortkiewicz (Allen 1975), the ratio of the Paasche to Laspeyres indexes can be expressed as a function of the weighted correlations of the price and quantity relatives and their weighted variances

$$\frac{P_P^t}{P_L^t} = 1 + r \cdot \frac{\sigma_p}{P_L^t} \cdot \frac{\sigma_q}{Q_L^t} \tag{5.17}$$

In equation (5.17) it makes no difference if the ratio on the left hand side is of the prices indexes or the quantity indexes. $P_P^t$, $P_L^t$, $Q_L^t$ are the Paasche and Laspeyres price indexes and the Laspeyres quantity index respectively, $r$ is the base period weighted correlation coefficient between the price and quantity relatives and $\sigma_p$, $\sigma_q$ are the base period weighted standard deviations of the price and quantity relatives.

The second term on the right hand side is the correlation coefficient multiplied by the coefficients of variation for the price and quantity relatives. The size of the correlation coefficient will measure the extent to which changes in price relatives affect quantity relatives. The size of the coefficients of variation will show how much dispersion there is in the price and quantity relatives.

If, as theory predicts, the correlation coefficient is negative, the RHS of equation (5.17) will be less than one, meaning that the Laspeyres index will be greater than the

Paasche index. The magnitude of the difference will be determined by the size of the correlation coefficient and the extent to which the movements in prices and quantities vary around their means.

Applications using the Laspeyres and Paasche indexes usually show that the Laspeyres index gives higher values than the Paasche index, leading to the conclusion that Laspeyres and Paasche indexes form upper and lower bounds to a "true" price index. Recognising this, a number of authors have proposed symmetric formulae that use weights that are an average of the current and base quantities or values.

Marshall and Edgeworth proposed the Edgeworth-Marshall index using the arithmetic mean of the quantities in the two periods as weights

$$P^t = \frac{\sum_{i=1}^{n} p_i^t \frac{1}{2}(q_i^t + q_i^0)}{\sum_{i=1}^{n} p_i^0 \frac{1}{2}(q_i^t + q_i^0)} \qquad \text{(Edgeworth-Marshall)} \qquad (5.18)$$

while Walsh (1901) favoured the geometric mean of the quantities

$$P^t = \frac{\sum_{i=1}^{n} p_i^t \sqrt{(q_i^t q_i^0)}}{\sum_{i=1}^{n} p_i^0 \sqrt{(q_i^t q_i^0)}} = \frac{\sum_{i=1}^{n} \left( \sqrt{(s_i^t s_i^0)} \sqrt{\frac{p_i^t}{p_i^0}} \right)}{\sum_{i=1}^{n} \left( \sqrt{(s_i^t s_i^0)} \sqrt{\frac{p_i^0}{p_i^t}} \right)} \qquad \text{(Walsh)} \qquad (5.19)$$

The right hand side of equation (5.19) shows that the Walsh index can also be expressed as a value share weighted average of the price relatives.

In his comprehensive review of index number formula, Fisher (1922) considered some 134 unique indexes including the ones listed above. To determine which of the indexes should be preferred, he devised a set of criteria or tests and judged each on its ability to meet these tests. This list of tests was based on those already suggested in the literature to that point as well as his own candidates. This systematic effort laid the basis for the "axiomatic" or "test" approach to developing index number formulae which is discussed further below.

Based on this analysis, Fisher nominated the geometric mean of the Laspeyres and Paasche indexes (his formula 353) as his "Ideal" index number, namely

$$P^t = \sqrt{\frac{\sum_{i=1}^{n} p_i^t q_i^0 \ \sum_{i=1}^{n} p_i^t q_i^t}{\sum_{i=1}^{n} p_i^0 q_i^0 \ \sum_{i=1}^{n} p_i^0 q_i^t}} \qquad \text{(Fisher)} \qquad (5.20)$$

Unlike the Laspeyres and Paasche indexes, the Fisher and Walsh indexes are *symmetric*, in the sense that they use all the price and quantity data from the two periods and give them equal treatment.

The other main index that is discussed widely in the literature and has been used in applications is the Tornqvist (1936) index, which was also derived by Theil (1967). This differs from the indexes considered to this point (except for the Jevons index) in that it takes the form of a weighted *geometric* index which has the general formula

$$P^t = \prod_{i=1}^{n} \left( \frac{p_i^t}{p_i^0} \right)^{w_i^t} \qquad (5.21)$$

The Tornqvist index uses the average of the value shares for the two periods as weights for the price relatives

$$w_i = \frac{1}{2} \left( s_i^t + s_i^0 \right) \qquad (5.22)$$

so that the Tornqvist index is given as

$$P^t = \prod_{i=1}^{n} \left( \frac{p_i^t}{p_i^0} \right)^{\frac{1}{2}\left( s_i^t + s_i^0 \right)} \qquad \text{(Tornqvist)} \qquad (5.23)$$

which can be expressed in logarithmic form as

$$\ln P^t = \sum_{i=1}^{n} \frac{1}{2} \left( s_i^t + s_i^0 \right) \ln \left( \frac{p_i^t}{p_i^0} \right) \qquad (5.24)$$

The Tornqvist index is also symmetric.

A limitation of geometric mean indexes is their performance when either of the prices is zero or approaches zero or when the price relatives take extreme values.

In the Tornqvist index formula equation (5.23), if the base period price for the *i*'th item is zero then the index is infinite, while if the current period price is zero, the value is minus infinity. If the current period price is much smaller than the base period price, the price relative approaches zero and the price index becomes large. While this

problem would be rarely encountered when price indexes are being calculated, it is a distinct problem for quantity indexes. If a popular new good is introduced towards the end of period *0*, the quantity relative for period *t* could be quite large. Under these circumstances the Tornqvist index could be unstable.

A geometric mean similar to the Tornqvist index which addresses this limitation was suggested by Vartia (1976) and Sato (1976) independently. It has a much more complex weighting system for the price relatives.

$$P^t = \prod_1^n \left( \frac{p_i^t}{p_i^0} \right)^{w_i^t} \qquad \text{(Vartia)} \qquad (5.25)$$

where

$$w_i = \frac{\left( v_i^t - v_i^0 \right) \Big/ \left( \ln v_i^t - \ln v_i^0 \right)}{\left( \sum_{i=1}^n v_i^t - \sum_{i=1}^n v_i^0 \right) \Big/ \left( \ln \left( \sum_{i=1}^n v_i^t \right) - \ln \left( \sum_{i=1}^n v_i^0 \right) \right)} \qquad (5.26)$$

or

$$\ln P^t = \sum_{i=1}^n \left( \frac{\left( v_i^t - v_i^0 \right) \Big/ \left( \ln v_i^t - \ln v_i^0 \right)}{\left( \sum_{i=1}^n v_i^t - \sum_{i=1}^n v_i^0 \right) \Big/ \left( \ln \left( \sum_{i=1}^n v_i^t \right) - \ln \left( \sum_{i=1}^n v_i^0 \right) \right)} \right) \ln \left( \frac{p_i^t}{p_i^0} \right) \qquad (5.27)$$

Equation (5.26) for the weights in the Vartia index takes the form of the ratio of two logarithmic means. The definition of a logarithmic mean for any two numbers a and b is

$$= \frac{(a-b)}{(\ln a - \ln b)} \quad \text{for } a \neq b$$

$$= a \text{ for } a = b \qquad (5.28)$$

When $v_i^t = v_i^0$ in equation (5.26), the weight becomes

$$w_i = \frac{v_i^t}{\left( \sum_{i=1}^n v_i^t - \sum_{i=1}^n v_i^0 \right) \Big/ \left( \ln \left( \sum_{i=1}^n v_i^t \right) - \ln \left( \sum_{i=1}^n v_i^0 \right) \right)}$$

and, in the unlikely event that $\sum_{i=1}^n v_i^t = \sum_{i=1}^n v_i^0$, the denominator becomes $\sum_{i=1}^n v_i^t$.

The form of the Vartia index specified by equations (5.25) to (5.27) uses the actual values, $v_i$, in the definition of the weights rather than the value shares, $s_i$. Vartia considered a variation of equation (5.27) where the actual values are replaced by the value shares, but rejected that variation because the index is then no longer consistent in aggregation. For this reason it has not been used in applications.

The discussion to this point has been couched largely in terms of price indexes. Each of the specific indexes discussed above has an analogous quantity index obtained by interchanging the price and quantity terms within the price index formula. These quantity index formulae are listed in Appendix B.

Once a price (or quantity) index formula has been determined directly, a quantity (or price) index can always be found that satisfies the decomposition of the ratio of values given in equation (5.3)

$$\frac{V^t}{V^0} = \frac{\displaystyle\sum_{i=1}^{n} p_i^t q_i^t}{\displaystyle\sum_{i=1}^{n} p_i^0 q_i^0} = P^t Q^t \tag{5.29}$$

For the direct price index, $P^t$, the implicit quantity index is then

$$Q^t = \frac{\left(V^t \big/ V^0\right)}{P^t} \tag{5.30}$$

For the Laspeyres and Paasche indexes this implicit quantity index does not have the same value as obtained through direct application of the quantity index number formula, so these two indexes do not satisfy the *factor reversal* test, ie

$$\frac{V^t}{V^0} \neq P^t Q^t$$

However the product of Laspeyres price index and the Paasche quantity index does satisfy equation (5.3) as does the product of the Paasche price index and the Laspeyres quantity index. They therefore satisfy a *weak factor reversal* test. Of the other indexes considered to this point, only the Fisher and Vartia indexes satisfy the factor reversal test exactly. Although the factor reversal test seems reasonable in that the price and quantity indexes calculated using the same type of formula should exactly reproduce

the value ratio, the importance of this test is a matter of some controversy within the literature.

## 5.3 Assessing index number formulae

This discussion has identified the main index number formulae that have been proposed within the literature and forms the basis for the analysis conducted in subsequent chapters. The candidate formulae are the Laspeyres and Paasche indexes and their geometric mean, the Fisher index, the Walsh index and the Tornqvist and Vartia indexes based on geometric means. Within the index number literature, the task of identifying the "best" index from these candidates has been approached from 3 main perspectives, namely the

- Axiomatic or test approach
- Economic approach
- Stochastic or statistical approach

Each of these approaches has its supporters but the conclusion of Clements et al (2006) is likely to be correct – 'No single approach to index number theory is perfect'.

### *Axiomatic approach*

The "axiomatic" or "test" approach to index numbers judges an index number formula on its ability to satisfy exactly or approximately a number of tests that might be expected of a reasonable index. Tests have been proposed by a number of authors but this approach was systematically developed by Fisher (1922) and Eichhorn and Voeller (1976). The CPI Manual reviews these and proposes a set of 20 tests.

It has been shown that the Fisher index is the only index that satisfies all 20 tests. The Laspeyres and Paasche indexes fail three reversal tests, of which the most important is the time reversal test. The Walsh index fails 4 tests while the Tornqvist index fails nine tests. Unfortunately, the CPI Manual does not report on the number of tests satisfied by the Vartia index.

From the point of view of the tests given above therefore, the Fisher index is clearly superior. Of the other symmetric indexes, the Walsh seems better than the Tornqvist.

The difficulty with using the axiomatic approach to decide on the best index to use is that the decision depends on which tests are considered and the degree of importance given to each test. There is not a consistent body of theory that generates a definitive list of tests or a method of determining the weight to be given to each test. Judging which tests to include and their importance therefore comes down to an assessment of how "reasonable" each candidate test is. Hence there is an unavoidable subjective element in deciding among index number formulae based solely on the axiomatic approach.

In the CPI Manual, for instance, Chapter 16 considers first the 20 tests listed above, then a list of 17 tests including some of the ones in the first list to establish that the Tornqvist index is superior. Even then it is shown that the Tornqvist index (and potentially all geometric indexes) does not perform well against a further test proposed by Fisher, namely determinateness as to prices. This test requires that the index remain stable as prices approach or become zero.

### Economic approach

The limitations of the axiomatic approach have lead index number theorists to attempt to derive index number formulae from classical microeconomic theory. The theory of the consumer has been used to derive suitable formulae for the CPI and the theory of the firm for PPI indexes.

The derivation of indexes in this way begins in a systematic way with Konüs (1924). He assumes that the consumer is a price taker and will seek to minimize the cost of obtaining a given level of utility. In the base period then, the quantity vector for the consumer is determined by the vector of base period prices and the consumer's preference function. Similarly the consumer's quantity vector in period t will be determined by the period t price vector and the preference function.

The consumer is assumed to have well-defined preferences over different combinations of the $n$ items in the basket of commodities with each combination

being represented by a positive quantity vector, $q$. The consumer's preferences over alternative quantity vectors is assumed to be represented by a continuous, non-decreasing and concave utility (or aggregator) function,

$$u = f(q) \tag{5.31}$$

The consumer is assumed to minimize the cost of achieving this utility so that the observed quantity vector is assumed to be the solution of the consumer's cost function minimisation problem

$$C(u, p) \equiv \min_q \left[ \sum_{i=1}^n p_i q_i : f(q) \right] \tag{5.32}$$

$$= \sum_{i=1}^n p_i^t q_i^t \text{ in period t, and}$$

$$= \sum_{i=1}^n p_i^0 q_i^0 \text{ in period 0}$$

Konüs then defined the true cost of living index (COLI) for the two periods as the ratio of the minimum costs of achieving the same utility level in periods 0 and t, namely

$$P^t = \frac{C(f(q), p^t)}{C(f(q), p^0)} \tag{5.33}$$

He also showed that the Laspeyres and Paasche price indexes form the upper and lower bounds to this COLI.

Being more specific about the exact form of equation (5.33) requires some assumptions about the form of the utility function, equation (5.32). The usual assumption to make is that $f$ is linearly homogeneous, i.e. $f(\lambda q) = \lambda f(q)$, so that preferences are homothetic. This is fairly restrictive in that it implies that all income elasticities are equal to 1.

Equation (5.33) then becomes

$$P^t = \frac{c(p^t)}{c(p^0)} \tag{5.34}$$

where $c(p)$ is the unit cost function corresponding to $f$. If equation (5.34) is taken as the price index then the implicit quantity index is the ratio of utilities

$$Q^t = \frac{f(q^t)}{f(q^0)} \qquad (5.35)$$

The derivation of specific indexes needs some additional results. Using Wold's Identity (Wold 1944) and Shephard's Lemma (Shephard 1953) and assuming the utility function is linearly homogeneous, the following equations are derived

$$\frac{p_i^t}{\sum_{i=1}^{n} p_i^t q_i^t} = \frac{\partial f(q^t)/\partial q_i}{f(q^t)} \qquad (5.36)$$

$$\frac{q_i^t}{\sum_{i=1}^{n} p_i^t q_i^t} = \frac{\partial c(p^t)/\partial p_i}{c(p^t)} \qquad (5.37)$$

If the utility function has the following homogeneous quadratic form

$$f(q) = \sqrt{\sum_{i=1}^{n}\sum_{k=1}^{n} a_{ik} q_i q_k} \qquad (5.38)$$

then it can be shown (CPI Manual, Chapter 17) that the Fisher price and quantity indexes are equal to the true price and quantity indexes in equations (5.34) and (5.35) respectively.

Diewert (1976) has shown that a twice continuously differentiable function $f(q)$ of n variables $q \equiv (q_1, q_2,, q_n)$ can provide a second-order approximation to another such function $f^*(q)$ around the point $q^*$, if the level and all first-order and second-order partial derivatives of the two functions coincide at $q^*$. Diewert called such functions *flexible functional forms*. The utility function (5.32) can provide such an approximation to an arbitrary linearly homogeneous function $f^*(q)$ around a point $q^*$. A quantity index number formula exactly equal to the true quantity index number formula equation (5.35) with $f(q)$ as a flexible functional form is a *superlative* index number formula. Because the homogeneous quadratic form in equation (5.38) is a flexible functional form, the Fisher quantity index is superlative. Starting from a

homogeneous quadratic cost function, which is also a flexible form the Fisher price index can also be shown to be superlative.

If the cost function equation (5.32) has the translog (flexible) functional form

$$\ln C(u,p) \equiv a_0 + \sum_{i=1}^{n} a_i \ln(p_i) + \frac{1}{2}\sum_{i=1}^{n}\sum_{k=1}^{n} a_{ik} \ln(p_i)\ln(p_k)$$

$$+ b_0 \ln(u) + \sum_{i=1}^{n} b_i \ln(p_i)\ln(u) + \frac{1}{2}b_{00}\left(\ln(u)\right)^2 \qquad (5.39)$$

then it can be shown that the cost of living index equation (5.34) evaluated at a utility level that is the geometric mean of the utilities in period 0 and t is the Tornqvist price index. The Tornqvist index is therefore superlative.

A quantity index derived from a utility function which is a quadratic mean of order r

$$f(q) = \sqrt[r]{\sum_{i=1}^{n}\sum_{k=1}^{n} a_{ik} q_i^{r/2} q_k^{r/2}} \qquad (5.40)$$

will also be superlative.

If r=2, the Fisher quantity index is obtained, while if r=1, the Walsh quantity index is derived. As r approaches zero, the Tornqvist index is obtained. The Fisher, Walsh and Tornqvist quantity and price indexes are therefore all superlative.

The Laspeyres and Paasche indexes are not superlative and the Walsh index is the only fixed-basket superlative index. The Vartia index is pseudo-superlative in that it approximates a superlative index number formula (specifically the Tornqvist index) to the second order (Diewert 1978).

It can be seen from equation (5.40) that there are an infinite number of superlative index formulae and it was thought that they all approximated each other closely. Hill (2006) has shown however that not all superlative indexes are similar and that as r becomes large, the index is dominated by the values of the largest or smallest relatives. He shows using both time series and spatial data that the spread between two superlative indexes can exceed by large margins the Paasche-Laspeyres spread defined in equation (5.17). In general however this effect is minor for the Fisher, Tornqvist and Walsh indexes because r lies in the range 0-2.

### Stochastic or statistical approach

The third main approach to developing index number formulae is the stochastic or statistical approach whose principal impetus arose from attempts by 19th Century economists to estimate the general rate of inflation within the quantity theory of money.

Here it is assumed that the price relative for commodity $i$ between periods $0$ and $t$ is an estimate of the rate of inflation plus an error term reflecting exogenous factors peculiar to the i'th commodity, ie

$$\frac{p_i^t}{p_i^0} = \alpha + \varepsilon_i \tag{5.41}$$

where $\alpha$ is the inflation rate and $\varepsilon_i$ is a random variable with mean zero and variance $\sigma^2$.

The least squares estimator for $\alpha$ is then the Carli price index, equation (5.10) above.

If a logarithmic specification is used instead

$$\ln\left(\frac{p_i^t}{p_i^0}\right) = \beta + \varepsilon_i \tag{5.42}$$

where $\beta = \ln \alpha$, then the least squares estimator for $\alpha$ is the Jevons index, equation (5.11).

The unweighted stochastic specification was heavily criticized by Keynes and Walsh (1901) and was subsequently ignored.

Theil (1975) proposed a weighted stochastic specification using an argument similar to the following. Suppose that we draw at random transactions from the collection of all the transactions made in the common basket of goods in period $0$ and each transaction has an equal chance of being drawn. Then the probability of drawing a transaction in the $i$'th good, and hence its associated price relative, is equal to the share of item $i$ transactions in all transactions, namely

$$s_i^0 = \frac{p_i^0 q_i^0}{\displaystyle\sum_{i=1}^{n} p_i^0 q_i^0} \tag{5.43}$$

Repeating this for the period *t* transactions gives a probability of drawing a transaction in the *i'th* good of $s_i^t$. If these probabilities are averaged over period *0* and period *t*, and used to weight the logarithms of the price relatives, the result is the Tornqvist price index.

Other weighted stochastic specifications considered in CPI Manual (chapter 16) fail the time reversal test. As the Tornqvist index does not fail this test, it is suggested as the "best" index within the stochastic approach. Further work on the stochastic approach has been done by various authors within the context of the hedonic regression approach outlined in Section 5.5 below.

### *Consistency in aggregation*

A desirable property for an index is consistency in aggregation. This means that if a group of goods can be separated into subgroups and indexes calculated for each subgroup, then when these are combined they should produce the same result as an index calculated directly using all the goods in the group.

The Laspeyres, Paasche and Vartia indexes are exactly consistent in aggregation and the Fisher, Tornqvist, and Walsh indexes are approximately consistent in aggregation.

## 5.4 Decomposition of the change in value

An alternative approach to decomposing the change in value into a price and quantity measure is to specify this change as the difference between the value in the two periods rather than the ratio of value, namely

$$\Delta V = V^t - V^0 = p^t q^t - p^0 q^0 = \sum_{i=1}^{n} p_i^t q_i^t - \sum_{i=1}^{n} p_i^0 q_i^0 \tag{5.44}$$

This approach began with Bennet (1920) and Montgomery (1937) but has been largely ignored until a recent revival of interest. Diewert (2005a) in his review of this approach points out that engineering and accounting approaches to understanding change often wish to express the absolute change in an economic aggregate such as

revenue, cost and profit from one period to another as a portion due to price changes and a portion due to changes in volume or quantity. Variance analysis for example is a standard accounting technique which seeks to explain the difference between the forecast (or budgeted) value, based on expected prices and quantities, with the actual outcome in terms of variations due to deviations from the budgeted prices and budgeted quantities.

The interest in this approach is to find a measure of aggregate price change, $\Delta P$ and a measure of aggregate quantity change $\Delta Q$ such that

$$\Delta V = \Delta P + \Delta Q$$

or using Diewert's notation

$$\Delta V = I + V$$

where I and V are called the *indicators* of price change and quantity (or volume) change respectively.

Bennet proposed the following formulae for these indicators

$$I^t = \frac{1}{2}\left( \sum_{i=1}^{n} \left( q_i^0 + q_i^t \right)\left( p_i^t - p_i^0 \right) \right) \qquad \text{(Bennet)} \qquad (5.45)$$

$$V^t = \frac{1}{2}\left( \sum_{i=1}^{n} \left( p_i^0 + p_i^t \right)\left( q_i^t - q_i^0 \right) \right) \qquad \text{(Bennet)} \qquad (5.46)$$

If the Laspeyres and Paasche price indicators are defined as

$$I^t = \sum_{i=1}^{n} q_i^0 \left( p_i^t - p_i^0 \right) \qquad \text{(Laspeyres)} \qquad (5.47)$$

$$I^t = \sum_{i=1}^{n} q_i^t \left( p_i^t - p_i^0 \right) \qquad \text{(Paasche)} \qquad (5.48)$$

and the equivalent quantity indicators are defined analogously, then the Bennet price (quantity) indicator is just the arithmetic average of the Laspeyres and Paasche price (quantity) indicators.

Montgomery suggested the following logarithmic forms for the price and quantity indicators

$$I^t = \sum_{i=1}^{n} w_i \ln\left(\frac{p_i^t}{p_i^0}\right) \qquad \text{(Montgomery)} \qquad (5.49)$$

$$V^t = \sum_{i=1}^{n} w_i \ln\left(\frac{q_i^t}{q_i^0}\right) \qquad \text{(Montgomery)} \qquad (5.50)$$

where

$$w_i = \frac{v_i^t - v_i^0}{\ln v_i^t - \ln v_i^0} = \frac{p_i^t q_i^t - p_i^0 q_i^0}{\ln\left(p_i^t q_i^t\right) - \ln\left(p_i^0 q_i^0\right)} \qquad (5.51)$$

a form very similar to the weights for the Vartia price index given in equation (5.26).

Again, the weight is a logarithmic mean and when $v_i^t = v_i^0$, the weight becomes $\frac{v_i^t}{\ln v_i^t}$.

For the indicators considered here, the additive contribution of the $i$'th item to the overall value of the indicator is simply given by the $i$'th term within the indicator's formula. For instance the contribution of the $i$'th item to the Bennet price indicator is

$$\frac{1}{2}\left(q_i^0 + q_i^t\right)\left(p_i^t - p_i^0\right) \qquad (5.52)$$

Diewert considers the Bennet, Montgomery, Laspeyres and Paasche indicators from both an axiomatic and an economic approach. He proposes for these indicators a set of 18 tests closely paralleling those suggested for index formulae. He finds that the Bennet price and quantity indicators satisfy all 18 tests, the Laspeyres and Paasche satisfy 14 tests, while the Montgomery indicator satisfies 12 tests. However the Laspeyres and Paasche indicators fail the important time reversal test, although the Montgomery indicator does not.

From an economic approach similar to that employed in assessing index numbers, Diewert finds that a price (quantity) indicator expressed as a function of a superlative index is itself superlative. For example a Fisher indicator defined as a function of the Fisher price index is superlative. Any superlative indicator is considered equal from this point of view. Diewert goes on however to establish that both the Bennet and Montgomery indicators approximate any superlative indicator to the second order at any point where the two price vectors are equal and the two quantity vectors are equal.

Because the Bennet indicator performs better than the Montgomery indicator in the test approach and equally well in the economic approach, Diewert prefers its use.

## 5.5 New and disappearing goods

The indexes considered to this point are all defined in terms of both a common basket of goods and common quantity or expenditure weight.

The restrictive nature of these assumptions is highlighted when more than two periods enter into the comparison. This will arise if indexes are required for a succession of time periods, in which case the index for each period is calculated using the same base period, so that the indexes are

$$I_0^1, I_0^2, I_0^3, , I_0^T$$

If a Laspeyres index is calculated then the base period quantities become increasingly unrepresentative of the current period, the greater is the length of time between the base and current periods. Any average of weights also becomes unrepresentative of either the current or base period.

### *Chaining*

One way to address this problem is *chaining*. With this approach, if the data is available, the index is calculated for successive pairs of adjacent periods t-1 and t, where the base period is period t-1 and the current period is period t. The value for the index between period 0 and period T is then calculated by assuming a value of 1 for period 0 and multiplying together the indexes calculated for the periods between 0 and T, namely

$$I_0^T = 1.I_0^1.I_1^2.I_2^3..I_{T-1}^T \tag{5.53}$$

This process will generate a series of values for the chained index as follows

1

$1 . I_0^1$

$1 . I_0^1 . I_1^2$

…

$1 . I_0^1 . I_1^2 . I_2^3 .. I_{T-1}^T$

In general, prices and quantities can be expected to display some systematic trends, so that the vector of quantities consumed in a particular period will be much closer to that in adjacent periods than it is to more distant periods. Using weights from adjacent years in the calculation of an index will therefore minimize the spread between the Laspeyres and Paasche indexes and bring greater agreement among different formulae that might be used in the calculation.

It should be noted that the chaining sequence illustrated in equation (5.53) is not the only one that could have been chosen. When temporal indexes are being calculated there is a natural order to the chaining suggested by the progression of time periods. In spatial situations, for instance calculating indexes among a group of countries, there is no natural order that suggests itself. Chaining in this situation is more problematic, and various strategies have been developed to produce unbiased indexes.

It would be desirable if an index could be found that would satisfy the following transitivity test

$$J_0^T = 1 . I_0^1 . I_1^2 . I_2^3 .. I_{T-1}^T$$

where $J_0^T$ is the direct index comparing period 0 and T, but this is not possible for any weighted index.

The general caveat to the use of chaining is when there are periodic oscillations in prices or quantities. This is often the case for goods that have marked seasonal shifts in price and quantities during the course of a year. In constructing monthly or

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quarterly indexes in these situations, chaining can introduce a systematic bias, called "drift". If for instance prices and quantities vary considerably during the course of a year starting in January but return to their original values by January of the next year, then chaining will lead to a January-on-January index that will be significantly different from the value that might be expected, namely 1.

For the construction of annual indexes where the data is likely to have systematic trends and seasonal considerations are absent, chaining is preferred.

### *New and disappearing goods*

A second major drawback to the use of a common basket of goods in calculating indexes is that the collection of goods included within the basket becomes increasingly unrepresentative of the goods available in each of the two periods the further apart the periods are in time. This is because some goods that were available in the first period are no longer available in the other period – the "disappearing goods" problem – and conversely there will be goods available in the second period but not in the first – the "new goods" problem. This is illustrated in Figure 5.1

**Figure 5.1    New and disappearing goods**
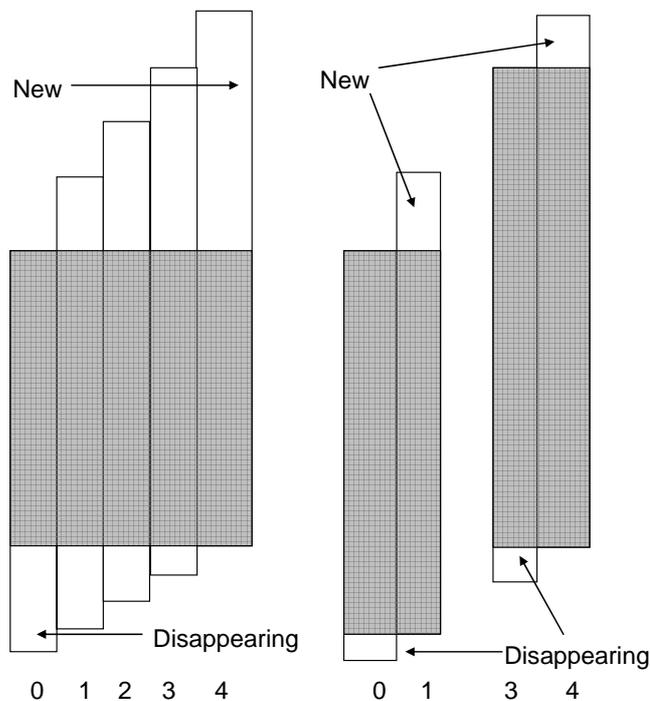
The diagram presents the vectors of goods for 5 years where the vector for each year is ordered so that the goods disappearing from the one year to the next are at the bottom of the vector and new goods are at the top. Goods common to two periods are shaded. If period 0 is compared to period 4, the goods common to both periods are less representative in period 4 than period 0. It can be seen that there are proportionally more goods in common if adjacent periods are compared.

Calculating indexes for adjacent periods and chaining them will minimize, although not eliminate, the problem of new and disappearing goods.

Several approaches have been suggested for incorporating new and disappearing goods within index calculations. For new goods, the challenge is to estimate the price for the good prior to its introduction, ie in the base period, while for disappearing goods the price is sought for the period after its disappearance, ie in the current period.

The reservation price for a good is defined as that price which will ensure that demand for the good is zero (Hicks 1940). If the reservation price for a new good can be estimated for the base period, then a Paasche index can be calculated which includes the new good by using this reservation price in the price relative with a current period weight. The corresponding Laspeyres index would give the price relative a base period weight of zero (which has the same effect as not including the good). The other symmetric indexes can also be calculated including the new good and would include only current period values in the weights.

A similar procedure could be adopted to handle disappearing goods with the estimated reservation price being used to include the good in the calculation of a Laspeyres index and the symmetric indexes. This use of reservation prices can only be used in the calculation of price indexes. Direct quantity indexes will always be faced with the problem of zeroes in the quantity relatives.

The chief difficulty in using reservation prices is how to estimate them.

Statistical agencies faced with the task of compiling indexes such as the CPI use a sample of goods as the basis for their collection of price data. The challenge is to maintain a basket of goods that is representative of the situation being sampled. There is constant turnover of products in the marketplace as existing products are upgraded, old products are withdrawn and entirely new products are introduced.

When a product included in the sample is no longer available, the agency will seek to replace the item with something of the same quality to maintain the continuity of the price series. Sometimes this is successful but often the replacement product is sufficiently different from the original that an adjustment needs to be made to either the price of the original or the replacement so that the price series composed of the original and replacement goods spliced together reflects the price of a good of constant quality. This problem is particularly acute for high technology based goods such as personal computers and consumer electronics where model turnover is rapid but is a feature of most products in the marketplace.

A similar problem arises when a new good enters the marketplace. If the new good is similar to products already available (evolutionary new goods) the price series for this product could be constructed by splicing it to the existing product. In some circumstances however the new good is sufficiently novel that no existing good can be found to do this (revolutionary goods). The introduction of personal computers, mobile phones, digital cameras and internet services might be examples of such products.

The statistical agency usually tries to adjust for disappearing items by finding a replacement to maintain the same common basket of goods over time. Eventually however the basket becomes increasingly unrepresentative of consumer spending so the sample must be reconstituted so that it is representative. The series based on the new basket can be spliced to that of the old basket if parallel collections of both baskets are undertaken for some period of time.

### *Hedonic regression techniques*

The technique used most commonly to link a disappearing item to its replacement is hedonic regression. The hedonic approach dates back at least to Court and other major contributions have come from Waugh, Griliches (1961), Houthakker (1952), and Lancaster (1966). Triplett (2004) provides a recent comprehensive review of hedonic techniques in the construction of price indexes.

In the hedonic approach, products are regarded as bundles of characteristics each of which can be assigned a price. The price of the product is therefore

$$p(z) = p(z_1, z_2, z_3, ..., z_K) \tag{5.54}$$

where $z = (z_1, z_2, z_3, ..., z_K)$ is a vector of the K characteristics that make up the product.

For personal computers for instance, the different characteristics could include CPU size and speed, RAM size, memory storage size and access speed, whether it has a CD or DVD drive, size and type of screen etc. The characteristics can be measured either as continuous variables (RAM size), ordinal variables or dichotomous variables (CD or DVD drive).

The relative importance of each characteristic in the determination of the price of the product can be established by estimating a price equation based on a sample of different models of the product with differing amounts of each characteristic. Typically the form of this equation is semi-logarithmic although other forms are possible. The specification is then

$$\ln p_i^t = \gamma_0 + \sum_{k=1}^{K} \beta_k z_{ki}^t + \varepsilon_i^t \tag{5.55}$$

and the coefficients $\beta_k$ show the importance of the each characteristic. The equation is estimated using data on $i = 1, .., n$ products

When a product in the sample is being replaced by another with different characteristics, the price of the original product can be adjusted by adding the prices of those characteristics which it lacks so that the consistency is maintained.

While hedonic functions have been used in this way to adjust prices and maintain consistency in the sample, they have also been used to estimate price indexes directly. For this purpose the specification of the equation is

$$\ln p_i^t = \gamma_0 + \sum_{t=1}^{T} \gamma_t D^t + \sum_{i=1}^{K} \beta_k z_{ik}^t + \varepsilon_i^t \qquad (5.56)$$

where $D^t$ are dummy variables with the value 1 in period t and zero otherwise. The exponents of the coefficients $\gamma_t$ are estimates of quality-adjusted price changes controlling for the influence of changes in quality as expressed in the characteristics variables.

Silver and Heravi (2006) refer to the indexes calculated using equation (5.56) as "Time Dummy Hedonic Indexes". They also explore the characteristics of an alternative approach which uses the coefficients generated by equation (5.55) to include new and disappearing goods in a generalized hedonic Tornqvist index. Such and index they call an "Hedonic Imputation Index".

Either approach is best suited to estimating the price index for one particular product like personal computers where there are observations on different models with differing mixtures of characteristics over time. The difficulty with this approach is being able to measure accurately all the relevant characteristics so that the equation is well specified and unbiased and efficient estimates of the coefficients of the time dummy and product characteristics variables are obtained. A further limitation in calculating indexes in this way is that there is no weighting, although this is being addressed within the literature (Silver 2002, Silver and Heravi 2006, Diewert 2005b).

Although there are still outstanding issues to be resolved within the hedonic technique literature, there seems to be a consensus that the semilogarithmic form as given in equation (5.56) is the best. Diewert (2003) argues that this form is likely to display less heterogeneity than the simple linear form.

As was argued in the case of traditional indexes, weighted hedonic indexes will be more accurate than their unweighted counterparts. Expenditure weights are preferred

to quantity weights and expenditure shares are preferred to expenditure levels, because they are unbiased in times of significant inflation (Diewert 2003, 2005b). Diewert (2003) also argues that outliers should be suppressed for unweighted hedonic indexes but retained for weighted indexes as is the case for ordinary indexes.

It is difficult to see how this type of hedonic approach can be used to calculate indexes for heterogeneous collections of goods as found in the CPI or even for groups of goods beyond a certain level of aggregation.

An hedonic approach that goes some way to resolving these limitations is the "Time Product Dummy" hedonic index.

This was first proposed by Summers (1973) to address the problem of missing goods in price comparisons among a group of countries and the literature has largely developed in this context. Rao (2004, 2005) and his colleagues are largely responsible for the renewed interest and Diewert (2005b) has also contributed.

In the temporal context the hedonic equation is usually written as

$$\ln p_i^t = \gamma_0 + \sum_{t=1}^{T} \gamma_t D^t + \sum_{i=1}^{N} \beta_i D^i + \varepsilon_i^t \tag{5.57}$$

where $D^t$ are time dummy variables with the value 1 in period t and zero otherwise, and $D^i$ are product dummy variables with the value 1 for product i and zero otherwise.

In this formulation the only characteristic of a product included in the index is the product itself. The product dummy therefore essentially controls for all characteristics of the product except for that component of its price that varies with time.

Again the exponents of the coefficients $\gamma_t$ are estimates of the price index for period t against the base period. To avoid singularity in the estimation of equation (5.57) one of the time dummy variables is omitted (typically the first period), so the base period for each of the price indexes is the period of the omitted variable.

If only data for two adjacent periods is included, there will only be one time dummy variable and the index will compare the two periods. Successive bilateral indexes can be obtained by estimating the equation using data from successive pairs of periods. These bilateral indexes can then be chained in the usual way to generate an index series.

If the coefficients of equation (5.57) are estimated using ordinary least squares (OLS), then the indexes calculated suffer from the same drawback as those based on the stochastic specification discussed in Section 5.3 above, namely the price data is unweighted so that equal importance is given to all observations. Rao (2005) and Diewert (2005b) therefore argue for estimating equation (5.57) using weighted least squares (WLS).

The OLS procedure seeks to obtain coefficients for equation (5.57) by minimising the following sum of squares

$$\sum_{t=1}^{T}\sum_{i=1}^{N}\left[y_{it}-\gamma_{t}-\beta_{i}\right]^{2}$$

while WLS will minimise

$$\sum_{t=1}^{T}\sum_{i=1}^{N}w_{it}\left[y_{it}-\gamma_{t}-\beta_{i}\right]^{2}$$

where $w_{it}$ is the weight.

The WLS approach is the same as applying OLS to equation (5.57) once all the observations for each variable have been multiplied by the square root of the weight, namely

$$\sqrt{w_{it}}\ln p_{i}^{t}=\sum_{t=1}^{T}\gamma_{t}\sqrt{w_{it}}D^{t}+\sum_{i=1}^{n}\beta_{i}\sqrt{w_{it}}D^{i}+u_{i}^{t} \tag{5.58}$$

Rao and Diewert propose that the weights be value shares.

Because the hedonic indexes estimated using the techniques discussed above do not use price or quantity relatives, it is not immediately obvious how these indexes relate to the more traditional indexes discussed earlier. Diewert (2005b) shows however that for the restricted case of the weighted TPD index where there are just two time

periods and all n products are available in each period, the TPD index is close to or identical to a superlative index.

If the weights in (5.58) are the share of the ith product in total value in time period t, then the TPD index is a pseudo-superlative index (using the terminology in Diewert 1978) and closely approximates a Tornqvist index. If the weights are the arithmetic average of the value shares in both periods, then the TPD index is exactly the superlative Tornqvist index. For the unweighted form of the TPD, the resulting index is the Jevons index (equation (5.11)).

If instead of the semilogarithmic form, the dependent variable is the square root of the price

$$\sqrt{p_i^t} = \sum_{t=1}^{T} \gamma_t D^t + \sum_{i=1}^{N} \beta_i D^i + \varepsilon_i^t \tag{5.59}$$

then the unweighted version results in the Dutot index (equation (5.9)), while the weighted version gives the Walsh index, where the weights are defined as the geometric means of the quantities in the two periods.

The unweighted semilogarithmic specification has been used by Aizcorbe, Corrado and Doms (2000, 2003) to estimate indexes for personal computers and microprocessors using traditional indexes, an hedonic index similar in form to equation (5.56), and the TPD specification. In these articles and a later one by Aizcorbe (2003) they find that the coefficients of the time dummies in the TPD index are more stable than the other hedonic index. They also note the conclusion of Diewert (2001) that the TPD form is essentially non-parametric and thus avoids some specification errors and that because the dummy variables are orthogonal, the TPD specification also avoids multicollinearity.

Heravi and Silver (2002) also report stability in the coefficients of the time dummies despite variability in the characteristics variables when hedonic specifications such as (5.56) are used.

While the exposition to this point has been in terms of estimating price indexes there seems to be no reason why an hedonic equation can not be defined in an analogous manner to enable quantity indexes to be estimated, namely

$$\sqrt{w_{it}} \ln q_i^t = \sum_{t=1}^{T} \gamma_t \sqrt{w_{it}} D^t + \sum_{i=1}^{n} \beta_i \sqrt{w_{it}} D^i + u_i^t \qquad (5.60)$$

## 5.6 Potential bias in pharmaceutical price indexes

Some of the issues that arise in decomposing an expenditure series have been addressed in the discussion of index number theory in previous sections. However a number of other problems have been identified by researchers interested in understanding the growth in pharmaceutical expenditure using decomposition analysis techniques.

Probably the most important issue that needs to be addressed is the degree of substitutability among medicines and how this should be handled in the calculation of price and quantity indexes. The issue turns around whether and to what extent indexes calculated with closely substitutable medicines considered as separate goods introduces a bias into the index, and if this is the case, what can be done to rectify it. A bias can arise because the market shares of medicines change over time and the effect of this may not be fully reflected in the index. One method of addressing the bias is to aggregate these close substitutes but this becomes progressively harder to justify at higher levels of aggregation as the degree of substitutability diminishes. The issue then becomes what is the most appropriate level of aggregation at which index number calculations should be undertaken. The answer to this partly depends on whether the subjective preferences of patients should be reflected in the value of indexes or whether an objective analysis of changes in prices and quantities can ignore these preferences.

This is a somewhat complex issue to elucidate so the following discussion starts by considering medicines where the degree of similarity and substitutability is high and then progressively considers groups consisting of medicines which are increasingly dissimilar and the degree of substitution diminishes.

The discussion in Chapter 1 on defining treatment markets for medicines argues that medicines are only substitutable for each other within fairly tightly defined treatment markets. There are for instance only relatively few medicines for treating major depression. These antidepressants cannot be used to treat other medicinal conditions, while other medicines would be ineffective (or potentially harmful) if taken for major depression. Within each treatment market, medicines will differ in the extent to which they are substitutable because they may have different efficacy and side effect profiles. On the other hand different brands of the same chemical entity will have high substitutability at least in terms of efficacy and side effects. The discussion below therefore is structured in terms of the degree of substitutability among the medicines being discussed.

### 5.6.1 Different brands of the same medicine

In considering the pharmaceutical component of the US Producer Price Index (PPI) constructed by the US Bureau of Labor Statistics (BLS), Griliches and Cockburn (1994) argue that the way the BLS incorporated different brands of the same medicine in the PPI introduced a bias in the price index. "Generic" brands are those brands of a particular medicine that are competitors with the "originator" brand belonging to the company that first introduced the medicine to the market. It was shown in earlier chapters that generic brands must be certified by a regulatory agency to be therapeutically equivalent to the originator brand. The generic brand must contain the same amount of the active ingredient(s) and be equally effective in treating the disease. The difference in quality between the originator and generic brand (ie the difference in their characteristics vectors as perceived by the patient) is therefore simply a matter of differences in the name of the company supplying a particular brand, the name of the brand, the colour and shape of the dose form (if any), the design of packaging, and possibly the inert ingredients used to bind the active ingredient within a specific form. It is generally agreed that these factors have no influence on the efficacy of the medicine but how they are regarded by consumers is important in deciding on how they should be treated within price index calculations.

Griliches and Cockburn assert that there are two extremes in this treatment. The first is the view of the BLS (at that time) which treats each new brand as a new good

differing in quality from other brands. This view holds that each brand must enter as a separate good in index number calculations but recognises that this inevitably induces a "new good" problem which must be addressed. At the other extreme is what they call the "FDA" view which holds the different brands as identical, or as they characterise it - "a pill is a pill is a pill".

This view could also be described as the "objective" view which might be expected to be held by institutional third party payers who would differentiate among brands solely on price and no other characteristic. To this extent they would agree with the regulatory agency certifying the different brands as completely interchangeable. The patient's view on the other hand to the extent it regards each brand as different might be described as the "subjective" view. It should be recognised however that this view can be rational because even though the regulatory authorities may assert that the two brands are identical in their ability to make a certain amount of medicine bioavailable, consumers may continue to display brand loyalty as a surrogate for quality control. Differences between the two brands which make no difference to efficacy, such as the shape and colour of a tablet, may also cause confusion to patients and hinder switching between brands.

The objective view in many ways makes the treatment of different brands within index number calculations a lot simpler because the price that enters the index is simply the (weighted) average price of all brands. This approach by and large circumvents or at least greatly reduces the "new good" problem. Because it is very tempting to adopt this approach, the extent of the problem identified by Griliches and Cockburn and the bias it induces in price indexes need to be assessed.

If all consumers did regard different brands of the same medicine as completely interchangeable and had perfect knowledge of all brands, the brand with the lowest price would gain 100% market share almost immediately after market entry. This is clearly not the case because observed market shares do not change so quickly – a phenomenon that Griliches and Cockburn refer to as "diffusion". Hence the "true" price index must lie somewhere between an index calculated using average prices and one which includes all brands as separate goods.

The issue identified by Griliches and Cockburn can be illustrated by the following example which is presented graphically in Figure 5.2.

**Figure 5.2   Originator and generic brands in index calculations**
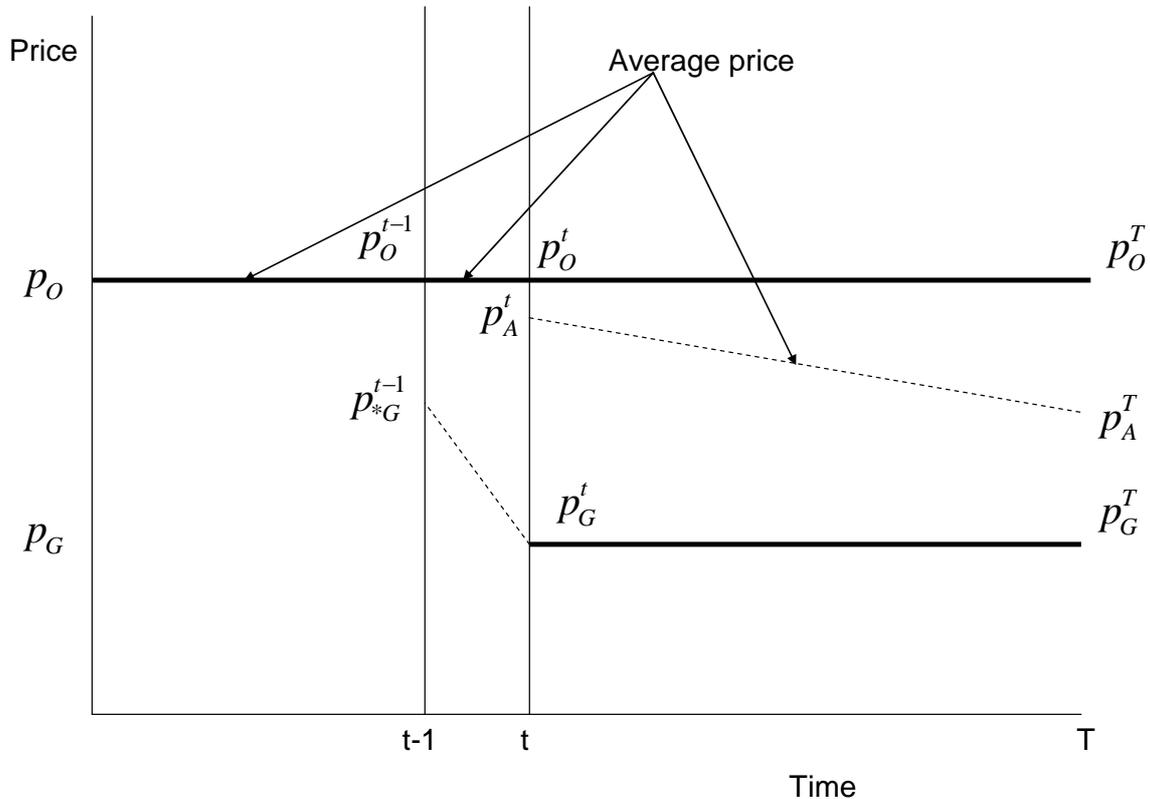


Consider the case of the sale of a particular form, say a 200 mg tablet, of a medicine M protected by patent, for which the originating supplier is company O. At time t patent protection is lost and a competitor brand of the 200 mg tablet of medicine M from company G enters the market. Assume that the price of the originator brand remains unchanged at $p_O$, shown by the line $p_O$ - $p_O^T$ both before and after the entry of the new brand. The competitor brand enters at price $p_G$ which remains unchanged thereafter, as shown by the line $p_G^t$ - $p_G^T$. The assumption of unchanged prices is simply made to demonstrate clearly the bias in index number calculations but the argument is the same if prices are allowed to vary.

If brand G is considered a new good distinct from brand O, any index calculated using standard formulae will show no increase in the price index, regardless of the market shares of the two brands, because the price relatives of both brand O and brand G will

always be equal to 1. Even if an attempt is made to circumvent the new good problem by imputing a reservation price for brand G in period t-1, say $p_{*G}^{t-1}$, this will only show a one-off change in the calculated price index for period t and no change in other periods.

However it is obvious that the average cost of acquiring the 200 mg tablet will fall over time as the market share of brand G increases at the expense of brand O. The average cost will follow a line such as $p_O - p_O^{t-1} - p_O^t - p_A^t - p_A^T$. This is the "objective" view of the "true" price index considered as simply this average price calculated as a weighted average of the prices of brands O and G, the weights being the quantities sold of the two brands. The "true" quantity index is then the sum of the quantities of brands O and G sold in each period, and these price and quantity indexes combined will exactly replicate an index of the expenditure on medicine M.

Drawing upon a more detailed analysis in Fisher and Griliches (1995), Griliches and Cockburn show that the problem of how to deal with the entry of a new brand cannot be contained simply to the period of entry. The "diffusion" of the new brand, ie the change in its market share over time must also be taken into account. They develop and test two versions of the Paasche index to account for new entry and diffusion. The first which they call "Paasche (u)" accounts for the introduction of a new brand by imputing a reservation price for it in the period just prior to its entry. They assert that this index will give very similar results to either the Fisher or Tornqvist index calculated with a reservation price for the new entry equal to the originator price in the base period. The second they call "Paasche (ud)" which adjusts the former index to account for diffusion over time. Both indexes are candidates for the true "subjective" index.

In their study Griliches and Cockburn compare monthly price indexes for two varieties of antibiotic – cephalexin and cephadrine – using a variety of different formulae: a formula similar to the then BLS index, standard Fisher and Tornqvist index formulae, Fisher and Tornqvist index formulae where the reservation price is the price of the originator, a Tornqvist index diffusion adjusted, the Paasche (u) index,

the Paasche (ud) index and the average price. Of these the Paasche (ud) index is closest to the average price index.

Feenstra (1994) proposes a different way of addressing the "new good" problem which requires knowing the elasticity of substitution between brands. Griliches and Cockburn explore this approach and derive estimates which are below the average price index although in his "Comment" on this (Feenstra 1997) proposes an alternative treatment which gives an index very close to the Paasche (ud) index, a result acknowledged by Griliches and Cockburn (1997).

Griliches and Cockburn (1996) report similar findings for cephalexin and the antihypertensive medicine prazosin as well as a group of 10 major medicines experiencing patent expiry in the 1980s first explored by Grabowski and Vernon (1992). Berndt, Cockburn, and Griliches (1996) extend this further by looking at all antidepressants.

All these studies demonstrate that treating highly substitutable generic brands as different goods introduces a bias to index number calculations and that an objective solution to this is to aggregate brands and use the resulting average prices while a view that incorporates patients' subjective preferences involves more complicated assumptions about reservation prices and modifying standard formulae. As noted earlier the objective approach both avoids the "new good" problem and the bias arising from changing market shares of brands. The subjective approach must still grapple with the "new good" problem as it addresses the bias. In the examples given in these studies the resulting subjective index is closer to the objective index than the index treating all brands as separate goods.

Although the example illustrated in Figure 5.2 assumes constant prices, the disparity between an index based on the weighted average price and one based on separate brands will continue to persist if the prices of brands O and G are allowed to vary over time. The size of the difference will depend on the differences in prices between brands O and G, the difference in the growth rates of their prices and the size of the changes in market share.

This can be illustrated by a simple model which assumes that the total amount of medicine M sold is fixed and that in period 1 brand O with a price of 1 has 100% market share. Brand G enters the market in period 2 with a price half that of brand O which then loses market share at 10% per period thereafter. With the prices of both O and G not changing, a Fisher price index takes the value of 1 for all periods, the average price falls steadily and the ratio of the two increases over time, as shown in the first three columns of Table 5.1.

**Table 5.1    Bias in index calculations from changing market shares**

| | 0% growth in prices | | | 0% growth in prices | | | 5% change in prices of O and G | | |
|---|---|---|---|---|---|---|---|---|---|
| | 10% change in share | | | 20% change in share | | | 10% change in share | | |
| Period | Av. price | Fisher | Ratio | Av. price | Fisher | Ratio | Av. price | Fisher | Ratio |
| 1 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 |
| 2 | 0.95 | 1.00 | 1.05 | 0.90 | 1.00 | 1.11 | 0.95 | 1.00 | 1.05 |
| 3 | 0.91 | 1.00 | 1.10 | 0.82 | 1.00 | 1.22 | 0.94 | 1.04 | 1.11 |
| 4 | 0.86 | 1.00 | 1.16 | 0.76 | 1.00 | 1.32 | 0.93 | 1.08 | 1.17 |
| 5 | 0.83 | 1.00 | 1.21 | 0.70 | 1.00 | 1.42 | 0.91 | 1.12 | 1.23 |
| 6 | 0.80 | 1.00 | 1.26 | 0.66 | 1.00 | 1.51 | 0.88 | 1.15 | 1.31 |
| 7 | 0.77 | 1.00 | 1.31 | 0.63 | 1.00 | 1.58 | 0.86 | 1.19 | 1.38 |
| 8 | 0.74 | 1.00 | 1.35 | 0.60 | 1.00 | 1.65 | 0.83 | 1.22 | 1.47 |
| 9 | 0.72 | 1.00 | 1.40 | 0.58 | 1.00 | 1.71 | 0.80 | 1.25 | 1.55 |
| 10 | 0.69 | 1.00 | 1.44 | 0.57 | 1.00 | 1.76 | 0.78 | 1.28 | 1.65 |

Note that in this simple example no attempt is made to estimate a reservation price for brand G in period 1. If the market share of O decreases more rapidly at 20% per period, the average price falls more rapidly and the disparity widens (as shown in the next three columns). Finally if it is assumed that the price of O grows at 5% per period and the price of G falls at 5% per period, the Fisher index will increase (although at a slowing rate) while the average price falls. Again the disparity increases over time.

In this model the Fisher index treats brands as separate goods so has the inherent bias, while the average price is the "objective" index and the "subjective" index will therefore lie somewhere between the two and closer to the "objective" index.

While this discussion has been presented on the basis that O and G are originator and generic brands, the conclusions about bias and its treatment apply equally if they are both generic brands as long as there is some difference in their prices. The most usual

situation is that the originator brand is more expensive than the generic brand so the index which treats brands as separate goods will overestimate the growth in prices when compared to the "true" index whether specified as the "objective" index or as some intermediate index. The size of the bias will obviously depend on the difference between the prices of the originator and generic brands. In the USA where these differences can be large the bias can therefore be significant, however as shown in Chapter 4, under the PBS where the difference is relatively small the bias might be expected to be minor.

The problem identified by Griliches and Cockburn pervades the calculation of indexes. Although they concentrate on the bias arising from neglecting the shift in market shares of different brands of the same medicine, the bias will also arise as shares change among different strengths of the medicine, and among different medicines for treating a particular disease. The more general application of the procedure for addressing this bias at higher levels of aggregation however faces more difficult conceptual and practical problems than does the aggregation of virtually identical brands.

## 5.6.2 Different strengths and forms of the same medicine

It can be argued that the issues raised in the previous section with regard to the treatment of different brands of the same medicine apply equally to the case of two different strengths of the same medicine. In Figure 5.2, O and G now represent say a 400 mg tablet and a 200 mg tablet of medicine M, respectively. If there is a shift by patients from one strength to the other and prices remain unchanged throughout the time interval, this will generate the same diffusion problem and hence the same bias in index calculations as arises with different brands. Again an "objective" index would be one based on an average price of the two strengths and would simultaneously address both any "new good" problem arising from the introduction of a new strength and the diffusion bias. The "subjective" index would lie between the "objective" index and the index based on treating different strengths as separate goods.

Applying the same solution depends crucially on whether it is possible to convert the two different strengths to the same measure. On the face of it, the simplest way to do

this is to regard the 400 mg tablet as delivering twice the number of milligrams of medicine M and weight it accordingly when an average price is calculated.

Doing this however ignores some important differences between the two situations. While the two different brands of the same strength differ only in consumers' perceptions of quality based on brand name, various strengths of a medicine can have more substantial differences in quality.

Firstly a higher strength version is often introduced to be more convenient for patients to take and because of this it improves patients' compliance with medication regimens. It is more convenient for instance to take one tablet a day rather than 2 or more per day; or to take one per week rather than one per day. In addition weaker doses are often introduced for children or the elderly. These reflect real differences in quality which are not captured by simply adjusting for strength pro rata in calculating quantities or prices.

Secondly, medicines often have pharmacological properties that are not proportional to strength, so that a tablet with twice as much active ingredient may not make twice as much available to the target site within the body.

Differences in form or route of administration present greater problems. Some of these are relatively minor – for instance differences in the shape of a tablet may make it easier for patients to swallow the tablet. However a 200 mg tablet taken orally and an injection of 200 mg of the same medicine usually make significantly different amounts of the medicine available within the body. Similarly inhaled forms, suppositories and eye and ear drops will all differ in their influences on disease. Even oral forms such as tablets and capsules can come in extended or sustained release forms which are designed to release the active ingredient more slowly or in different parts of the intestinal tract to deliver more precisely the desired amount of medicine to its target.

Some differences of form indicate that the same medicine is being used to treat different diseases. The ATC system for instance often uses a separate code for medicines such as antibiotics in the form of eye or ear drops which are used to treat

diseases of these organs. Similarly medicines in the form of a cream or ointment applied topically to treat skin diseases are sufficiently different in terms of the disease being targeted to warrant a separate classification.

Ideally when aggregating different strengths and forms they should be weighted by factors that measure their ability to deliver the same amount of medicine to the disease site. Unfortunately these factors are generally not available. Further aggregation should only be done for those forms of the medicine with the same ATC or similar code, as a proxy for the disease target being constant.

Prices for medicines of different strengths are generally not proportional to the strength and it is common for higher strengths to be cheaper per unit than lower strengths. In the example of aciclovir given in Appendix A, for instance the 200 mg tablet costs about 0.89 cents per mg while the 800 mg tablet costs about 0.68 cents per mg. It should also be noted that the cream form has a price of about 16.9 cents per mg.

The difference in price per unit can go to extremes. In discussing the markets for different strengths of the same medicine Berndt (2002) refers to the practice found in the market for some medicines of "flat" pricing, namely tablets of the same medicine with different strengths having the same price or prices that are very close.

The "objective" approach to aggregating different strengths and forms should be restricted only to those strengths and forms that fall within the same combination of molecule and ATC7 classification.

The nature of any bias associated with movements in market shares among different strengths and forms is not as obvious as that for different brands. If there is a tendency to move from lower to higher strengths then a price index which aggregates these would have a lower value than one that does not. The objective index then would be lower than the unaggregated version. The effect of moving from one form to another will depend on the price per unit of the various forms and there is no apriori reason for thinking this will result in an upward or downward bias.

### 5.6.3 Different medicines having similar modes of action

While assessing the degree of substitutability among different brands or strengths or forms of the same medicine may be relatively straightforward, once different chemical entities are being compared this becomes more difficult.

In Figure 5.2, O and G are now two treatments for a particular disease with different chemical compositions but similar modes of action in the body. They might for instance be different kinds of proton pump inhibitor for treating peptic ulcers or different SSRIs for treating depression, or different types of statin for reducing blood cholesterol.

The index calculation bias now arises when market shares of these different medicines change and forming an "objective" index means aggregating all the medicines within a particular therapeutic group such as that defined by an ATC5 code.

The additional difficulty beyond combining different brands, strengths and forms is trying to find factors that enable the different medicines to be combined. The Defined Daily Doses (DDD) estimated by the WHO Collaborating Centre for Drug Statistics Methodology is the "the assumed average maintenance dose per day for a drug used for its main indication in adults" and is based on the manufacturer's recommendations which have been approved by the regulatory agency. By working out the number of DDDs delivered by each form and strength of a particular medicine a total amount of DDDs for this medicine can be calculated. Combining these DDDS for different medicines with similar action gives the number of DDDs prescribed for treatment of the particular disease by this group of medicines

DDDs by themselves however make no allowance for any differences in quality among the medicines and factors to adjust for this are not readily available. The cost-effectiveness methodology applied by the PBS in determining the price of new medicines, the formation of Reference Pricing Groups based on this methodology and the application of the WAMTC and similar procedures for determining the prices of medicines over time is an explicit attempt to address these differences in quality

among similar medicines. Nonetheless the factors used by the PBS in comparing medicines in these ways can be quite different to their DDDs and in most cases these factors are not readily accessible.

Calculating an "objective" index to account for bias arising from changing market shares among these medicines by adjusting quantities using DDDs and aggregating to say the ATC5 level necessarily ignores any differences in quality among these medicines.

Many of the sectoral studies of the markets for medicines to treat specific diseases explain the differences in market shares of medicines or their prices econometrically by including among the explanatory variables measures of quality such as efficacy and side effect profiles. For instance, Cockburn and Anis (2001) have used this approach in their analysis of the market for arthritis medicines in the USA, as have Berndt et al (1994), Suslow (1996), and Berndt et al (1999) in their analyses of the market for anti-ulcer medicines. The market for antidepressants has been examined similarly by Berndt et al (2002), Cleanthous (2004), and Donohue and Berndt (2006) and Ellison and Hellerstein (1999) have applied this to the market for antibiotics.

Most of these studies find that at least some of these measures have an influence on market outcomes which suggests that approaches that seek to aggregate different medicines for treating a particular disease need to account for their differences in quality in some way before this can be done successfully.

### 5.6.4 Different medicines having different modes of action

From time to time the search for new medicines leads to discoveries that are qualitatively different from the existing treatments. These may arise for instance from better understanding of disease processes or new classes of compounds being discovered. Such innovations can lead to the development of new classes of medicines with different efficacy and side effect profiles from those in the existing classes of treatments. Examples of new classes are the proton pump inhibitors replacing the older $H_2$-receptor antagonists in the treatment of peptic ulcers, the SSRIs replacing the

older tricyclic antidepressants, and statins replacing other lipid modifying agents in treating blood cholesterol.

The introduction of a new class of medicines can have a dramatic effect on usage. The market for the treatment of depression is largely associated with the introduction of SSRIs which were safer to use than the older medicines available. Similarly the availability of statins virtually created the market for cholesterol lowering medicines due to their greater efficacy, better side effect profiles and ease of use.

The Griliches-Cockburn bias associated with changing market shares among different classes of medicines for treating a particular disease therefore might be expected to be greater than the bias associated with the groups of medicines considered in previous sections. The difficulty in forming the "objective" index through aggregation is correspondingly greater. As in the previous case, it is not possible to rely simply on conversion to DDDs to enable aggregation – the medicines being aggregated across different classes are sufficiently different to require significant adjustments for quality. While efficacy and side effects may be similar for all medicines within the same class, they will usually differ substantially across classes.

Generally speaking it is possible to be confident that all the medicines within a particular ATC5 group will treat the same disease so they can be aggregated even if there are difficulties in knowing how to do this in a way that accounts for differences in quality. But using the ATC system to specify all the medicines used for treating a particular condition is not straightforward. In some cases the ATC4 level will provide a complete coverage of all the medicines. For instance *A02B - Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)* includes all 5 ATC5 groups of medicines for treating peptic ulcers. The category *N06A – Antidepressants* covers all 5 ATC5 groups of antidepressants although the PBS also includes Lithium (N05AN01) among the antidepressants.

Guidelines for treating the common condition of hypertension (eg Therapeutic Guidelines Limited 2007) recommend either a thiazide diuretic from *C03 – Diuretics*, an ACE inhibitor or angiotension II antagonist from *C09 - Agents acting on the renin-angiotensin system*, a calcium channel blocker from *C08 - Calcium channel blockers*,

or a beta blocker from *C07 – Beta blocking agents.* However the selection of the medicine should be guided by the extent of comorbidities such as diabetes and heart failure. In this case a single disease can be treated by medicines from a number of ATC4 classes drawn from different ATC3 codes.

These examples make clear that an "objective" index to address any bias arising from shifts in the market shares of all medicines for treating a particular disease by mechanically aggregating to the ATC4 level faces substantial difficulties even if the obstacles to doing so can be overcome.

The task of allocating all PBS (or any other) medicines to specific disease treatment markets without relying on an existing classification such as the ATC system would be a significant undertaking and in the absence of specific restriction indications would best be done by medical experts.

The bias due to a shift by patients from one medicine to another only arises within the context of a single disease treatment market. This means that once all the medicines used to treat a single disease have been aggregated it makes no sense to go beyond this point (to say the ATC3 or ATC1 or whole of market levels).

The issues discussed in this section can be summarised as follows. Within a market for medicines to treat a particular disease, biases may arise if price indexes are calculated using standard formulae and with data that treats all the brands of medicines in that market as separate goods. At the basic level, the bias can be addressed by aggregating brands of the same form and strength of a certain medicine. The "objective" index obtained in this way can be compared to that calculated without aggregating brands and the direction and extent of any bias assessed. If patients' preferences are to be taken into account the "subjective" index will lie somewhere between the two indexes and the bias will be correspondingly reduced. Calculating the extent of biases arising from shifts in market shares among different strengths and forms of the same medicine, different medicine of the same type and different medicines from different generations becomes progressively harder to ensure accurate results because it becomes more difficult to find the right factors to adjust the data for

the quality differences that become more pronounced the higher the level of aggregation.

If a price index is originally calculated without aggregating brands then it is likely to overestimate any increase in prices if patients move from higher priced originator brands to cheaper generic brands as is usually the case. The "objective" index will therefore be less than the original index. Similarly if patients move to higher strengths and these higher strengths have lower prices per unit of medicine then the "objective" index using aggregate strengths and forms will be less than the "objective" index without aggregation and also less than the original index. Given the choice among medicines with similar modes of action it might be expected that patients will migrate to those with the slightly better efficacy and side effect profiles and any bias arising from this depends crucially upon whether there is any price premium for these characteristics. Because there is competition among suppliers of these medicines, it might be expected that prices will adjust so that the prices per unit of quality adjusted medicine will converge. In any event, the PBS pricing mechanisms attempt to ensure that this occurs. The extent of any bias at this level of aggregation is likely to be relatively small and its direction is uncertain. At the final level of aggregation suppliers of new generations of medicines may be able to command a price premium above that of earlier generations and in excess of that warranted by an increased in quality. An "objective" index calculated at this level is therefore likely to produce higher values than those calculated at lower levels of aggregation.

[i] Index number formulae are preferably named after the author(s) that first suggested them. Inevitably however the names most often used in the literature do not follow this convention. Thus the Fisher "ideal' index was first suggested by Bowley, the Tornqvist index was derived independently by Theil (1967) and is sometimes referred to as the Tornqvist-Theil index, the Vartia index was derived also by Sato (1976) and is sometimes called the Sato-Vartia index. Diewert (2005a) asserts that the Vartia index was first suggested by Montgomery (1937). The convention used here is to use the name most commonly found in the literature.

[ii] This defines the Palgrave index.

# Chapter 6

## Price and Quantity Indexes for PBS Expenditure

### 6.1 Introduction

The purpose of this chapter is to provide an introduction to the empirical analysis of the growth in PBS expenditure by investigating the most appropriate way of specifying price and quantity indexes with respect to two of the major characteristics discussed in the previous chapter – the formula that is used and the level of aggregation at which the analysis is undertaken. The aim is to choose which among the candidate formulae should be used for the decomposition of PBS expenditure undertaken in Chapter 7 and to provide some insight into the amount of bias if any associated with indexes defined at different levels of aggregation.

The PBS data available for analysis allows two distinct ways of defining the price and quantity data to be used in index calculations – the derived price (DP) approach and the derived quantity (DQ) approach. Both have attractions and drawbacks but both approaches are necessary for all the analysis desired in subsequent chapters. The third major topic of this chapter therefore is to assess how much the choice of approach influences index results.

The following section describes these two approaches and the datasets that underpin them. It shows how they can be used to calculate price and quantity indexes for both patients and the Government and for pharmacists and suppliers, the results of which are reported in Chapter 7. It also describes the mechanics of aggregating the raw PBS data to the unique brand level, the item level, the molecule/ATC level and the ATC5 and ATC4 levels.

Section 6.3 presents price and quantity indexes based on the derived price approach using the Laspeyres, Paasche, Fisher, Walsh, Tornqvist, and Vartia indexes at the item level. Results for Time Product Dummy (TPD) indexes are also given at the item level. Comparisons are made among the various candidate formulae and with price indexes from the Australian Institute for Health and Welfare (AIHW) and the

Australian Bureau of Statistics (ABS). The Bortkiewicz decomposition of the ratio of the Paasche to Laspeyres index is presented to show the relationship among the price and quantity relatives. The results given in Section 6.3 show that there is little to choose among the competing index formulae so the Fisher index is used for most of the analysis in the rest of this chapter and in subsequent chapters.

The differences between index results based on the derived price and derived quantity approaches are illustrated in Section 6.4 using the Fisher price and quantity indexes at both the unique brand and item levels of aggregation. Once again, the two approaches produce quite similar results (at least at the item level) so the derived price approach is adopted for most of the subsequent index analysis, principally because of its ease of computation.

The differences between results at the unique brand level and the item level are not great so Section 6.5 considers "objective" indexes calculated at higher levels of aggregation to investigate the extent of any bias associated with changes in shares of PBS medicines within treatment markets defined at these various levels. Comparisons are made based on Fisher price indexes using the derived price approach. The resulting indexes are broadly similar except for the one calculated at the highest aggregation level – ATC4. The difficulty of interpreting indexes increases with the level of aggregation and this is further pursued in Chapter 7.

Sometimes the discussion in this chapter makes reference to index results that are not reported in the tables. This is particularly the case for the bilateral indexes that form the basis of the chained indexes given in the tables and to results at levels of aggregation other than the item level. In these cases the data supporting the results given can be obtained from the author.

## 6.2 Data and measurement issues

The data sources for the expenditure, price, quantity and other measures used in the index calculations are described in some detail in Appendix A. As noted there the CSES maintains two databases of information on the PBS. The first of these contains annual financial year data for each combination of PBS item and manufacturer code listed on the PBS in that year. This includes data on the number of scripts dispensed,

the cost of these to the government and the cost to the patient. Total cost or expenditure is then the sum of the government and patient costs. Annual information from 1991-92 to 2001-02 was provided by the Department of Health and Ageing while monthly data from July 2002 to June 2006 was provided by Medicare Australia. As these sources only provide data on private hospital use of medicines in the Highly Specialised Drug Program, information on expenditure and usage for this program for both public and private hospitals was obtained from the section of the Department responsible for managing this program.

The second principal data source is based on electronic copies of the PBS Schedule provided by the Department of Health and Ageing. This contains among other things, data on listed prices for PBS medicines dispensed by pharmacists as well as the price they pay to wholesalers for these items. Dispensed prices are quoted both for the base price payable by the government and for the manufacturer's price which includes any premium payable by the patient. Similarly the price to the pharmacist is quoted both with and without allowance for the premium. The Schedule also includes information on the maximum quantity that can be dispensed for each PBS item, the manufacturer's pack size for each brand within an item, the restriction level, type of program within the PBS, and ATC code. With each release of the Schedule, the Department also provides information on the fees and margins that pharmacists can apply, and the copayments payable by different types of patients. The data from this source is for the months July 1991 to the present.

Because monthly expenditure and usage data is only available from July 2002, only annual data is used for the analysis within this and subsequent chapters.

### 6.2.1 Price and quantity measures

Calculating price and quantity indexes using the formulae and approaches discussed in Chapter 5 necessarily relies on matched observations for both price and quantity. With the data available for this thesis there are two ways of obtaining these price and quantity observations. The first relies on deriving prices given expenditure and quantity while the second derives quantity given expenditure and prices. Because actual prices are used in the second approach it produces indexes that are conceptually

closer to the usual type of price indexes produced by statistical agencies, such as the CPI.

*The derived price approach - actual quantities and derived prices*

It is possible to obtain a value for the price of a PBS medicine by dividing expenditure on that medicine by the number of scripts dispensed for it. The price derived in this way is a unit value rather than an observed price. Although this is a simple way of obtaining a price, there are drawbacks to using the number of scripts as the measure of quantity in this fashion. Firstly it assumes that the amount of medicine specified by a script is constant among prescribers and over time. However the doctor writing a script is not bound to prescribe the maximum quantity allowed for that PBS item code, so this means that the amount of medicine dispensed could vary from script to script. Unfortunately it is not possible within the information available to assess the extent to which this is the case. As noted earlier, although Medicare Australia records the number of units of a medicine dispensed by a script it has advised that this measure is often not reported by pharmacists and its accuracy is therefore suspect.

There are two main sources of data on the prescribing patterns of general practitioners. The BEACH dataset maintained by the Family Medicine Research Centre at the University of Sydney is based on paper records kept by a sample of GPs on patient encounters. The records note among other things the GP's diagnosis and a description of the type and amount of medicine prescribed. A more detailed description of BEACH is provided in Britt et al (2007). Similarly the General Practice Research Network (GPRN) dataset maintained by Health Communications Network Pty Ltd records information from a sample of GPs and specialists using the Medical Director software package (Sayer et al 2003). The BEACH data starts in 1998 and the GPRN data in 1999. Both these data sources are used by the Department of Health and Ageing and others to assess how much is prescribed on average per script.

If the number of scripts is to be used as the quantity measure in index number calculations or any other analysis, it is therefore assumed that either the same quantity (say the maximum quantity allowable) is prescribed by all prescribers or that the

distribution of fractional prescribing is constant over time and hence does not introduce a bias in the calculations.

The second limitation on using scripts as the quantity measure is that the maximum quantity allowable for a prescription by the PBS can and does change over time. This means that, even assuming that a script represents the maximum amount at any one time, the amount of medicine per script may differ from one time period to another. This source of bias can be rectified by multiplying the number of scripts by the maximum quantity to obtain a measure of the number of units (such as a tablet or capsule) that have been dispensed and using this as the quantity measure. Because the maximum quantity is obtained from the monthly PBS Schedule dataset it is necessary to convert this to an annual series before it can be used to adjust the annual scripts data. For the purposes of the analysis reported in this thesis, a simple unweighted annual arithmetic average is calculated using the 12 monthly values for a particular financial year. Ideally the annual average would be calculated by weighting the monthly values by their share in annual expenditure but this information was not available. In practice maximum quantities change infrequently and only for a limited number of items so the bias arising from an unweighted mean is likely to be small.

In this derived price approach then, dividing total cost just by scripts gives a unit value that is the average dispensed price across all transactions for a particular combination of PBS item and manufacturer code in a particular year. The price so obtained is comparable to the annual average of the manufacturer's dispensed price for maximum quantity (MDPMQ) quoted in the PBS Schedule.

If the total cost is divided by the number of scripts multiplied by the maximum quantity allowable the unit value obtained is the average dispensed price per unit (such as a tablet or capsule) and is comparable to MDPMQ divided by the maximum quantity (MQ).

In the discussion of the outlier problem in Appendix A, it is pointed out that the expenditure data sometimes contains outlier observations, ie there are transactions recorded for periods when the medicine is no longer listed on the PBS Schedule and therefore there is no Schedule information available for the medicine. Obtaining a

derived price by dividing total cost by scripts retains these outliers and therefore gives a price for them. On the other hand once any modification is made to the expenditure or script data by introducing a variable from the PBS Schedule, such as obtaining a derived price per unit by dividing total cost by scripts times maximum quantity, this necessarily suppresses these outlier observations.

This procedure can be extended to obtain unit value price series for other components of PBS expenditure. For instance, dividing the government cost by scripts times maximum quantity gives a price series showing the price paid by the Government for medicines, while dividing the patient cost by scripts times maximum quantity gives the price paid by patients. Similarly the different categories of patients can be considered separately so that for instance dividing total patient cost for general patients by the number of scripts for general patients times maximum quantity gives the average price paid by general patients.

*The derived quantity approach - actual prices and derived quantities*

An alternative approach to specifying prices and quantities is to start with the actual prices given in the PBS Schedule and use these to derive a quantity measure by dividing the total expenditure by this price. Because the total expenditure refers to the actual cost incurred at the pharmacist's cash register, the appropriate price to use is the manufacturer's dispensed price for maximum quantity (MDPMQ). However because the maximum quantity can vary over time the best price to use is the MDPMQ divided by the maximum quantity which is the manufacturer's dispensed price for a unit of the medicine.

This approach as already noted suppresses any outlier observations.

In deriving quantities in this way, the prices used are those in the monthly PBS Schedule dataset. As was the case for the maximum quantity, annual prices are obtained by a simple unweighted average of the 12 monthly observations.

Once the quantity series has been derived it can be used in price index calculations not only for the dispensed price but for the other prices in the PBS Schedule. Thus

indexes can be calculated for the Commonwealth dispensed price for maximum quantity (CDPMQ), and the manufacturer's and Commonwealth price to pharmacist for manufacturer's pack (MPPMP and CPPMP). Again, the preferred price for the Commonwealth dispensed price for maximum quantity is actually CDPMQ divided by MQ. For the prices to pharmacist, the preferred prices are MPPMP and CPPMP divided by the size of the manufacturer's pack (PS). It should be noted here that the manufacturer's pack size can vary among different suppliers within a particular item, unlike the maximum quantity which is the same for all suppliers. Further to this, a price reflecting the pharmacist's markup, ie the difference between the price paid by the pharmacist to the wholesaler and the dispensed price can be defined as the difference between MDPMQ divided by MQ and MPPMP divided by PS.

For the period over which the analysis of PBS expenditure is undertaken – 1991-92 to 2005-06 - 10% of the price paid by the pharmacist went to the wholesaler and 90% to the manufacturer. A price index calculated for the price received by the manufacturer is therefore the same as that for the price received by the wholesaler, ie for MPPMP.

The derived quantity approach using the information in the PBS Schedule therefore enables price indexes to be calculated for the different points in the supply chain: manufacturer, wholesaler, pharmacist and patient. In the derived price approach, indexes can only be calculated at the dispensed point.

However the dispensed price is essentially an administrative device and differs from the actual price faced by the two payers in the PBS - the patient and the government. The price faced by the patient is the relevant copayment if any plus the premium (or SPC) if the brand being purchased has one. The price paid by the Government is the dispensed price less the price paid by the patient.

The price paid by the patient differs by type of patient, because there are three levels of copayment - the general copayment (paid by general non-safety net patients), the concessional copayment (paid by concessional non-safety net and general safety net patients) and free (paid by concessional safety net patients).

The premium is simply the difference between MDPMQ and CDPMQ. The general and concessional copayments are known (and given in Chapter 3) and can be added to the premium to obtain the price paid by those that pay the general and concessional copayment. For those that do not pay a copayment, the price is simply the premium if there is one. In this latter case, most items will have a zero price (which makes calculating price indexes problematic), while for patients paying the general or concessional copayment the price will always be positive.

All these prices can then be divided by the maximum quantity to obtain the price per unit as before.

Indexes can be calculated for the prices paid by the different categories of patients by using the prices calculated in this way in conjunction with an appropriate derived quantity measure. For those patients paying the general copayment the quantity measure is the total PBS expenditure by these patients divided by MDPMQ per unit. Similarly for those paying the concessional copayment it is the total PBS expenditure by these patients divided by MDPMQ per unit. The price indexes for the price paid by the Government for these two types of patients are calculated using the same quantity measures and prices equal to MDPMQ minus both the premium and the appropriate copayment. For the patients with no copayment, the price index for the price paid by the Government is simply the one for CDPMQ per unit.

The two approaches to obtaining prices and quantities therefore throw up a somewhat complex set of possibilities for calculating price and quantity indexes for various groups of participants in the PBS. Not all of these are attempted within this thesis. In this chapter only overall results are presented using the following combinations of price and quantity.

**A. Overall – derived price and derived quantity**

| Quantity | Derived Price |
|---|---|
| Scripts*MQ | Total expenditure/(Scripts*MQ) |

| Derived Quantity | Price |
|---|---|
| Total expenditure/(MDPMQ/MQ) | MDPMQ/MQ |

In Chapter 7 these overall results are contrasted with those calculated firstly for different categories of payers and patients and secondly for manufacturers and pharmacists. These cases use the following combinations of price and quantity.

**B. By payer – Government and patient – derived price**

| Quantity | Derived Price |
|---|---|
| Scripts*MQ | Government expenditure/(Scripts*MQ) |
| Scripts*MQ | Patient expenditure/(Scripts*MQ) |

**C. By patient category and payer – derived price**

| Quantity | Derived Price |
|---|---|
| GEN Scripts*MQ | GEN patient expenditure/(GEN scripts*MQ) |
| CON Scripts*MQ | CON patient expenditure/(CON scripts*MQ) |
| GEN Scripts*MQ | GEN government expenditure/(GEN scripts*MQ) |
| CON Scripts*MQ | CON government expenditure/(CON scripts*MQ) |

**D. Manufacturer and pharmacist price – derived quantity**

| Derived Quantity | Price |
|---|---|
| Total expenditure/(MDPMQ/MQ) | MPPMP/PS |
| Total expenditure/(MDPMQ/MQ) | (MDPMQ/MQ) – (MPPMP/PS) |

where

| | |
|---|---|
| Scripts | = number of scripts dispensed |
| MQ | = maximum quantity |
| PS | = manufacturer's pack size |
| GEN | = those patients paying general copayment |
| CON | = those patients paying concessional copayment |
| MDPMQ | = manufacturer's dispensed price for maximum quantity |
| MPPMP | = manufacturer's price to pharmacist for manufacturer's pack |
| GEN COPAY | = general copayment |
| CON COPAY | = concessional copayment |

## 6.2.2 Different levels of aggregation for analysis

The discussion in Chapter 5 indicated that it is possible to undertake index analysis of expenditure at different levels of aggregation and that doing so could provide some insights into the degree of substitution among medicines within the PBS and the extent of bias introduced into index calculations by this substitution. It was also noted that aggregating the data has the potential to reduce significantly any bias arising from the omission of new and disappearing goods from the index calculations.

In this chapter results are presented mainly for data aggregated to two levels – (i) the combination of PBS item code and unique brand and (ii) the PBS item code itself. Summary results are also given for indexes using data aggregated to the combination of molecule and ATC7 code, and the ATC5 and ATC4 codes.

The lowest level of aggregation used is that defined by the combination of a PBS item code and a unique brand name. The discussion in Appendix A on data sources presents the argument in favour of this definition and how the raw data is adjusted to achieve this.

The next level of aggregation is to combine the brands within an item to form observations at the item code level. For the expenditure and scripts data this can be done simply by adding together the values for the brands within an item code.

For the monthly PBS Schedule data most of the characteristics of the item are invariant among brands. Thus the form, strength, maximum quantity, and Commonwealth dispensed price are the same for all brands within an item. Hence the item level values of these characteristics are easily obtained. The characteristics that can vary among brands are the premium, and hence the manufacturer's dispensed price, the manufacturer's and Commonwealth price to pharmacist, as well as the size of the manufacturer's pack.

In forming item level values for these characteristics the choices are to take either an unweighted average of the brand values within an item or an average which weights each brand value by its share of expenditure within the item. For most results reported

below the unweighted average is used although some results are given for the weighted version to indicate how much difference this makes.

The next level of aggregation is to combine the various PBS items of different strength and form of the same "molecule" to enable indexes to be calculated at the unique molecule/ATC level. Here "molecule" is equivalent to "generic name" within the PBS nomenclature, ie it represents a unique chemical entity or combination of entities. As noted in Chapter 1, the same chemical entity may have different ATC7 codes particularly for different forms of the entity and these different ATC codes indicate separate treatment markets. The appropriate definition at this level of aggregation is therefore the combination of molecule and ATC7 code.

Combining different strengths and forms of molecules within the same ATC7 code requires giving weights to each item reflecting the amount of active ingredient within each one. For instance for the combination of aciclovir and ATC code J05AB01 the 200 mg tablet form in items 1003T and 1007B is given the weight 1 while the 800 mg tablet form in items 1052J and 8234J is given the weight 4. Careful examination of the descriptions for each item enabled weights to be determined for all but 8 PBS molecule/ATC combinations. These are omitted in calculations at this level of aggregation.

Aggregating further necessarily entails combining values for different chemical entities and establishing equivalence among these is difficult as discussed in Chapter 5. The most widely used technique is to determine the defined daily dose (DDD) contained within each molecule/ATC/form combination listed on the PBS and to use this as a common measure of quantity for further analysis. As reported in Chapter 1, DDDs are not defined for some groups of medicines, principally those for treating cancer and for medicines applied topically. For aciclovir (J05AB01) the DDD is 4 grams which would be supplied by 20 of the 200 mg tablets and 5 of the 800 mg tablets. On the other hand the DDD is not defined for the eye ointment form (item 1002R). There are some 231 molecule/ATC combinations for which there are no DDDs and these were excluded from calculations reported below.

Aggregation using DDDs as quantity measures can be undertaken at any level but are most meaningful within the treatment groups defined at the ATC5 and ATC4 levels.

## 6.3 Results using alternative index formulae

This section compares the results obtained for price and quantity indexes using the alternative formulae discussed in Chapter 5. Most of the results are for indexes calculated at the item level but some comparisons are provided with those calculated at the unique brand level.

### 6.3.1 Item level results

Table 6.1 presents chained price indexes calculated at the item level using the Laspeyres (L), Paasche (P), Fisher (F), Tornqvist (T), Vartia (V) and Walsh (W) formulae for the period 1991-92 to 2005-06, with prices and quantities based on the derived price approach. All indexes are chained from bilateral indexes of adjacent pairs of years with 1991-92 = 1.000.

**Table 6.1     Chained price indexes, 1991-92 to 2005-06, item level**

|  | L | P | F | T | V | W | TPD |
|---|---|---|---|---|---|---|---|
| 1991-92 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 |
| 1992-93 | 1.0043 | 0.9979 | 1.0011 | 1.0012 | 1.0012 | 1.0012 | 1.0012 |
| 1993-94 | 1.0230 | 1.0112 | 1.0171 | 1.0175 | 1.0173 | 1.0175 | 1.0175 |
| 1994-95 | 1.0309 | 1.0161 | 1.0234 | 1.0240 | 1.0239 | 1.0240 | 1.0244 |
| 1995-96 | 1.0437 | 1.0245 | 1.0340 | 1.0346 | 1.0343 | 1.0346 | 1.0350 |
| 1996-97 | 1.0330 | 1.0094 | 1.0211 | 1.0220 | 1.0217 | 1.0216 | 1.0221 |
| 1997-98 | 1.0171 | 0.9917 | 1.0043 | 1.0053 | 1.0052 | 1.0050 | 1.0057 |
| 1998-99 | 0.9888 | 0.9663 | 0.9774 | 0.9782 | 0.9786 | 0.9775 | 0.9779 |
| 1999-00 | 0.9649 | 0.9457 | 0.9553 | 0.9558 | 0.9568 | 0.9556 | 0.9566 |
| 2000-01 | 0.9503 | 0.9326 | 0.9414 | 0.9419 | 0.9434 | 0.9421 | 0.9434 |
| 2001-02 | 0.9421 | 0.9171 | 0.9295 | 0.9301 | 0.9318 | 0.9303 | 0.9317 |
| 2002-03 | 0.9407 | 0.9153 | 0.9279 | 0.9286 | 0.9302 | 0.9287 | 0.9300 |
| 2003-04 | 0.9396 | 0.9139 | 0.9267 | 0.9274 | 0.9290 | 0.9275 | 0.9288 |
| 2004-05 | 0.9323 | 0.9066 | 0.9193 | 0.9200 | 0.9215 | 0.9198 | 0.9186 |
| 2005-06 | 0.9148 | 0.8906 | 0.9026 | 0.9033 | 0.9049 | 0.9030 | 0.9018 |

All formulae produce indexes showing PBS prices rising on average through to 1995-96, falling consistently through to 2001-02, remaining constant for the next two years, before falling again in the last two years, most notably between 2004-05 and 2005-06.

As predicted by theory, the chained Laspeyres and Paasche indexes provide upper and lower bounds to the true price index with the Fisher index tracking between these two

(Figure 6.1). A close examination of the bilateral indexes (which are included in Table 6.8 below) shows however that for certain years – 1998-99, 1999-00, 2000-01 and 2005-06 - the Paasche index is slightly higher than the Laspeyres index.

**Figure 6.1   Laspeyres, Paasche and Fisher price indexes, item level**
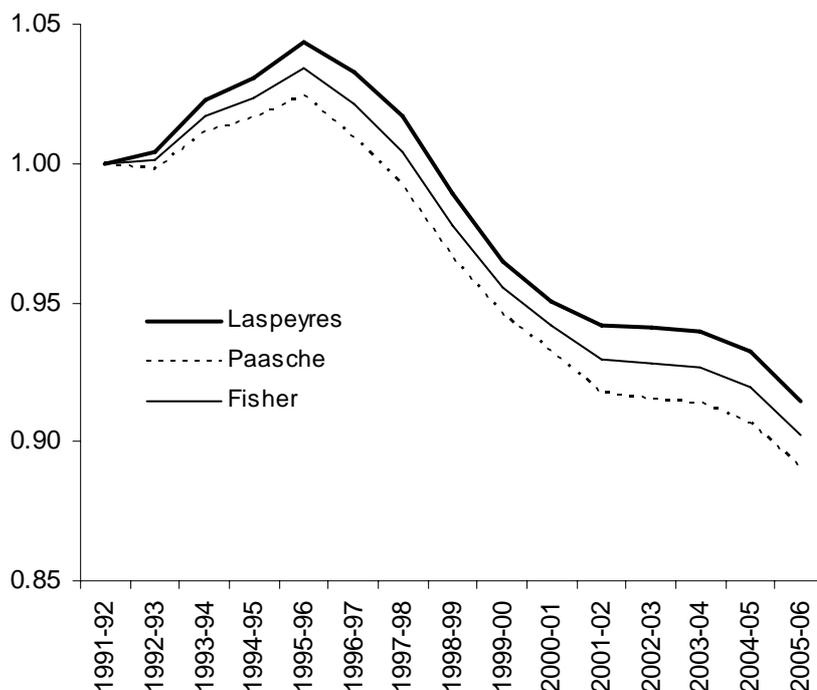


Among all the price indexes there is a very high degree of similarity (with the exception of the Laspeyres and Paasche indexes), so much so that it is almost impossible to differentiate them when they are plotted together. The Fisher and Tornqvist indexes are virtually indistinguishable and the Walsh and Vartia indexes are only slightly different from the Fisher index – being a little higher in some years. The close agreement among the indexes is demonstrated further if the Fisher index is regressed against the other indexes. The statistics from these regressions shown in Table 6.2 below demonstrate that the Tornqvist and Walsh indexes provide the closest fit with the Fisher index, followed by the Vartia index. All coefficients are significant at the 5% level except for the coefficient of the constant for the Tornqvist index.

**Table 6.2    Regression of Fisher price index on other indexes, item level**

| Explanatory variable | Constant | Coefficient | Adjusted $R^2$ |
|---|---|---|---|
| Laspeyres index | -0.0492 | 1.0403 | 0.9933 |
| Paasche index | 0.0547 | 0.9531 | 0.9945 |
| Tornqvist index | -0.0017* | 1.0011 | 1.0000 |
| Vartia index | -0.0204 | 1.0197 | 0.9999 |
| Walsh index | -0.0022* | 1.0018 | 1.0000 |
| TPD index | -0.0019* | 1.0011 | 0.9995 |

n=15, * coefficient is not significant at 5% level

While all the price indexes show increases to 1995-96 followed by decreasing prices for every year thereafter, it should be emphasized that overall the change in average prices has been modest. Taking the Fisher index as representative, over the 15 year period the index has changed from a value of 1.0000 in 1991-92 to 0.9026 in 2005-06, ie a 9.7% fall over 15 years or 0.7% per year on average. By way of contrast, the Consumer Price Index rose by about 2.5% per year over the same period while the "Health" component of the CPI increased by 3.8% per year (RBA 2007a).

The Australian Institute of Health and Welfare provides estimates of components of national expenditure on health in both current and constant (2004-05 prices) terms. Comparing the AIHW values for current and constant national expenditure on "Benefit paid pharmaceuticals" for the period 1991-92 to 2005-06 (the most recent data available at time of writing) gives the implicit price deflator for this series (AIHW 2007b). Rebasing the series to 1991-92 = 1.000 produces a value in 2005-06 of 1.0452 implying a 4.5% increase in PBS prices over 15 years or 0.3% per year on average.

The corresponding chained quantity indexes in Tables 6.3 and Figure 6.2 also display a high degree of similarity except for the Tornqvist index. Once again the Laspeyres and Paasche indexes provide upper and lower bounds for the Fisher index, while the Walsh index is virtually identical to the Fisher index and the Vartia also tracks it closely. While these indexes imply an increase in quantity from 1.0 in 1991-92 to 4.2 in 2005-06, or about 10.9% per year, the Tornqvist index has a value in 2005-06 of 5.3. Table 6.4 below also demonstrates the close agreement among the Fisher, Walsh and Vartia quantity indexes based on regressing the Fisher quantity index on the other index formulae.

**Table 6.3    Chained quantity indexes, 1991-92 to 2005-06, item level**

|         | L      | P      | F      | T      | V      | W      | TPD    |
|---------|--------|--------|--------|--------|--------|--------|--------|
| 1991-92 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 |
| 1992-93 | 1.2387 | 1.2308 | 1.2347 | 1.2914 | 1.2345 | 1.2346 | 1.1992 |
| 1993-94 | 1.4297 | 1.4133 | 1.4215 | 1.5094 | 1.4211 | 1.4211 | 1.3637 |
| 1994-95 | 1.5661 | 1.5435 | 1.5548 | 1.6615 | 1.5541 | 1.5541 | 1.4789 |
| 1995-96 | 1.7724 | 1.7398 | 1.7560 | 1.9003 | 1.7556 | 1.7553 | 1.6475 |
| 1996-97 | 1.9243 | 1.8803 | 1.9022 | 2.0698 | 1.9011 | 1.9009 | 1.7722 |
| 1997-98 | 2.0627 | 2.0112 | 2.0368 | 2.2342 | 2.0350 | 2.0353 | 1.8839 |
| 1998-99 | 2.3005 | 2.2482 | 2.2742 | 2.6245 | 2.2716 | 2.2727 | 2.0088 |
| 1999-00 | 2.6003 | 2.5485 | 2.5743 | 2.9991 | 2.5702 | 2.5728 | 2.2473 |
| 2000-01 | 2.8952 | 2.8412 | 2.8681 | 3.3919 | 2.8621 | 2.8665 | 2.4791 |
| 2001-02 | 3.2153 | 3.1300 | 3.1723 | 3.8411 | 3.1644 | 3.1702 | 2.6771 |
| 2002-03 | 3.4469 | 3.3536 | 3.3999 | 4.1277 | 3.3915 | 3.3976 | 2.8559 |
| 2003-04 | 3.7631 | 3.6599 | 3.7111 | 4.5283 | 3.7018 | 3.7085 | 3.0944 |
| 2004-05 | 4.0724 | 3.9601 | 4.0158 | 5.0015 | 4.0062 | 4.0129 | 3.2996 |
| 2005-06 | 4.2864 | 4.1730 | 4.2293 | 5.3014 | 4.2188 | 4.2263 | 3.4493 |

**Figure 6.2    Laspeyres, Paasche, Fisher and Tornqvist quantity indexes, item level**
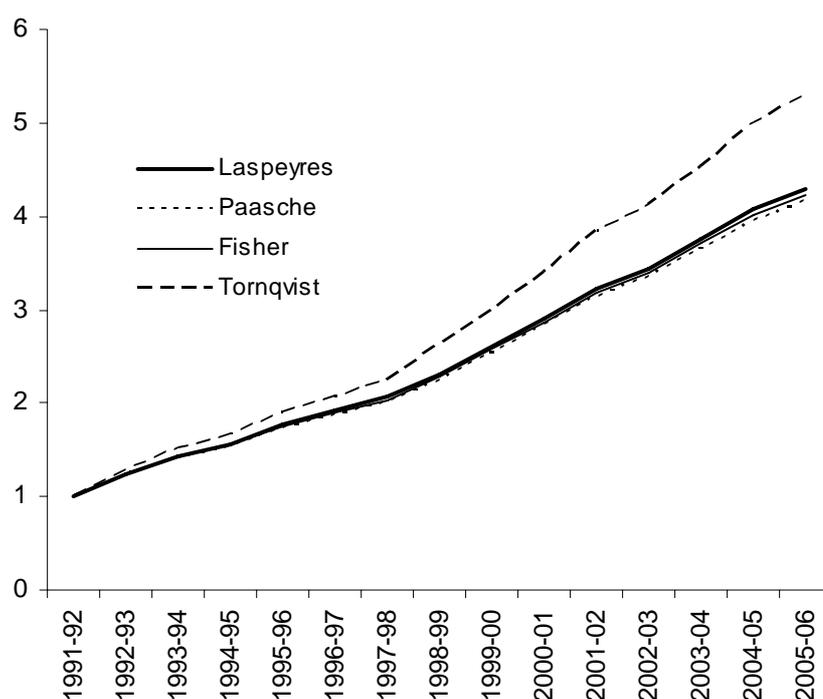


**Table 6.4    Regression of Fisher quantity index on other indexes, item level**

| Explanatory variable | Constant | Coefficient | Adjusted $R^2$ |
|----------------------|----------|-------------|----------------|
| Laspeyres index      | 0.0158   | 0.9824      | 1.0000         |
| Paasche index        | -0.0161  | 1.0179      | 1.0000         |
| Tornqvist index      | 0.3145   | 0.7459      | 0.9989         |
| Vartia index         | -0.0051  | 1.0038      | 1.0000         |
| Walsh index          | -0.0008  | 1.0009      | 1.0000         |
| TPD index            | -0.4057  | 1.3321      | 0.9986         |

n=15

The reason why the Tornqvist index gives a series so different to the other formulae has been discussed in Chapter 5, namely that it is unduly affected by extreme values of the quantity relatives. In the case of the PBS this can arise if a popular medicine is growing strongly. In 1995-96 for instance, one PBS item (1327W – omeprazole, brand name *Losec*) was responsible for about 19% of the total value of the Tornqvist quantity index in that year.

This weakness in the Tornqvist index is only likely to occur with the quantity index, because prices do not change by large multiples so the price relatives will not be affected in the same way. This can be seen by the close agreement among the Tornqvist index and the Fisher and other preferred price indexes.

Again as noted in Chapter 5, this characteristic of the Tornqvist index arises from its geometric mean (or logarithmic) specification and its weighting structure. The Vartia index, which has a similar geometric mean specification but with different weights, is unaffected by these extreme values of the quantity relatives.

### 6.3.2 Time product dummy specification

Each of the formulae discussed to this point are all examples of matched goods formulae, ie they compare the same set of goods in the two periods even though the amount consumed of each good can differ between the periods. They necessarily omit new and disappearing goods unless reservation prices for these have been calculated using hedonic or other techniques. As noted in Chapter 5 however, chaining reduces any bias arising from the omission of these goods. The time product dummy approach, on the other hand, includes both the goods common to the two periods as well as the new and disappearing goods and hence all information on transactions in the two periods.

The estimation of price indexes using the TPD technique can be undertaken in two ways. The first of these uses all the observations available and includes enough time and product dummy variables to cover all the time periods and products. As noted in Chapter 5, to avoid singularity, the first time dummy variable is omitted so that the estimated coefficients of the other time dummy variables result in price indexes for

each time period with respect to the first time period, ie they show the changes in price from the base period to the current period. This way is therefore an analogue for the calculation of direct bilateral indexes using the standard formulae where the common basket is defined as those goods common to the base and current period.

The second way is to calculate TPD price indexes for successive pairs of adjacent years and chain the resulting direct indexes. This is the approach recommended by Diewert (2006). Here only the current time period dummy and product dummies for the goods available in at least one of the two time periods are included in the regression. Again the base period dummy variable is omitted.

The chief difficulty with using the TPD approach is that the specification requires estimating an equation with a large number of explanatory variables. In the results reported below for instance, there are a total of 25779 observations with 14 time dummy variables and 3142 product dummies. Standard econometric packages have difficulty accommodating such a large number of variables. Simply creating the matrix of observations for the explanatory variables results in files of the order of 1 or 2 gigabytes. It is however possible to make the task more tractable by exploiting some features of both the structure of the explanatory variables and of linear algebra. Appendix 9 describes these features and the procedure used for estimating the coefficients and other parameters of the TPD equation.

Several software packages are available for performing operations on large matrices and vectors, the most well known of which is probably the *MATLAB* family of products from The MathWorks (2007). *Scilab* is a free open source package similar to *MATLAB* produced by a consortium of mainly French scientific and technical bodies and is hosted by the French National Institute for Research in Computer Science and Control (INRIA) (Scilab 2007). Version 4.1.1 of *Scilab* was used for the matrix manipulation underlying the TPD calculations.

Table 6.5 reports the results of estimating the TPD equation for all 14 time periods and with 3142 product dummy variables where the price and expenditure data is the same as that used in calculating the index results at the item level using the derived price approach. The coefficients of the time dummy variables are shown for the years

1992-93 to 2005-06 as well as the standard errors for each variable and the associated t-statistic. The price indexes derived by exponentiating the coefficients are shown in the last column. All coefficients are significant at the 5% level except for the year 2000-01.

**Table 6.5    Results from TPD price regression, all years and products**

| Explanatory year dummy variable | Coefficient | Standard error | t-statistic | Implied index |
|---|---|---|---|---|
| 1991-92 | | | | 1.0000 |
| 1992-93 | 0.0098 | 0.0034 | 2.8 | 1.0098 |
| 1993-94 | 0.0304 | 0.0035 | 8.8 | 1.0309 |
| 1994-95 | 0.0457 | 0.0035 | 13.1 | 1.0468 |
| 1995-96 | 0.0665 | 0.0035 | 18.9 | 1.0687 |
| 1996-97 | 0.0591 | 0.0035 | 16.7 | 1.0609 |
| 1997-98 | 0.0466 | 0.0036 | 13.0 | 1.0477 |
| 1998-99 | 0.0251 | 0.0036 | 6.9 | 1.0254 |
| 1999-00 | 0.0080 | 0.0037 | 2.2 | 1.0081 |
| 2000-01 | 0.0002 | 0.0037 | 0.1 | 1.0002 |
| 2001-02 | -0.0112 | 0.0037 | -3.0 | 0.9889 |
| 2002-03 | -0.0135 | 0.0038 | -3.6 | 0.9866 |
| 2003-04 | -0.0148 | 0.0038 | -3.9 | 0.9853 |
| 2004-05 | -0.0243 | 0.0039 | -6.3 | 0.9760 |
| 2005-06 | -0.0390 | 0.0039 | -9.9 | 0.9618 |

Adjusted $R^2$ = 0.9978, Standard error of estimate = 0.002409

Table 6.6 on the other hand shows the results from successive equations in which only pairs of adjacent years are included. For each of these equations there is only one time dummy variable included so the table shows the coefficient of this variable, its standard error and associated t-statistic and adjusted coefficient of determination. The index derived by exponentiation is shown as well as the index formed by chaining these derived direct indexes. This latter chained TPD index is also included in Table 6.1 above.

**Table 6.6    Results from bilateral TPD price regressions, adjacent years, item level**

| Explanatory year dummy variable | Coefficient | Standard error | t-statistic | Adjusted $R^2$ | Implied index | Implied chained index |
|---|---|---|---|---|---|---|
| 1991-92 | | | | | | 1.0000 |
| 1992-93 | 0.0012 | 0.0027 | 0.46 | 0.9987 | 1.0012 | 1.0012 |
| 1993-94 | 0.0161 | 0.0238 | 0.68 | 0.8982 | 1.0162 | 1.0175 |
| 1994-95 | 0.0068 | 0.0105 | 0.64 | 0.9788 | 1.0068 | 1.0244 |
| 1995-96 | 0.0102 | 0.0154 | 0.66 | 0.9520 | 1.0103 | 1.0350 |
| 1996-97 | -0.0125 | 0.0194 | -0.64 | 0.9237 | 0.9876 | 1.0221 |
| 1997-98 | -0.0161 | 0.0251 | -0.64 | 0.8709 | 0.9840 | 1.0057 |
| 1998-99 | -0.0280 | 0.0425 | -0.66 | 0.6409 | 0.9724 | 0.9779 |
| 1999-00 | -0.0221 | 0.0338 | -0.65 | 0.7821 | 0.9782 | 0.9566 |
| 2000-01 | -0.0139 | 0.0215 | -0.65 | 0.9158 | 0.9862 | 0.9434 |
| 2001-02 | -0.0125 | 0.0194 | -0.64 | 0.9301 | 0.9876 | 0.9317 |
| 2002-03 | -0.0019 | 0.0030 | -0.63 | 0.9983 | 0.9981 | 0.9300 |
| 2003-04 | -0.0013 | 0.0021 | -0.61 | 0.9992 | 0.9987 | 0.9288 |
| 2004-05 | -0.0110 | 0.0168 | -0.66 | 0.9516 | 0.9890 | 0.9186 |
| 2005-06 | -0.0184 | 0.0282 | -0.65 | 0.8688 | 0.9818 | 0.9018 |

**Figure 6.3    TPD and Fisher chained price indexes item level**
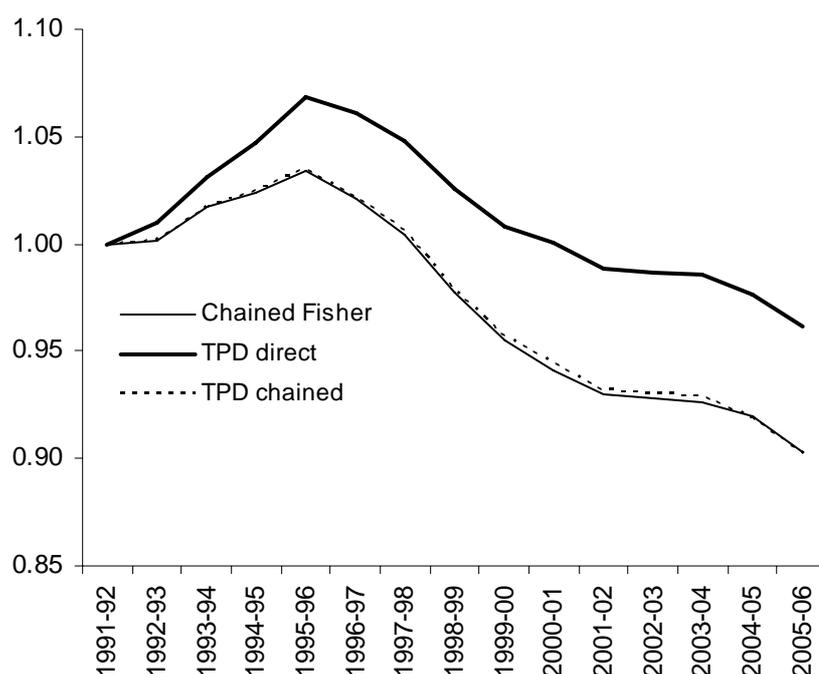


The results from the two ways of estimating the TPD indexes are depicted graphically in Figure 6.3 which also includes the chained Fisher index for comparison. Clearly there is a significant difference between the TPD index estimated with all 14 time dummies and the chained Fisher index. While the basic shape of the two price series is the same, the direct TPD index has prices rising more rapidly to the peak in 1995-

96 and with a more gradual decline thereafter resulting in an overall decline across the period of 3.8% or 0.2% per year on average.

Somewhat remarkably the chained TPD price index almost exactly reproduces the chained Fisher index. The results of regressing the chained Fisher index on the chained TPD index are given in Table 6.2 above and while the overall fit is slightly less than those for the Tornqvist, Vartia and Walsh chained indexes, the constant is closer to zero and the coefficient on the index closer to one than these other indexes.

Because the chained TPD indexes include all goods common to the two periods as well as new and disappearing goods which are excluded from the standard chained index formulae, this very close agreement among the TPD and standard indexes suggests that the exclusion of new and disappearing goods from the standard formulae has little if any effect on determining accurate price indexes for the PBS. It should be remembered that Diewert (2005b) has shown that the bilateral TPD price index calculated using just the goods common to both periods and the weights as specified in equation (5.58) results in an index that is a close approximation of the Tornqvist index. In assessing the effect of including or excluding new and disappearing goods, this means that the comparison should be between the TPD index which includes these goods and the Tornqvist index which excludes them. Again, because the difference is so small between these two indexes it is safe to assume that excluding these goods will not bias the resulting price index.

Despite this agreement however there are some features of the regression results in Tables 6.5 and 6.6 that are puzzling. While the overall fit of the equation for the index over 14 periods is very good, the significance of the coefficients varies from year to year. It can be seen that the standard error of the coefficient is relatively invariant from year to year so the significance is determined by the value of the coefficient – the closer this is to zero (ie the closer the index is to the value in the base period 1991-92) the lower the significance.

On the other hand, the adjusted $R^2$ for the individual bilateral equations varies considerably with noticeably poorer values in 1998-99 and 1999-00. However, all coefficients on the time dummy variables are insignificant because the standard errors

vary with the size of the coefficient leaving the t-statistics very similar. Part of the explanation for this is that the actual coefficients for a particular year are usually smaller than in the previous case because the price change from year to year will generally be smaller than a comparison over a number of years. In addition, for the bilateral equations the number of observations is considerably less than for the inclusive equation and the ratio of observations to explanatory variables is much less. This effects the calculation of both the goodness of fit statistics and the significance of the coefficients.

A TPD quantity index can be derived in the same manner as the TPD price index by estimating equations with the weighted log of the quantity as the dependent variable (equation 5.60 in Chapter 5). Again this can be done with all 14 time periods or bilaterally. The results of doing this are disappointing however. Both the direct and the chained bilateral quantity indexes are significantly different from the chained Fisher index (Figure 6.4). The direct version implies a growth in quantity over the period of 177% while the chained version implies a growth about twice as much – 344% which is still lower than the growth of 423% given by the chained Fisher index. It might be thought that, as the TDP price index is a close approximation to the Tornqvist price index, the disparity in the quantity index results might be due to the weakness already identified for the Tornqvist quantity index – namely that it is unduly affected by extreme values. However, as Figure 6.2 shows, the Tornqvist quantity index gives much higher values for the quantity index than the Fisher, Walsh and Vartia quantity indexes while the TPD quantity index values are significantly lower.

The results are also somewhat puzzling because, as is shown in Chapter 7, the contribution to expenditure from new items greatly exceeds the loss from the disappearing items. A quantity index such as the TPD which includes this net contribution might be expected to have a greater value than a standard index such as the Fisher index which excludes them.

**Figure 6.4    TPD and Fisher chained quantity indexes item level**
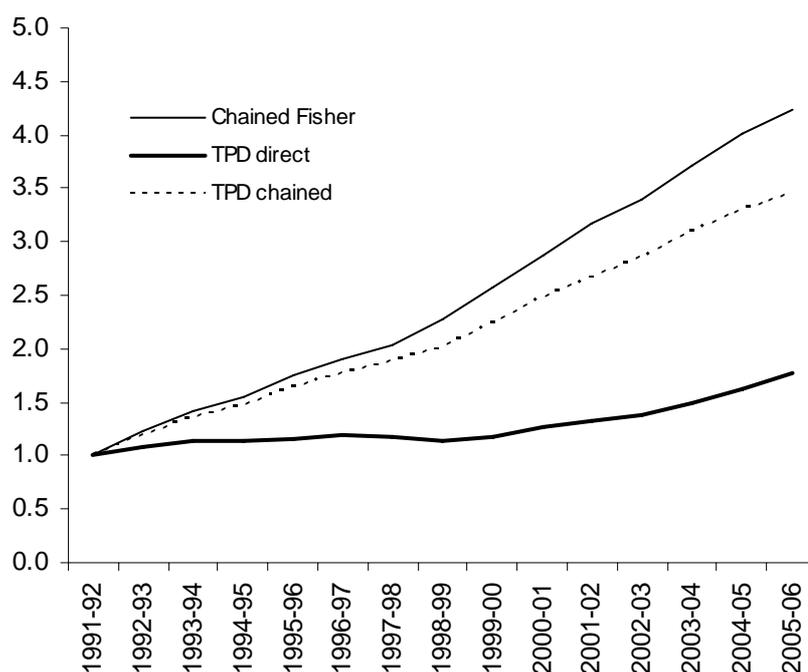


The issues raised by the results from the TPD approach suggest that its use needs to be considered carefully and seems to be best used in price index calculations rather than for quantity indexes. To use the TPD approach at the unique brand level involves some 40191 observations for 5762 product dummy variables as well as the 14 time dummy variables. Attempts to estimate TPD regressions at this level quickly produced highly implausible results probably because of the size of the matrices that are involved. This means that the number of product dummy variables at the item level probably represent about as far as it is possible to go in applying this technique at a disaggregated level while still producing reliable results.

### 6.3.3 Comparison of item level and unique brand level results

Price and quantity indexes can be calculated at the unique brand level using standard index number formulae in exactly the same way as for the item level. Doing so produces results that are very similar both in terms of how the various index number candidates perform against each other and in comparison to indexes calculated at the item level. Again the Fisher index tracks between the Laspeyres and Paasche indexes and the Fisher, Tornqvist, Walsh and Vartia indexes are virtually indistinguishable from each other. The various formulae produce very similar results at both item and

unique brand levels so only the Fisher chained indexes are shown in Table 6.7 for comparison.

**Table 6.7    Chained Fisher price and quantity indexes**

|         | Price  | Price        | Quantity | Quantity     |
|         | Item   | Unique brand | Item     | Unique brand |
|---------|--------|--------------|----------|--------------|
| 1991-92 | 1.0000 | 1.0000       | 1.0000   | 1.0000       |
| 1992-93 | 1.0011 | 1.0009       | 1.2347   | 1.2341       |
| 1993-94 | 1.0171 | 1.0168       | 1.4215   | 1.4236       |
| 1994-95 | 1.0234 | 1.0229       | 1.5548   | 1.5528       |
| 1995-96 | 1.0340 | 1.0332       | 1.7560   | 1.7595       |
| 1996-97 | 1.0211 | 1.0202       | 1.9022   | 1.9046       |
| 1997-98 | 1.0043 | 1.0036       | 2.0368   | 2.0363       |
| 1998-99 | 0.9774 | 0.9769       | 2.2742   | 2.2678       |
| 1999-00 | 0.9553 | 0.9548       | 2.5743   | 2.5783       |
| 2000-01 | 0.9414 | 0.9423       | 2.8681   | 2.9290       |
| 2001-02 | 0.9295 | 0.9302       | 3.1723   | 3.2274       |
| 2002-03 | 0.9279 | 0.9286       | 3.3999   | 3.4485       |
| 2003-04 | 0.9267 | 0.9272       | 3.7111   | 3.7522       |
| 2004-05 | 0.9193 | 0.9202       | 4.0158   | 4.0286       |
| 2005-06 | 0.9026 | 0.9042       | 4.2293   | 4.1997       |

In Chapter 5, the problem raised by Griliches and Cockburn (1994) in the calculation of pharmaceutical price indexes was discussed. This concerned how the introduction and continuing presence of different brands of the same medicine with different prices should best be handled. They differentiate between a view that (i) all brands should be treated as the same and that the price for a medicine entering a price index formula should be the weighted average of all the brands of the same form and strength of the one medicine, and a view (ii) that consumers will value different brands differently and hence individual brands should enter the formula as distinct goods.

Calculating PBS price indexes at the unique brand level where each brand is considered as a separate good and at the item level where the price is the average of all the brands enables the importance of the Griliches and Cockburn effect to be evaluated. It is clear from the results in Table 6.7 that there is virtually no difference in outcome between indexes calculated at the two levels and therefore no bias arising from shift in market shares among brands. In this case the "objective" index is the same as the "subjective" index and it is safe to assume that indexes calculated at the item level are unbiased at least in terms of shifting market shares of brands.

This suggests that it makes no difference when decomposing PBS expenditure whether the analysis is done at the unique brand level or at the item level. The results also mean that substitution among different brands of the same medicine can be ignored in this analysis. In Chapter 4 it was shown that the premiums were only charged by some suppliers for a minority of PBS items and even then the premium over the base price was small and relatively constant over time. It should be emphasized that the results quoted to date in this chapter are all based on a derived price approach and this way of defining prices necessarily means that item level prices are weighted averages of prices of brands, so that full weight is given to premiums in constructing these averages.

### 6.3.4 Bortkiewicz decomposition of Paasche/Laspeyres ratio

A comparison of the Laspeyres and Paasche indexes calculated at the item level (Table 6.1) shows that the disparity between them is not great. Both follow similar courses over time and the overall falls in prices implied by the chained indexes – 9.5% and 10.9% respectively – do not differ by a large amount.

The description of the two indexes in Chapter 5 suggested that the Laspeyres index will overstate the extent of any price change while the Paasche indexes will understate the effect. This is because both ignore any change in the relative quantity of goods consumed arising from a change in their relative prices. The Bortkiewicz decomposition of the ratio of the Paasche to Laspeyres index sheds some light on the extent to which this occurs and the reasons for it and is reproduced below

$$\frac{P_P^t}{P_L^t} = 1 + r.\frac{\sigma_p}{P_L^t} \cdot \frac{\sigma_q}{Q_L^t}$$

where $P_P^t$, $P_L^t$, $Q_L^t$ are the Paasche and Laspeyres price indexes and the Laspeyres quantity index respectively, $r$ is the base period weighted correlation coefficient between the price and quantity relatives and $\sigma_p$, $\sigma_q$ are the base period weighted standard deviations of the price and quantity relatives.

The decomposition is shown in Table 6.8 for indexes calculated at the item level using the derived price approach. The first two columns are the biltaeral Laspeyres and Paasche price indexes, the third column is the Paasche/Laspeyres ratio (P/L) and the

next two show the coefficients of variation (CV) for the price and quantity relatives. The last column is the correlation coefficient.

**Table 6.8     Bortkiewicz decomposition of Paasche/Laspeyres ratio**

|          | Laspeyres | Paasche | P/L    | CV prices | CV quantities | Correlation coefficient |
|----------|-----------|---------|--------|-----------|---------------|-------------------------|
| 1992-93  | 1.0043    | 0.9979  | 0.9936 | 0.0687    | 7.7264        | -0.0148                 |
| 1993-94  | 1.0186    | 1.0134  | 0.9949 | 0.0631    | 2.9508        | -0.0310                 |
| 1994-95  | 1.0077    | 1.0048  | 0.9970 | 0.0490    | 0.5459        | -0.1176                 |
| 1995-96  | 1.0124    | 1.0083  | 0.9959 | 0.0598    | 1.8841        | -0.0393                 |
| 1996-97  | 0.9898    | 0.9853  | 0.9955 | 0.0762    | 0.5853        | -0.1067                 |
| 1997-98  | 0.9846    | 0.9824  | 0.9978 | 0.0547    | 0.7037        | -0.0594                 |
| 1998-99  | 0.9722    | 0.9743  | 1.0023 | 0.0714    | 2.0722        | 0.0172                  |
| 1999-00  | 0.9759    | 0.9787  | 1.0029 | 0.0662    | 1.0067        | 0.0506                  |
| 2000-01  | 0.9849    | 0.9862  | 1.0013 | 0.0449    | 1.2817        | 0.0273                  |
| 2001-02  | 0.9913    | 0.9833  | 0.9920 | 0.0682    | 1.3436        | -0.1035                 |
| 2002-03  | 0.9985    | 0.9980  | 0.9995 | 0.0324    | 0.5641        | -0.0336                 |
| 2003-04  | 0.9989    | 0.9985  | 0.9996 | 0.0308    | 0.5797        | -0.0247                 |
| 2004-05  | 0.9921    | 0.9920  | 0.9998 | 0.0386    | 2.1586        | -0.0021                 |
| 2005-06  | 0.9813    | 0.9824  | 1.0011 | 0.0542    | 0.6331        | 0.0385                  |

The ratio of the two indexes is very close to 1 in all years the largest difference being 0.008 in 2001-02. By itself this is a strong indication that there is little if any relationship between the price and quantity relatives and this is confirmed by the size of the correlation coefficient. The absolute value of this only manages to rise above 0.1 in three years and the relationship can be characterised as very weak or non-existent. The coefficients of variation for the price relatives are very small indicating that the movements in PBS medicine prices are very similar from year to year. This is not particularly surprising because in most circumstances prices remain unchanged for the majority of items. Reference pricing will also ensure that where there are price changes these will tend to be of a similar magnitude. The quantity relatives display a greater degree of variation and the size of this varies significantly from year to year. This reflects the heterogeneity in demand for medicines as their market shares change as new medicines enter and new therapeutic markets develop.

The very weak relationship between price and quantity relatives is also to be expected because patients are not exposed to the price series being used – the dispensed price – so this will not influence the quantity of medicines consumed. The demand by patients for medicines is more likely to be influenced by the copayment plus any premium and this relationship is explored in Chapters 7 and 8.

## 6.4 Comparison of derived price and derived quantity approaches

The results reported in Section 6.3 are all based on the derived price (DP) approach which uses, as the quantity measure for each observation, the number of scripts multiplied by the maximum quantity. PBS expenditure is then divided by this quantity to derive the price as a unit value. The alternative is the derived quantity (DQ) approach which uses the quoted PBS price per unit and derives the quantity by dividing PBS expenditure by this price. It is important however to recall when considering the results given below that the PBS prices used in the indexes are annual averages of monthly prices. Further the item level prices are then defined in two ways – as simple unweighted averages of the brand prices within an item and as weighted averages where the brand prices are weighted by their expenditure.

Price and quantity indexes estimated using the derived quantity approach produce very similar results to those from the derived price approach. The various candidate formulae perform in a similar manner with the Fisher, Tornqvist, Walsh and Vartia indexes being highly correlated, except for the Tornqvist quantity index which diverges in the same way as for the derived price approach. Because of this similarity, the discussion from this point on will concentrate solely on the Fisher index.

Despite the similarities however there are some differences between the two approaches for indexes calculated at the unique brand or item levels. The tight agreement between the price indexes at the two levels using the derived price approach becomes significantly looser under the derived quantity approach. At the item level, Table 6.9 compares the chained Fisher price and quantity indexes calculated using the derived price approach and the two variants of the derived quantity approach. Table 6.10 provides the same comparisons at the unique brand level.

**Table 6.9    Index comparison, derived price and derived quantity, item level**

|  | Price index | | | Quantity index | | |
|---|---|---|---|---|---|---|
|  | **DP** | **Unweighted DQ** | **Weighted DQ** | **DP** | **Unweighted DQ** | **Weighted DQ** |
| 1991-92 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 |
| 1992-93 | 1.0011 | 1.0125 | 1.0148 | 1.2347 | 1.2417 | 1.2185 |
| 1993-94 | 1.0171 | 1.0324 | 1.0360 | 1.4215 | 1.4252 | 1.3961 |
| 1994-95 | 1.0234 | 1.0349 | 1.0393 | 1.5548 | 1.5647 | 1.5316 |
| 1995-96 | 1.0340 | 1.0385 | 1.0441 | 1.7560 | 1.7795 | 1.7397 |
| 1996-97 | 1.0211 | 1.0222 | 1.0287 | 1.9022 | 1.9338 | 1.8888 |
| 1997-98 | 1.0043 | 1.0055 | 1.0118 | 2.0368 | 2.0703 | 2.0464 |
| 1998-99 | 0.9774 | 0.9850 | 0.9918 | 2.2742 | 2.2967 | 2.2432 |
| 1999-00 | 0.9553 | 0.9569 | 0.9643 | 2.5743 | 2.6153 | 2.5522 |
| 2000-01 | 0.9414 | 0.9434 | 0.9509 | 2.8681 | 2.9127 | 2.8416 |
| 2001-02 | 0.9295 | 0.9304 | 0.9378 | 3.1723 | 3.2252 | 3.1468 |
| 2002-03 | 0.9279 | 0.9274 | 0.9349 | 3.3999 | 3.4622 | 3.3770 |
| 2003-04 | 0.9267 | 0.9255 | 0.9330 | 3.7111 | 3.7816 | 3.6888 |
| 2004-05 | 0.9193 | 0.9168 | 0.9244 | 4.0158 | 4.1005 | 3.9968 |
| 2005-06 | 0.9026 | 0.8969 | 0.9041 | 4.2293 | 4.3357 | 4.2258 |

**Table 6.10   Index comparison, derived price and derived quantity, unique brand level**

|  | Price index | | Quantity index | |
|---|---|---|---|---|
|  | **DP** | **DQ** | **DP** | **DQ** |
| 1991-92 | 1.0000 | 1.0000 | 1.0000 | 1.0000 |
| 1992-93 | 1.0009 | 1.0150 | 1.2341 | 1.2170 |
| 1993-94 | 1.0168 | 1.0364 | 1.4236 | 1.3967 |
| 1994-95 | 1.0229 | 1.0403 | 1.5528 | 1.5269 |
| 1995-96 | 1.0332 | 1.0459 | 1.7595 | 1.7381 |
| 1996-97 | 1.0202 | 1.0319 | 1.9046 | 1.8830 |
| 1997-98 | 1.0036 | 1.0171 | 2.0363 | 2.0093 |
| 1998-99 | 0.9769 | 0.9979 | 2.2678 | 2.2200 |
| 1999-00 | 0.9548 | 0.9712 | 2.5783 | 2.5346 |
| 2000-01 | 0.9423 | 0.9596 | 2.9290 | 2.8761 |
| 2001-02 | 0.9302 | 0.9481 | 3.2274 | 3.1664 |
| 2002-03 | 0.9286 | 0.9466 | 3.4485 | 3.3828 |
| 2003-04 | 0.9272 | 0.9464 | 3.7522 | 3.6762 |
| 2004-05 | 0.9202 | 0.9389 | 4.0286 | 3.9481 |
| 2005-06 | 0.9042 | 0.9202 | 4.1997 | 4.1267 |

When calculated at the item level the Fisher price indexes are still quite similar in their profile over the 15 year period (Figure 6.5) and show close agreement about the actual change over this time – falls of 9.7%, 9.6% and 10.3% respectively for the derived price and weighted and unweighted derived quantity approaches.

**Figure 6.5    Fisher price index, derived price and quantity, item level**
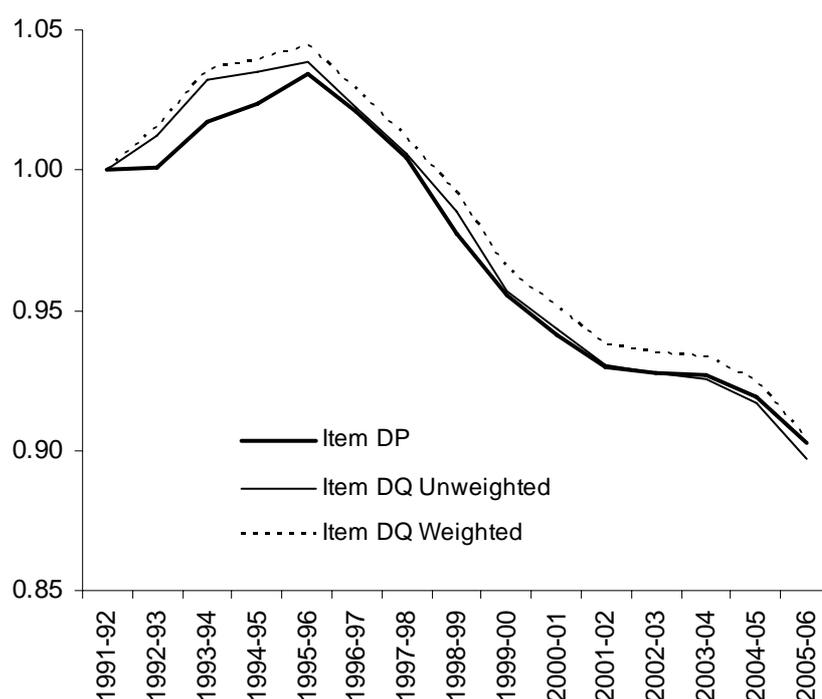


Each index reaches a maximum in 1995-96 and falls steadily thereafter. However the indexes from the derived quantity approach shows significantly larger increases in the first few years before converging to the derived price index from 1995-96 onwards. The unweighted version converges more rapidly. Quantity indexes calculated using the two approaches also show similar outcomes with increases of 323%, 323% and 334% respectively.

The same comparison when indexes are calculated at the unique brand level however shows a greater divergence with the price index from the derived quantity approach being consistently higher than the one from the derived price approach. Here the change over the 15 years is -9.6% versus -8.0%. As with the item level results, the divergence is higher in the early years of the period. The paths after 1995-96 are much closer than suggested in Figure 6.6. In contrast to the price indexes, the quantity indexes are quite similar showing increases of 320% and 313%.

One reason for the difference in results between the two approaches may lie in the way the average prices are calculated in the derived quantity approach. At the unique brand level the average is an unweighted average of monthly prices. As all periods show significant growth in quantity and most show declining prices, an unweighted

average will give equal weight to prices in the first half and the last half of the year. An average formed by weighting each month's price by its expenditure would usually give a little more weight to prices in the second half of the year than the first half, these prices in the second half being on average lower than the first half. The weighted price would on average be lower than the unweighted price. Because monthly expenditure data was not available, only unweighted average prices could be used in the index calculations.

**Figure 6.6    Fisher price index, derived price and quantity, unique brand level**
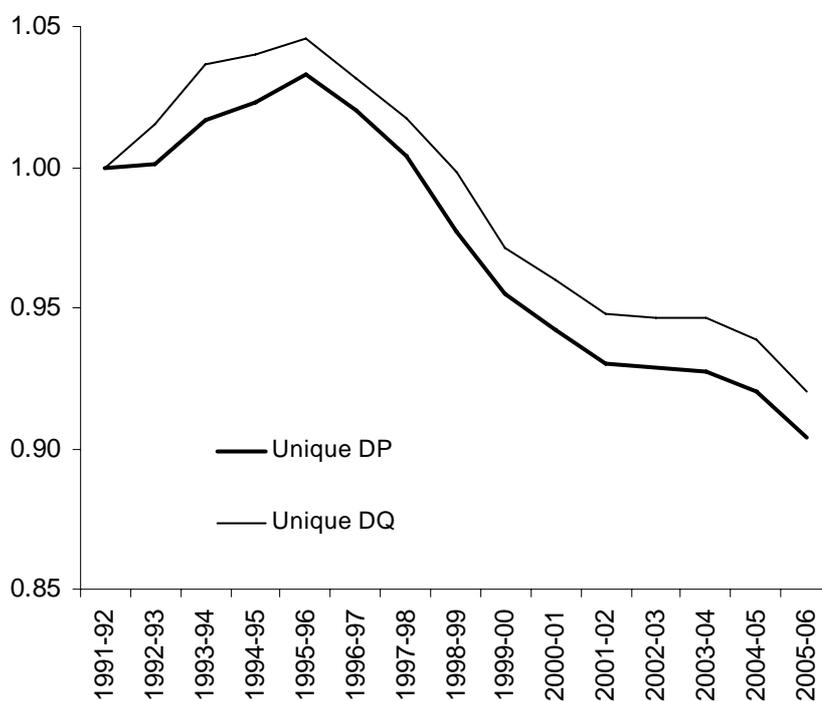


Unfortunately this does not explain why the unweighted derived quantity index at the item level is closer to the derived price index than its weighted equivalent (Figure 6.5). Nor does it explain the greater divergence at the unique brand level than at the item level (Figure 6.6).

It was noted in the previous section that the lack of any significant difference between the DP price index calculated at the unique brand and item levels was a strong argument for the absence of the Griliches-Cockburn bias arising from shifts in market shares of brands within PBS items. With the DQ approach on the other hand there is a distinct difference between price indexes at the two levels of aggregation as illustrated in Figure 6.7.

**Figure 6.7    Fisher price index, derived quantity, unique brand and item levels**
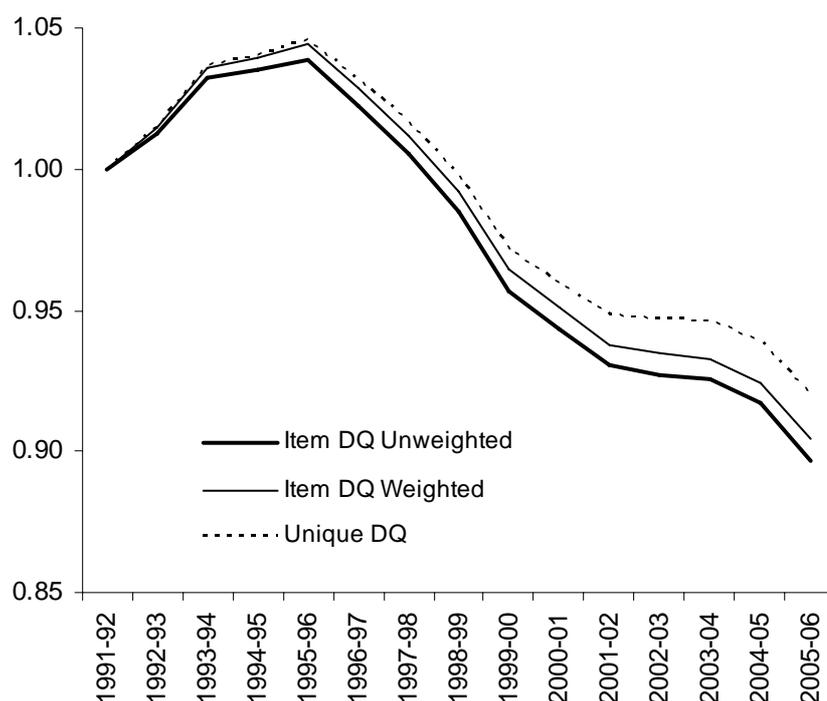


This may provide some support for the presence of a bias because the index which uses prices that are averages of brands falls more sharply than one that treats all brands as distinct goods. It might be remembered in this context that the item level index is the "objective" index and that the two indexes calculated in this way form upper and lower bounds for the "subjective" index as proposed by Griliches and Cockburn. If this lies half way between the two it reduces the difference between the "subjective" index and either of the two Fisher indexes by half.

Over the 15 year period the total price decline is 9.6% and 10.0% for the weighted and unweighted item level indexes (ie the "objective" indexes) and 8.0% for the unique brand level index, so the decline in the "subjective" index might be around 9% using this argument.

The "objective" or item level view has the advantage that indexes are very similar whether calculated using the derived price or derived quantity approach and the derived price method is easier to use. Whichever view is preferred however it can be seen from the results presented above, that the item level index is an acceptable approximation to a "subjective" index.

While there is no clearcut argument favouring the derived price approach above the derived quantity approach or for preferring indexes calculated at the unique brand or item level, in practice the absolute differences are minor in drawing conclusions about the course of prices and quantities within the PBS. For reasons of ease of use therefore, the bulk of the analysis in subsequent chapters relies on chained Fisher price and quantity indexes calculated at the item level using the derived price approach. The chief exception is the discussion of prices and retail and wholesale level where the only data available necessitates the use of the derived quantity approach.

## 6.5 Different levels of aggregation

While the price indexes at the unique brand and item levels are very similar and therefore indicate that any bias arising from shifts in markets shares of brands is very small and can be safely ignored, this is does not mean that there is no bias arising from shifts in market shares among different strengths and forms of the same medicine, or among similar medicines, or from medicines of one generation to another.

The discussion in Chapter 5 however highlights the real difficulties in forming the "objective" index at progressively higher levels of aggregation so that the extent of any bias at each stage can be assessed. As argued there, the problem is finding the right factors to use to adjust the quantity data for differences in quality. The need to make this adjustment is important when the aggregation is of similar medicines and much more so when aggregating different generations of medicines. In these circumstances it is not possible to rely on defined daily doses (DDD) as the sole adjustment factor.

The Fisher price indexes estimated at different levels of aggregation in Table 6.11 do not include any adjustment for quality differences and must be assessed with this in mind. All the indexes use data defined by the derived price approach. Indexes are estimated at the unique brand, item, molecule/ATC, ATC5 and ATC4 levels. Figure 6.8 provides a graphical comparison. As already noted there is virtually no difference between price indexes at the unique brand and item levels, so only the item level index is shown in Figure 6.8.

**Table 6.11　Fisher price indexes by level of aggregation**

|  | Unique brand | Item | MolATC Prop | MolATC DDD | ATC5 | ATC4 | All PBS |
|---|---|---|---|---|---|---|---|
| 1991-92 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 |
| 1992-93 | 1.0009 | 1.0011 | 1.0074 | 1.0050 | 0.9930 | 1.0032 | 0.9366 |
| 1993-94 | 1.0168 | 1.0171 | 1.0232 | 1.0186 | 1.0139 | 1.0475 | 1.0105 |
| 1994-95 | 1.0229 | 1.0234 | 1.0292 | 1.0240 | 1.0291 | 1.0859 | 1.1098 |
| 1995-96 | 1.0332 | 1.0340 | 1.0371 | 1.0299 | 1.0400 | 1.1265 | 1.1861 |
| 1996-97 | 1.0202 | 1.0211 | 1.0238 | 1.0151 | 1.0345 | 1.1366 | 1.2848 |
| 1997-98 | 1.0036 | 1.0043 | 1.0002 | 0.9904 | 1.0149 | 1.1438 | 1.4957 |
| 1998-99 | 0.9769 | 0.9774 | 0.9660 | 0.9550 | 0.9750 | 1.1272 | 1.5405 |
| 1999-00 | 0.9548 | 0.9553 | 0.9301 | 0.9174 | 0.9415 | 1.1127 | 1.5633 |
| 2000-01 | 0.9423 | 0.9414 | 0.9053 | 0.8923 | 0.9204 | 1.1507 | 1.7070 |
| 2001-02 | 0.9302 | 0.9295 | 0.8869 | 0.8731 | 0.9046 | 1.1798 | 1.8001 |
| 2002-03 | 0.9286 | 0.9279 | 0.8810 | 0.8675 | 0.8994 | 1.2042 | 1.9336 |
| 2003-04 | 0.9272 | 0.9267 | 0.8735 | 0.8606 | 0.8995 | 1.2272 | 2.0466 |
| 2004-05 | 0.9202 | 0.9193 | 0.8610 | 0.8470 | 0.8900 | 1.2310 | 2.0895 |
| 2005-06 | 0.9042 | 0.9026 | 0.8406 | 0.8262 | 0.8729 | 1.2275 | 2.1220 |

**Figure 6.8　Fisher price indexes by level of aggregation**
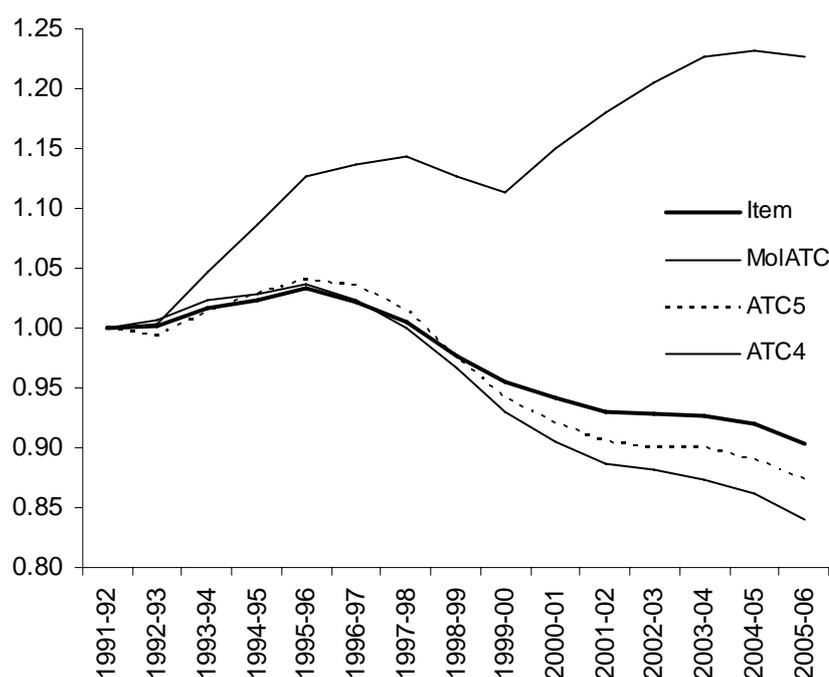


The index at the molecule/ATC level shows the steepest decline in prices suggesting that if there is a systematic shift from lower strengths to higher strengths this does lead to lower prices because higher strengths have a lower price per unit of medicine. As described in Section 6.2.2 above, aggregating to this level by weighting the different strengths pro rata can be done for all except 8 molecule/ATC combinations, so there is little data lost when moving from the item level to the molecule/ATC level. The molecule/ATC index therefore can stand as the "objective" index against the item

level index, as long as it is accepted that there is no additional quality difference among strengths except for the amount of active ingredient present. The implied reduction in prices from the molecule/ATC index over the 15 year period is 16% versus about 10% for the item level index.

In Table 6.11 two versions are given for the molecule/ATC level – for the first of these (Prop) the aggregation is as described above, namely pro rata aggregation of strength. The second version uses DDDs as the basis for aggregation resulting in many more observations being omitted. It is included to provide a comparison for indexes at the ATC5 and ATC4 level which are aggregated using DDDs. As can be seen, the two versions are quite close with the second implying a 17% decrease in prices over the period.

Further aggregation to the ATC5 level, as a proxy for medicines with similar chemical composition for treating the same disease, results in an "objective" index that lies midway between the molecule/ATC and item level indexes. Taken at face value this implies that compared to the item level index a shift in market shares among these similar medicines results in lower prices and a shift downward in the price index. The effect is not as great as the lower prices resulting from a shift among strengths however.

Within the PBS, 71 of the 110 Reference Pricing Groups (RPG) consist solely of medicines belonging to the same ATC5 code, 39 have medicines drawn from more than one ATC5 code, 18 have medicines from more than one ATC4 code and 8 have medicines have medicines drawn from more than one ATC3 code.

Because prices of medicines within an RPG change in the same proportions, aggregating medicines to the ATC5 level in most cases involves adding together medicines that are still relatively homogeneous in terms of their quality as assessed by the PBAC. The absence of a quality adjustment factor in the aggregation to this level may not imply too much distortion in the index, and hence may be acceptable as the "objective" index at this level. Nonetheless it should be remembered that only about 65% of PBS expenditure is accounted for by medicines within RPGs, the rest being

stand-alone medicines with prices not set with reference to another PBS medicine once the initial price has been determined.

Aggregating further to the ATC4 level produces an "objective" index which is very different to any of the others. It shows broadly rising prices with an implied increase in prices of 23% over the period in contrast to the decreases suggested by the other indexes. It is difficult here to determine how much of the difference between the ATC4 level index and the others is due to a genuine shift in price among medicines of different generations for treating the same disease or how much reflects the absence of the quality adjustment to the data that is necessary for an acceptable aggregation.

However an index calculated at this level may be considered unreliable because of the conceptual and practical difficulties of aggregating data and adjusting for quality differences among medicines. This quality difference becomes particularly acute at the ATC4 level. At the ATC5 level many of the medicines being aggregated are within the same RPG while at the ATC4 level different RPGs are being aggregated. The further examination of indexes at the ATC level might best be undertaken by case studies of particular pharmaceutical markets properly defined and by the use of appropriate quality adjustment factors.

# Chapter 7

## Decomposition of PBS Expenditure

### 7.1 Introduction

This chapter looks at the decomposition of PBS expenditure from a number of perspectives. Firstly it explores for each year, the contribution to PBS expenditure growth from three sources – the entry of new medicines, the change in prices of medicines already listed and the change in the quantity of these medicines consumed by patients. In doing this it illustrates the different ways in which indexes and indicators can be used to determine the relative importance of these three sources of growth. The rules governing the determination of wholesale and retail prices within the PBS might be expected to produce different outcomes for participants in the supply chain at three different levels – pharmacists, wholesalers, and manufacturers. These outcomes are described by using price indexes calculated appropriately for each participant. Similarly the policies governing how much of the dispensed price is paid for by the patient and the Government will produce different outcomes for each. Different levels and changes in copayments and safety net levels for general and concessional patients will affect them in different ways and the outcomes for the Government will also differ according to patient category.

The breakdown of the analysis among these different participants can quickly lead to confusion so it should be borne in mind that the while the prices faced by wholesalers, manufacturers and pharmacists may be different the quantities used in the calculation of these price indexes are the same for each participant, reflecting the volume of medicines flowing through the supply chain. Similarly, when price indexes are calculated for the patient and the Government for a particular type of patient, the quantities used are just the amount consumed by that type of patient.

### 7.2 Prices, quantities and new goods

This section presents the decomposition of the change in PBS expenditure from one year to the next into its major components: (i) the contribution from new and

disappearing goods and (ii) the contribution from PBS medicines common to each year. The change in expenditure due to common medicines is further broken down into the change due to prices and the change due to the quantity of medicines consumed by patients. All the analysis in this chapter is based on PBS price and quantity data defined at the item level using the derived price approach except where noted.

Table 7.1 shows in the first two columns the actual annual expenditure on PBS medicines from 1991-92 to 2005-06. The first column has the value for the current year while the second has the value for the base year, ie the previous year.

**Table 7.1    Importance of new and disappearing items in PBS expenditure**

|         | Total current | Total base | Common current | Common base | New | Dis-appearing | New | Dis-appearing |
|---------|---------|---------|---------|---------|---------|---------|---------|---------|
|         | $m | $m | $m | $m | $m | $m | % | % |
| 1991-92 | 1,429.9 | | | | | | | |
| 1992-93 | 1,809.5 | 1,429.9 | 1,756.4 | 1,421.0 | 53.1 | 8.9 | 2.9 | 0.6 |
| 1993-94 | 2,137.5 | 1,809.5 | 2,108.2 | 1,802.4 | 29.2 | 7.1 | 1.4 | 0.4 |
| 1994-95 | 2,403.4 | 2,137.5 | 2,349.0 | 2,134.3 | 54.4 | 3.2 | 2.3 | 0.1 |
| 1995-96 | 2,765.3 | 2,403.4 | 2,732.3 | 2,394.3 | 33.1 | 9.1 | 1.2 | 0.4 |
| 1996-97 | 3,016.9 | 2,765.3 | 2,927.7 | 2,736.9 | 89.2 | 28.5 | 3.0 | 1.0 |
| 1997-98 | 3,288.1 | 3,016.9 | 3,157.9 | 2,998.5 | 130.2 | 18.3 | 4.0 | 0.6 |
| 1998-99 | 3,603.4 | 3,288.1 | 3,561.9 | 3,277.8 | 41.5 | 10.3 | 1.2 | 0.3 |
| 1999-00 | 4,083.9 | 3,603.4 | 3,938.8 | 3,560.5 | 145.1 | 42.9 | 3.6 | 1.2 |
| 2000-01 | 4,827.3 | 4,083.9 | 4,452.7 | 4,055.2 | 374.6 | 28.6 | 7.8 | 0.7 |
| 2001-02 | 5,305.7 | 4,827.3 | 5,246.7 | 4,804.4 | 59.0 | 23.0 | 1.1 | 0.5 |
| 2002-03 | 5,795.8 | 5,305.7 | 5,658.8 | 5,289.1 | 137.0 | 16.6 | 2.4 | 0.3 |
| 2003-04 | 6,381.6 | 5,795.8 | 6,298.7 | 5,778.1 | 82.9 | 17.6 | 1.3 | 0.3 |
| 2004-05 | 6,879.2 | 6,381.6 | 6,822.3 | 6,355.1 | 56.9 | 26.5 | 0.8 | 0.4 |
| 2005-06 | 7,129.0 | 6,879.2 | 7,042.9 | 6,811.1 | 86.1 | 68.1 | 1.2 | 1.0 |

As the standard index number formulae use the goods that are common to both years and exclude new and disappearing goods, the value of those items in common for the adjacent pairs of current and base years are shown in the next two columns. The values of the new and disappearing goods excluded from the index calculated for that year are given in the next two columns. The relative importance of the excluded new items is shown as a percentage of the value of the current year and the importance of the disappearing items as a percentage of the base year. It should be emphasized for new goods however that what is being measured here is their contribution to change in their first year of introduction. They will continue to influence expenditure

outcomes in subsequent years but will do so through their contribution to the price and quantity indexes.

To illustrate the contributions from new, disappearing and common goods, consider the values used to calculate indexes for 2005-06. The values used are those for the current year 2005-06 and the base year 2004-05 and total PBS expenditure in each of these years was $7,129.0 million and $6,879.2 million respectively. Items to the value of $86.1 million were newly listed in 2005-06 while items worth $68.1 million were present in 2004-05 but had disappeared by 2005-06. Subtracting these excluded items gives the value of items common to both years as $7,042.9 million in 2005-06 ($7,129.0 million minus $86.1 million) and $6,811.1 million in 2004-05 ($6,879.2 million minus $68.1 million). The value of the new items in 2005-06 was 1.2% of total expenditure in that year while the disappearing items were worth 1.0% of PBS expenditure in 2004-05.

Table 7.2 shows the same breakdown expressed in terms of the number of items rather than their value. There were 2,174 items in 2005-06 and 2,098 in 2004-05 of which 1,978 were common to both years. There were 196 new items in 2005-06 and 120 disappearing items in 2004-05.

**Table 7.2    Importance of new and disappearing items by number of items**

|  | Total current | Total base | Common | New | Dis-appearing | New | Dis-appearing |
|---|---|---|---|---|---|---|---|
|  | No. | No. | No. | No. | No. | % | % |
| 1991-92 | 1295 |  |  |  |  |  |  |
| 1992-93 | 1324 | 1295 | 1228 | 96 | 67 | 7.3 | 5.2 |
| 1993-94 | 1359 | 1324 | 1284 | 75 | 40 | 5.5 | 3.0 |
| 1994-95 | 1512 | 1359 | 1311 | 201 | 48 | 13.3 | 3.5 |
| 1995-96 | 1551 | 1512 | 1445 | 106 | 67 | 6.8 | 4.4 |
| 1996-97 | 1582 | 1551 | 1460 | 122 | 91 | 7.7 | 5.9 |
| 1997-98 | 1675 | 1582 | 1499 | 176 | 83 | 10.5 | 5.2 |
| 1998-99 | 1697 | 1675 | 1606 | 91 | 69 | 5.4 | 4.1 |
| 1999-00 | 1759 | 1697 | 1626 | 133 | 71 | 7.6 | 4.2 |
| 2000-01 | 1823 | 1759 | 1695 | 128 | 64 | 7.0 | 3.6 |
| 2001-02 | 1938 | 1823 | 1751 | 187 | 72 | 9.6 | 3.9 |
| 2002-03 | 1935 | 1938 | 1833 | 102 | 105 | 5.3 | 5.4 |
| 2003-04 | 2057 | 1935 | 1835 | 222 | 100 | 10.8 | 5.2 |
| 2004-05 | 2098 | 2057 | 1971 | 127 | 86 | 6.1 | 4.2 |
| 2005-06 | 2174 | 2098 | 1978 | 196 | 120 | 9.0 | 5.7 |

The values for new and disappearing items represent their contributions to change in PBS expenditure, being positive and negative respectively. Between 2004-05 and 2005-06 for instance, total PBS expenditure increased by $249.8 million comprising contributions from common items of $231.8 million, from new items of $86.1 million, and from disappearing items of -$68.1 million.

The importance of the new and disappearing items varies significantly from year to year in both absolute and relative terms. As might be expected, the contribution of new items to PBS expenditure usually far outweighs the reduction due to the disappearance of items. The biggest contribution from new items was $374.6 million in 2000-01 or 7.8% of the value in that year but, on average, new and disappearing items are only about 2.4% and 0.6% of current and base year values.

The picture is somewhat different when the comparisons are expressed in terms of the actual number of items, rather than their values. Here the numbers of new and disappearing items are much closer and they account for a higher proportion of the total number of items in a particular year - on average about 8.0% and 4.5% of current and base year items. They are a smaller proportion of total value because, as was seen in Chapter 4, sales for new items are usually small in their first year while disappearing items might also be expected to have low sales in their last year of listing.

While the value of items excluded from the index calculations is small in value terms, they nonetheless represent a significant loss in the number of observations. In calculating the index for 2005-06 some 1978 observations were used while 316 potential observations were excluded, a ratio of 16.0%. However, the results quoted in Chapter 6 comparing price indexes calculated using the standard formulae and the TPD method suggest that the exclusion of these observations has little effect on the value of a price index, although there is a significant difference for quantity indexes.

Carrying out these same kinds of comparisons with indexes calculated at the unique brand level reveal a greater importance both in value and in numbers for new and disappearing brands Proportionally more observations are excluded and on average new and disappearing brands are about 2.8% and 0.9% of current and base year

values. This is to be expected as new brands are listed more frequently than are new items and they disappear at a greater rate as well. Indexes calculated at the item level therefore avoid more of the new and disappearing goods problem than do indexes calculated at the more disaggregated unique brand level.

The contributions to PBS expenditure from new and disappearing items can be combined with the chained Fisher price and quantity indexes to give an accounting of the relative importance of all factors to growth. In Table 7.3, the first column is the annual rate of growth in total PBS expenditure (column 1 in Table 7.1) expressed as a percentage. The second column is the rate of growth of the expenditure for items common to adjacent years, ie the percentage difference between the current and base columns in Table 7.1. The difference between these is the implied growth contribution from net new items. For most years this contribution is small although in 2000-01 it rivals that from arising from increased demand for items common to both years. On average the contribution of net new items is 2.1% compared to the growth in expenditure of 12.3%.

**Table 7.3    Contributions to PBS expenditure growth, %**

|         | Total | Common | Net new | Fisher price index | Fisher quantity index |
|---------|-------|--------|---------|--------------------|-----------------------|
| 1992-93 | 26.5  | 23.6   | 2.9     | 0.1                | 23.5                  |
| 1993-94 | 18.1  | 17.0   | 1.2     | 1.6                | 15.1                  |
| 1994-95 | 12.4  | 10.1   | 2.4     | 0.6                | 9.4                   |
| 1995-96 | 15.1  | 14.1   | 0.9     | 1.0                | 12.9                  |
| 1996-97 | 9.1   | 7.0    | 2.1     | -1.2               | 8.3                   |
| 1997-98 | 9.0   | 5.3    | 3.7     | -1.6               | 7.1                   |
| 1998-99 | 9.6   | 8.7    | 0.9     | -2.7               | 11.7                  |
| 1999-00 | 13.3  | 10.6   | 2.7     | -2.3               | 13.2                  |
| 2000-01 | 18.2  | 9.8    | 8.4     | -1.4               | 11.4                  |
| 2001-02 | 9.9   | 9.2    | 0.7     | -1.3               | 10.6                  |
| 2002-03 | 9.2   | 7.0    | 2.2     | -0.2               | 7.2                   |
| 2003-04 | 10.1  | 9.0    | 1.1     | -0.1               | 9.2                   |
| 2004-05 | 7.8   | 7.4    | 0.4     | -0.8               | 8.2                   |
| 2005-06 | 3.6   | 3.4    | 0.2     | -1.8               | 5.3                   |
|         |       |        |         |                    |                       |
| Average | 12.3  | 10.2   | 2.1     | -0.7               | 10.9                  |

The annual percentage change in prices and quantities implied by the direct bilateral Fisher indexes are given in the next two columns of Table 7.3. Inspection of these values and a comparison to the percentage change in the value of common items

shows that adding the percentage changes of prices and quantities does not reproduce this percentage change exactly. While the ratio of the current to base value of the common items is exactly equal to the sum of the price and quantity indexes, the percentage change is given by the sum of the percentage changes in these indexes plus their product. In most cases this last term is quite small so the percentage changes implied by the price and quantity indexes give a reasonably good picture of their contributions to growth. On average over the 15 year period, the change in prices deducted 0.7% per year from PBS expenditure while increase in quantity consumed added 10.9%, for a net increase due to common medicines of 10.2% or about five times the contribution from net new items.

The growth in PBS expenditure is depicted graphically in Figure 7.1 where it is presented as an index with 1991-92 = 1.000.

**Figure 7.1    PBS expenditure, price and quantity indexes**
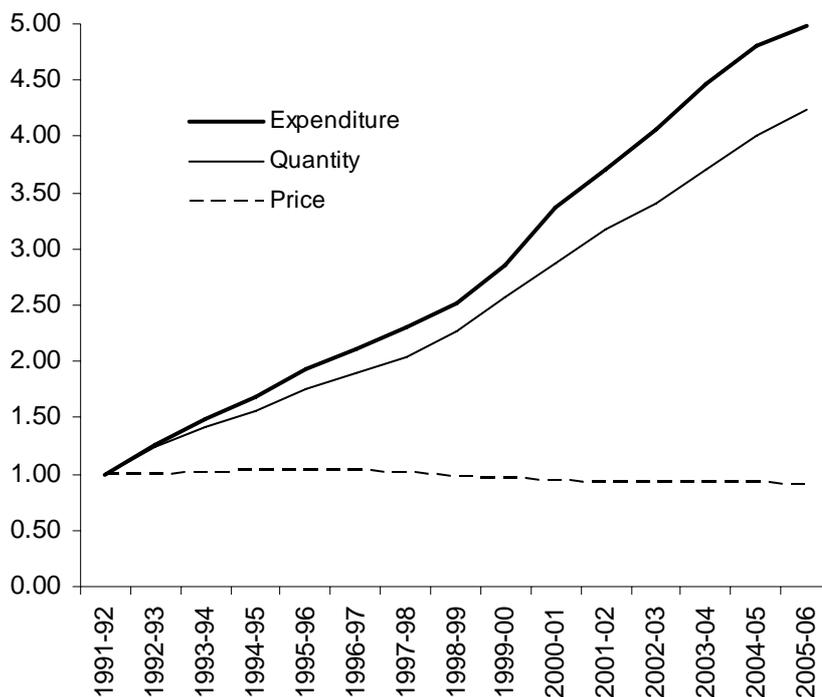


Expenditure in 2005-06 was almost exactly five times higher than in 1991-92. Because prices changed only slightly over this period, the increase in expenditure can be accounted for almost exclusively by the strong rate of growth for demand for PBS medicines and the expansion of choice as new medicines are added and new therapeutic markets are opened. Figure 7.1 shows the strong increase in the quantity

index against an almost stationary price index with the gap between the expenditure and quantity indexes indicating the effect of new medicines.

It has been shown in Chapter 6 that calculating the PBS price index using the standard Fisher index formula or estimating it using the Time Product Dummy approach leads to very similar results even though the first excludes and the second includes new and disappearing goods. This suggests therefore that the Fisher price index could be used to deflate the PBS expenditure series directly to derive a quantity index incorporating both the effect of increased demand and of new medicines being added to the PBS (and of medicines being delisted). Because the profile of the price index is essentially flat over the 15 year period this would produce a quantity index closely paralleling the index for overall expenditure, implying that the growth in "real" expenditure is virtually the same as the growth in "nominal" expenditure.

Another way of describing the contributions of changes in prices and quantities to growth is by using the indicators discussed in Chapter 5 to decompose the difference in values from one year to the next rather than using indexes to decompose their ratio. This is illustrated in Table 7.4 where the change in PBS expenditure from the previous year is given in the first column while the second shows the change in values for the items common to both years.

**Table 7.4    Contributions to annual change in PBS expenditure, $m**

|  | Total | Common | Net new | Bennet price indicator | Bennet quantity indicator |
|---|---|---|---|---|---|
| 1992-93 | 379.6 | 335.4 | 44.2 | 1.2 | 334.2 |
| 1993-94 | 328.0 | 305.8 | 22.2 | 30.7 | 275.1 |
| 1994-95 | 265.9 | 214.7 | 51.2 | 13.8 | 200.9 |
| 1995-96 | 362.0 | 338.0 | 24.0 | 26.1 | 311.9 |
| 1996-97 | 251.5 | 190.8 | 60.8 | -35.9 | 226.6 |
| 1997-98 | 271.2 | 159.4 | 111.8 | -51.3 | 210.7 |
| 1998-99 | 315.3 | 284.1 | 31.2 | -92.5 | 376.6 |
| 1999-00 | 480.5 | 378.3 | 102.2 | -85.8 | 464.1 |
| 2000-01 | 743.5 | 397.4 | 346.0 | -61.8 | 459.3 |
| 2001-02 | 478.4 | 442.3 | 36.0 | -65.3 | 507.6 |
| 2002-03 | 490.1 | 369.7 | 120.4 | -9.5 | 379.2 |
| 2003-04 | 585.9 | 520.6 | 65.3 | -8.0 | 528.6 |
| 2004-05 | 497.6 | 467.2 | 30.4 | -52.5 | 519.7 |
| 2005-06 | 249.8 | 231.8 | 18.0 | -126.9 | 358.7 |

As previously, the contribution from net new items is the difference between these two values. The Bennet price and quantity indicators calculated at the item level using the derived price approach are given in the next two columns. In this case the sum of the price and quantity indicators is exactly equal to the change in the common items.

It is clear that, while prices change only by small percentages, this is enough to make a substantial impact on the change in expenditure from year to year. The largest reduction due to price changes occurs in 2005-06 and is undoubtedly a reflection of the impact of the 12.5% mandatory price reduction on entry of a new brand which commenced in August 2005. In addition price reductions have made major contributions to restraining PBS expenditure in 1998-99 and 1999-00. As noted earlier, the contribution from net new items has been considerable in some years, particularly 2000-01. It is clear however that the major contribution to PBS expenditure comes from increased demand for medicines already listed. In 2005-06 for instance, an increase of $358.7 million for listed items and $18.0 million for net new items was offset by a reduction of $126.9 million due to price cuts, resulting in a net increase in expenditure of $249.8 million. This increase in demand was the smallest rise of the past eight years and reflects in part the dampening effect on patients of the increase in the copayment in January 2005. The other big rise in the copayment occurred in January 1997 and is likely also to have played a role in the more subdued increase in 1996-97 and 1997-98.

It was shown in Chapter 5 that one of the advantages of using indicators to decompose the change in a value rather than using indexes to decompose the value ratio is that it is a much simpler procedure with indicators to quantify the contributions to price and quantity changes of particular medicines or groups of medicines. This advantage is exploited in Table 7.5 which reproduces the Bennet price and quantity indicators for PBS expenditure from Table 7.4 and adds the same indicators for two groups of medicines – those that fall within the Weighted Average Monthly Treatment Cost (WAMTC) pricing methodology and those that make up the Reference Pricing Groups (RPG). As noted in Chapter 2, WAMTC groups are the most important of the RPGs.

**Table 7.5**      **WAMTC and RPG contributions to annual change in PBS expenditure, $m**

|  | Total Bennet Price | Total Bennet Quantity | WAMTC Bennet Price | WAMTC Bennet Quantity | RPG Bennet Price | RPG Bennet Quantity |
|---|---|---|---|---|---|---|
| 1992-93 | 1.2 | 334.2 | -16.9 | 151.8 | -12.1 | 269.0 |
| 1993-94 | 30.7 | 275.1 | 0.4 | 143.8 | 17.4 | 218.6 |
| 1994-95 | 13.8 | 200.9 | -8.9 | 129.4 | 4.1 | 156.7 |
| 1995-96 | 26.1 | 311.9 | -2.5 | 206.6 | 10.1 | 291.1 |
| 1996-97 | -35.9 | 226.6 | -45.1 | 192.6 | -42.8 | 229.6 |
| 1997-98 | -51.3 | 210.7 | -39.8 | 94.9 | -53.9 | 184.3 |
| 1998-99 | -92.5 | 376.6 | -80.7 | 120.5 | -85.1 | 266.6 |
| 1999-00 | -85.8 | 464.1 | -65.5 | 85.7 | -72.4 | 289.9 |
| 2000-01 | -61.8 | 459.3 | -40.9 | 171.6 | -53.6 | 327.5 |
| 2001-02 | -65.3 | 507.6 | -98.2 | 233.8 | -72.9 | 352.9 |
| 2002-03 | -9.5 | 379.2 | -11.9 | 161.0 | -14.1 | 266.3 |
| 2003-04 | -8.0 | 528.6 | -7.5 | 211.2 | -7.6 | 349.7 |
| 2004-05 | -52.5 | 519.7 | -61.5 | 149.9 | -57.8 | 292.5 |
| 2005-06 | -126.9 | 358.7 | -114.3 | 17.8 | -127.4 | 160.5 |

It is clear that the change in PBS expenditure due to prices can largely be accounted for in most years since 1996-97 by the fall in prices of WAMTC medicines with some additional contribution from other members of RPGs. In 2005-06 for instance changes in prices deducted $126.9 million from PBS expenditure with WAMTC medicines being responsible for $114.3 million and a further $13.1 million ($127.4m-$114.3m) from medicines in other RPG groups. The WAMTC procedure for determining prices therefore is probably the main reason for the change in expenditure due to changes in prices within the PBS over the period from 1991-92 to 2005-06. Generally speaking, the contribution to growth in demand from WAMTC medicines as shown by the quantity indicator has been less dominant although still significant in most years and medicines within other RPGs have made a greater contribution. Over time the impact of both the WAMTC and other RPGs have diminished, reinforcing the picture presented in Figure 4.4 in Chapter 4. The influence of the mandatory 12.5% price policy can be seen clearly in the results for 2005-06 because the two most important WAMTC groups – statins and SSRIs – were subject to these cuts in August 2005.

The picture of strong persistent growth in demand for pharmaceuticals accompanied by sustained falls in prices that emerges from Tables 7.1 and 7.3 is not exclusive to Australia or the PBS. Decompositions of pharmaceutical expenditure in a number of countries and markets show similar trends over time.

Graphs published in the *Annual Review* of the New Zealand Pharmaceutical Management Agency (PHARMAC 2006) which is responsible for managing expenditure on medicines in that country show that prices of subsidised medicines fell by about 50% between June 1993 and June 2006, and demand followed a similar upward trend to that in Australia. PHARMAC's listing and pricing policies are similar to those of the PBS but it also must meet specific budget targets so it has acted more aggressively to cut prices and restrict demand to meet these targets. Actual expenditure in New Zealand fell from NZ$564.6 million to NZ$563.5 million between 2004-05 and 2005-06 before an increase to NZ$599.4 million in 2006-07.

A study by the UK Department of Health and the Association of the British Pharmaceutical Industry (2002) found that a Paasche price index for all pharmaceuticals available under the Pharmaceutical Price Regulation Scheme in England showed falling or unchanged prices in each of the years between 1992 and 2000. During this period, expenditure grew by on average by 8.7% per year while prices fell by 1.8% per year. Unpublished chained Fisher price estimates by the author using the data from the same source (Department of Health 2007, National Health Service 2007) showed that prices fell by 1.3% per annum between 2000 and 2003.

Similarly, Kontozamanis et al (2003) reported that medicinal product prices in Greece fell by over 24% between 1995 and 2000 based on official CPI data; Cavalie (2003) reported that retail pharmaceutical prices in France fell by 3% between 1995 and 2001 based on a chained Laspeyres index using official data; and Rinta (2001) that prescription medicines fell in Finland between 1994 and 2000 by similar amounts based on data from Statistics Finland. Haga and Sverre (2002) reported falling prices in Norway and Gerdtham and Lundin (2004) showed the same thing in Sweden over the period 1990 to 2000. Using data from the Federal Statistical Office, the German Association of Research-Based Pharmaceutical Companies (2007) demonstrates that pharmaceutical prices fell by 6.7% from 1995 to 2006.

In Canada, the Patented Medicine Prices Review Board (PMPRB) reports each year on trends in expenditure and prices for patented medicines in that country. In its *Annual Report* for 2006 (PMPRB 2007), it provided values for the annual rates of change in its chained Laspeyres Patented Medicine Price Index based on ex-factory

prices. For the period 1997 to 2006 this index grew by 1.7 percent or about 0.2% per year. In a series of studies on pharmaceutical markets in Canada at both national and provincial levels, Morgan and colleagues at the University of British Columbia have also demonstrated that price indexes calculated in a variety of ways show little or no change in prices over extended periods of time. For instance for Canada as a whole, prices fell by 2% between 1988 and 2002 (Morgan 2004) for oral solid medicines and by 0.3% between 1998 and 2004 (Morgan 2005b).

In the United States a number of institutions provide complete or partial decompositions of pharmaceutical expenditure. The Center for Medicaid and Medicare Services uses the prescription drugs component of the US CPI compiled by the Bureau of Labor Statistics as a measure of price changes (Smith 2004) as does the Kaiser Family Foundation in its regular analysis of prescription drug trends (Kaiser Family Foundation 2007). Although the BLS introduced a chained Tornqvist CPI in 2002 the only published reports as yet are for broad categories of goods not for detailed categories such as prescription drugs. The older Laspeyres type CPI shows that pharmaceutical prices grew on average by 4.1% per annum over the period 1997 to 2006 with some moderation in recent years (BLS 2008).

**Table 7.6     Rate of growth in US pharmaceutical prices, various sources**

|  | CPI Prescription | Express Scripts | US Pharmacy | US Prescription |
|---|---|---|---|---|
| Source | 1 | 2 | 3 | 4 |
| 1996 | 3.4 | 3.3 |  | 1.6 |
| 1997 | 2.6 | 2.4 |  | 2.5 |
| 1998 | 3.7 | 5.1 |  | 3.2 |
| 1999 | 5.7 | 5.4 | 3.5 | 4.2 |
| 2000 | 4.4 | 5.4 | 3.5 | 3.9 |
| 2001 | 5.4 | 5.6 | 4.5 |  |
| 2002 | 5.2 | 7.5 | 5.5 |  |
| 2003 | 3.1 | 6.9 | 5.5 |  |
| 2004 | 3.3 | 6.0 |  |  |
| 2005 | 3.5 | 5.3 |  |  |
| 2006 | 4.3 | 4.3 |  |  |
| 2007 | 1.5 |  |  |  |

Sources: 1 BLS (2008), 2 Express Scripts (2007), 3 CSES unpublished, 4 Berndt (2002)

In their annual *Drug Report*, Express Scripts (2007) undertake a decomposition of expenditure based on an analysis of the prescriptions processed by it as one of the

largest pharmacy benefit managers (PBM) in the US. Although not explicit about their analysis techniques it is clear from the way the decomposition is reported that they employ a chained price index similar to the ones used in this thesis. Over the period 1997 to 2006 the average price change reported is 5.4%. Merlis (2000) provided a summary of decompositions carried out in the 1990s by Express Scripts and Merck-Medco (another PBM) using their claims data and two studies from Brandeis University and the National Institute for Health Care Management and found that price change was again about 4% per year. Dubois et al (2000) analyzing claims data from the period 1994 to 1998 found that while prices increased, this varied significantly among categories of medicines and was greatly outweighed by volume increases. Using data from IMS Health on the US prescription pharmaceutical market from 1987 to 2000, Berndt (2002) estimates that the average annual growth rate for prices was 4.7%. Finally the author has calculated a chained Fisher price index for the US Pharmacy sector for the period 1998 to 2003 using annual data from IMS Health described in Appendix A. This index is calculated at the same level as the PBS unique brand level index discussed in Chapter 6, and shows an annual average increase of 4.5%. Results are similar for other sectors of the US market except for hospitals and clinics which had lower rates of increase.

Berndt (2002) explains the difference in the way medicines are priced in the USA and elsewhere by noting that "Outside the United States, most countries have national or regional purchasing bodies, with whom brand manufacturers negotiate a drug reimbursement price. In these contexts, both buyer and seller have significant but not necessarily equal market power. Once on the market, allowed price changes are frequently subject to national price controls. Hence, when negotiating for reimbursement prices with government buying authorities, the price at new product launch time is a critical economic variable for brand manufacturers". By contrast in the USA, "empirical evidence is consistent with the notion that manufacturers price based primarily on marginal value". While generic brands may offer lower prices after patent expiry, originator brands often react by raising their prices. Unlike other countries, payers in the USA also seem to tolerate price adjustments for general inflation.

All these studies accept that a decomposition of pharmaceutical expenditure using price and quantity relatives and the standard index formulae will produce a price index that validly indicates the correct movement in prices from period to period and as noted this usually demonstrates a fall in the price of pharmaceuticals, the chief exception being the United States which accounts for about half of global pharmaceutical expenditure. The question that arises is how the values of the quantity index should be interpreted regardless of whether it is estimated directly or by using the estimated price index to deflate the expenditure series. Given that the price series shows at best little increase in prices for most countries outside the USA, the quantity index typically shows strong growth similar to that of the original expenditure series (as shown earlier for PBS expenditure). The quantity index also usually grows much faster than other indicators of real consumption of medicines, such as the total number of prescriptions or the total number of units whether measured as units such as tablets or converted into defined daily doses.

A straightforward way of accounting for some of the growth in both expenditure and quantity is to adjust for the increase in the number of patients and most of the studies cited above make some allowance for this. Population growth however will account for at most about 2-3% of any annual increase in the quantity of medicines consumed. However population growth for those aged 60 or more has been somewhat higher than this and this is expected to continue in the future and the consequences of this for the PBS and other health services have been explored by the Productivity Commission (2005a, 2005b) and Department of the Treasury (2002, 2007). This is discussed further in Chapter 9.

Even if expressed on a per capita basis, this will still leave a disparity between the quantity index and other consumption measures to be explained. These explanations often look for a hidden "price" effect within the quantity index which is the result of a shift within demand such as from lower priced old medicines to higher priced newer medicines used to treat the same disease or from higher priced originator brands to lower priced generic brands. Within the context of the decomposition of pharmaceutical expenditure, this effect has been described by Gerdtham and colleagues (Gerdtham et al 1993, Gerdtham et al 1998, Gerdtham and Lundin 2004) and has been pursued in particular by Morgan and colleagues (Morgan 2002, 2004,

2005a, 2005b, 2006, Morgan, Agnew and Barer 2004, Morgan, Bassett and Mintzes 2004).

The argument used by these and some of the other authors cited earlier is similar to the one already canvassed in Chapter 5, namely that if a newer medicine is introduced in competition with an existing medicine but at a higher price, then in the absence of any price changes for either medicine the standard price index will not show an increase in price even though the "average" price of the two medicines increase as demand shifts to the higher priced one. Ignoring this effect leads to the price index being understated and the quantity index being overstated. If the effect is due to the introduction of lower price generics then the change in the price index will be overstated and the quantity index understated.

The argument for such an effect has lead to the quantity index being reinterpreted as an index of "utilization" combining the effects of increased consumption with shifts in consumption patterns and accompanying price effects.

However such an interpretation of the quantity index needs to be carefully assessed. The effect arises from the disparity between the quantity index and the consumption measure so it is important to understand how valid this latter measure is. Even if the number of prescriptions or units is adjusted for different forms and strengths by conversion to defined daily doses, aggregation is only really valid when close substitutes are involved as has been argued in Chapter 5. The greater the degree of non-substitutability there is among the medicines being aggregated the harder it is to interpret what the resulting series measures. The difficulty is compounded as the distribution of consumption among broad categories of medicines changes over time.

If it is accepted that such a "price" effect is nonetheless present, it is likely to be minimal within a decomposition of expenditure of PBS medicines. New PBS medicines are listed at a price determined either on a cost-minimisation basis so that the price of the new medicines is set to produce the same therapeutic outcome as the comparator or on a cost-effectiveness basis where the price of the new medicine is set according to the incremental benefit derived from the new medicine. Given that the initial price is set in this way and that the prices of medicines treating the same

conditions subsequently move in the same way, any "price" effect arising from a shift from, say, the comparator to the new medicine is fully accounted for in the quantity index as a "quality" effect reflecting the increased treatment benefit received by patients. The quantity index is then a quality-adjusted measure of consumption which avoids the problems inherent in aggregating heterogeneous measures such as prescriptions, units or doses.

In Chapter 2 it was shown that cost-effectiveness listings represent between 26% and 35% of all new listings on the PBS, with cost-minimisation listings accounting for 65% to 74%. For the cost-minimisation listings, the quality effect is fully taken up in the listed price. For cost-effectiveness listings the extent to which the price differential with the comparator fully accounts for the improved effectiveness of the new medicine is harder to assess. Sometimes the PBAC will recommend that a medicine be listed although the incremental cost-effectiveness is "high". This seems to imply that the price premium for these medicines is higher than justified by comparison with the comparator. On the other hand, the final price for cost-effectiveness listings is negotiated with the Government and the agreement with the supplier often includes provision for "special pricing arrangements" designed to limit the impact of any price premium beyond that justified by the cost-effectiveness analysis. It appears therefore that for most new listings on the PBS any difference in price from the comparator reflects a proportionate increase in quality.

It is often stated that programs such as the PBS which use economic analysis and reference pricing to determine the price of medicines only list new medicines on the condition that they provide "value for money". If the PBS listing and pricing procedures work in this way and it is accepted that prices have remained unchanged over time then the increase in PBS expenditure from $1.4 billion in 1991-92 to $7.1 billion in 2005-06 represents a commensurate increase in value and benefit for consumers of PBS medicines.

## 7.3 Prices received by pharmacists and their suppliers

To this point, decomposition techniques have been used to identify separate price and quantity effects for overall expenditure within the PBS. They can also be used to show

how the various stakeholders within the PBS have fared and to illustrate the differential impact of the rules governing the operations of the PBS.

The first group to be considered comprises the participants in the supply chain from manufacturer to wholesaler to pharmacist. In this analysis it is necessary to use the derived quantity approach because there is no consistent common dataset that identifies the sales of all three types of participant. By its nature, the PBS expenditure data represents how much is received by pharmacists, not by wholesalers or manufacturers. On the other hand, the data from IMS Health describes sales at the wholesale level to Australian pharmacies but does not separately identify the PBS component.

The PBS Schedule provides both the dispensed price charged by the pharmacist (MDPMQ) and the wholesale price to the pharmacist (MPPMP). The formula linking these prices is described in some detail in Chapter 2. As noted there, the wholesale price is split 90% to the manufacturer and 10% to the wholesaler for the whole of the period 1991-92 to 2005-06, so a price index calculated at the wholesale level will be the same for both manufacturer and wholesaler. The derived quantity approach expresses the dispensed price and the wholesale price in terms of price per unit by dividing MDPMQ by maximum quantity and MPPMP by pack size respectively. To calculate price indexes a common measure of quantity is used, namely total expenditure divided by the dispensed price per unit (ie MDPMQ divided by maximum quantity). Within any one year this represents the amount of medicines sold by pharmacists to patients. Because there is no separate data on the amounts of medicines sold by manufacturers to wholesalers and by wholesalers to pharmacists, this common quantity measure is taken to represent these amounts. As with most supply chains, just-in-time principles have been increasingly adopted for the supply of pharmaceuticals, so the lag between sales at various stages of the supply chain would be expected to be short, perhaps a few months between manufacturer and sale to patient. This means that the physical volume of medicines sold by pharmacists must be a reasonably good approximation to the volume sold by manufacturers and wholesalers. Using such a common measure of quantity is therefore unlikely to lead to any significant bias when used to calculate price indexes for each of these supply chain participants.

Table 7.7 and Figure 7.2 show indexes for three prices – the dispensed price (the weighted MDPMQ per unit from Table 6.9), the price paid by the pharmacist to the wholesaler (MPPMP per unit) and the pharmacist's margin which is defined as the difference between the dispensed price and wholesale price.

**Table 7.7     PBS wholesale and retail price indexes**

|         | Wholesale price | Pharmacist margin | Dispensed price | CPI | Dispensed price/CPI |
|---------|-----------------|-------------------|-----------------|--------|---------------------|
| 1991-92 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 |
| 1992-93 | 1.0075 | 1.0327 | 1.0148 | 1.0186 | 0.9828 |
| 1993-94 | 1.0227 | 1.0702 | 1.0360 | 1.0363 | 0.9814 |
| 1994-95 | 1.0123 | 1.1134 | 1.0393 | 1.0829 | 0.9450 |
| 1995-96 | 1.0045 | 1.1579 | 1.0441 | 1.1165 | 0.9261 |
| 1996-97 | 0.9858 | 1.1542 | 1.0287 | 1.1202 | 0.9115 |
| 1997-98 | 0.9639 | 1.1564 | 1.0118 | 1.1277 | 0.8906 |
| 1998-99 | 0.9413 | 1.1474 | 0.9918 | 1.1398 | 0.8575 |
| 1999-00 | 0.9092 | 1.1414 | 0.9643 | 1.1761 | 0.8122 |
| 2000-01 | 0.8928 | 1.1431 | 0.9509 | 1.2470 | 0.7549 |
| 2001-02 | 0.8719 | 1.1697 | 0.9378 | 1.2824 | 0.7248 |
| 2002-03 | 0.8683 | 1.1710 | 0.9349 | 1.3169 | 0.7046 |
| 2003-04 | 0.8649 | 1.1775 | 0.9330 | 1.3495 | 0.6867 |
| 2004-05 | 0.8552 | 1.1764 | 0.9244 | 1.3830 | 0.6647 |
| 2005-06 | 0.8303 | 1.1875 | 0.9041 | 1.4380 | 0.6277 |

**Figure 7.2     PBS wholesale and retail price indexes**
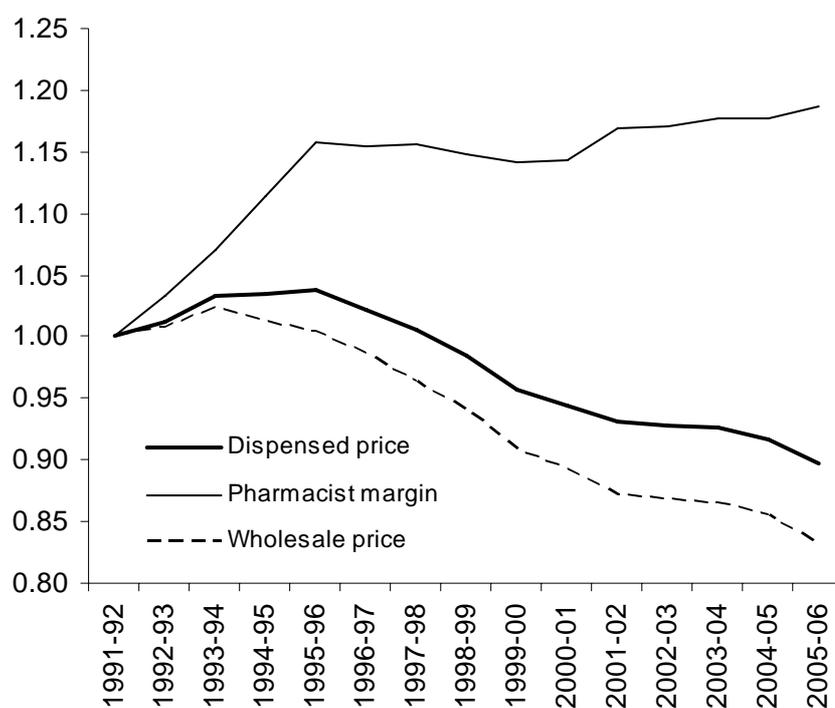
For most medicines sold this margin consists of a fixed dispensing fee plus a percentage markup on the wholesale price.

The prices received by wholesalers (and therefore manufacturers and other suppliers) declined more steeply over the period than the dispensed price peaking earlier in 1993-94 and at a lower level than the dispensed price which was at its highest levels in 1995-96. For some of this period the dispensed price was supported in part by adjustments for inflation but this was never the case for the prices received by manufacturers and wholesalers. From 1991-92 to 2005-06 wholesale and manufacturer prices declined by 17.0%, or by about 1.3% per year compared to the dispensed price which fell by 9.6% or 0.7% per year.

The pharmacist margin showed strong growth between 1991-92 and 1995-96 before a period of slight decline to 1999-00 and a subsequent period of more modest growth to 2005-06. Across the period the margin rose by 18.7% or 1.2% per year but from 1995-96 to 2005-06 the increase was only 2.6% or 0.3% per year The pharmacist margin consists of two components – the dispensing fee which is adjusted for inflation and the percentage markup on the wholesale price. The growth profile for the pharmacist's margin in Figure 7.2 is quite similar to that for the "ready prepared" dispensing fee illustrated in Figure 2.3 in Chapter 2. However the dispensing fee grew by about 44% over the period while the margin only increased by 18.7%, because the percentage markup component fell in line with the reduction in wholesale prices.

Pharmacists have relied therefore on increasing volumes to maintain revenue and profits in the face of little if any increase in prices. The situation is worse for manufacturers however who faced declining prices and have relied on expansion of the market through new medicines and strong growth in demand.

To compare these price changes with other price movements in the economy, Table 7.7 also includes an indicator of general inflation - the Australian Consumer Price Index rebased so that 1991-92 = 1.0 (RBA 2007a). Over the period the CPI rose by 43% or by 2.5% per annum on average. Adjusting the dispensed price for the CPI shows a decline of 36.2% in this "real" dispensed price or -3.3% per annum on average.

## 7.4 The two payers – Government and patients

The decomposition of total PBS expenditure into price and quantity components necessarily uses the dispensed price as the price series. In the derived quantity approach this is simply the quoted PBS dispensed price per unit (MDPMQ per unit) while in the derived price approach it is the estimated dispensed price formed by dividing expenditure by the quantity measure (scripts time maximum quantity). However the whole of this price is never paid by the patient (except for the case of general non-safety net patients where the price is less than the general copayment, and for which there is no detailed data) or by the government (except for concessional safety-net patients). Rather, the patient pays the copayment plus the premium if there is one, while the government pays the difference between this and the dispensed price.

PBS patients can be divided into 3 categories according to the price they pay

- GNSN – General non-safety net patients paying the general copayment ($30.70 in 2007),
- CON – Concessional non-safety net patients and general safety net patients, paying the concessional copayment ($4.90 in 2007), and
- FREE – Concessional safety net patients who do not pay any copayment

The prices paid by the patient and the Government will vary according to which category the patient falls into.

In assessing the different experiences of patients and the Government in the PBS, the picture can either be drawn at the overall level where the average patient experience is described, or by considering each patient category separately.

Using the derived price approach, the price paid by all patients considered together is the Patient Cost divided by the overall quantity measure (total scripts multiplied by maximum quantity). The price faced by the Government then is just Government Cost divided by the same quantity measure. Using these prices and the quantity measure, separate price indexes can be calculated for patients and the Government. In this situation it is not relevant to calculate separate quantity indexes as the quantities being

used are the same for both patients and Government. The two prices indexes are shown in Table 7.8, as well as the index for the dispensed price as reference.

**Table 7.8    PBS price indexes, patients and Government**

|  | Patients | Government | Dispensed |
|---|---|---|---|
| 1991-92 | 1.0000 | 1.0000 | 1.0000 |
| 1992-93 | 0.9520 | 1.0144 | 1.0011 |
| 1993-94 | 0.9228 | 1.0420 | 1.0171 |
| 1994-95 | 0.9682 | 1.0387 | 1.0234 |
| 1995-96 | 0.9514 | 1.0558 | 1.0340 |
| 1996-97 | 1.0175 | 1.0252 | 1.0211 |
| 1997-98 | 1.0419 | 0.9998 | 1.0043 |
| 1998-99 | 1.0166 | 0.9726 | 0.9774 |
| 1999-00 | 0.9842 | 0.9522 | 0.9553 |
| 2000-01 | 0.9860 | 0.9356 | 0.9414 |
| 2001-02 | 0.9877 | 0.9213 | 0.9295 |
| 2002-03 | 0.9879 | 0.9194 | 0.9279 |
| 2003-04 | 1.0020 | 0.9157 | 0.9267 |
| 2004-05 | 1.0599 | 0.8982 | 0.9193 |
| 2005-06 | 1.1302 | 0.8687 | 0.9026 |

**Figure 7.3    PBS price indexes, patients and Government**
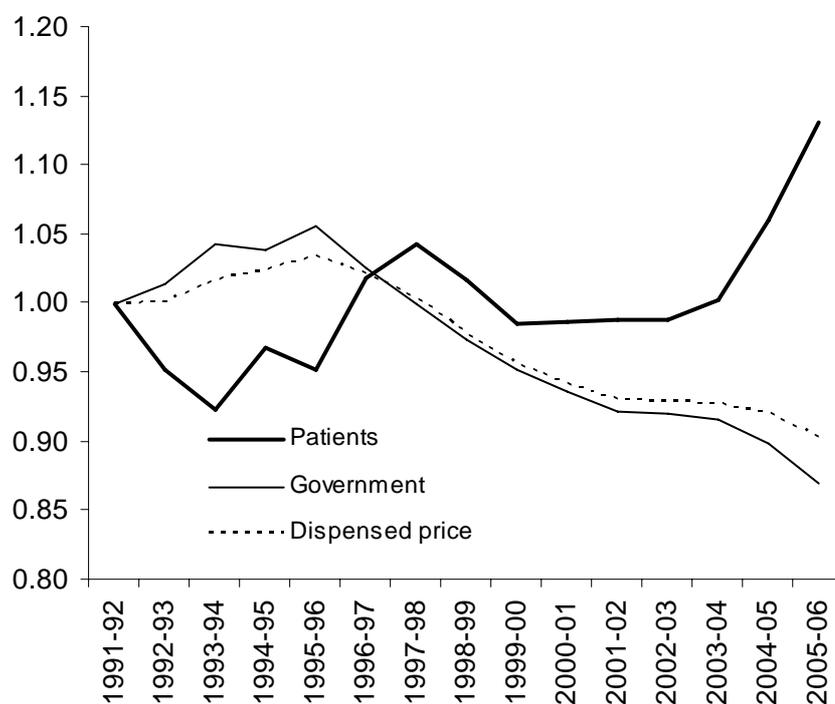


Figure 7.3 shows that the prices faced by the Government rose more strongly than the overall dispensed price in the period to 1995-96, fell more sharply to 1997-98, and followed a similar path for a number of years before diverging strongly from 2003-04 onwards. The patients' experience was the mirror image of this, although with greater

variation. Prices faced by patients fell to 1993-94, traced a generally upward path to 1997-98, fell until 1999-00 and remained flat thereafter until a steep rise between 2003-04 and 2004-05 and a larger one between 2004-05 and 2005-06.

Patient price indexes can be derived for the GNSN and CON categories because the Patient Cost will always include the copayment and sometimes the premium. For the FREE category on the other hand the derived price will be zero because there is no copayment and no premium. It becomes difficult therefore to construct a meaningful patient price index in such circumstances. For this category the Government pays all the dispensed price so the Government price index will be similar to the overall dispensed price index.

The data used to calculate the price indexes for the GNSN and CON categories exclude those items within the Highly Specialised Drugs Program, ie medicines provided within public and private hospitals. As discussed in Appendix A, the data on usage in public hospitals provided by DoHA is based on information given by State Governments on quantities and expenditure and this does not differentiate between Government and Patient Cost. As patients are treated for free in public hospitals they can be regarded as falling into the FREE category. While information is available on Government and Patient cost in private hospitals, this shows that Patient Cost is tiny compared to Government Cost. It is therefore not too unrealistic to simply allocate all HSD expenditure to the FREE category and exclude these items from the GNSN and CON categories.

The patient and government price indexes for the two types of patients are reported in Table 7.9 and Figure 7.4. It is clear that the patient price indexes for both categories follow very similar paths and imply that the prices paid by patients in these categories rose by almost identical amounts over the 15 year period - by 80.0% for patients paying the general copayment and by 77.3% for those paying the concessional copayment.

**Table 7.9    PBS price indexes, copayment categories**

| | Patient | Patient | Government | Government | Copayment | Copayment |
|---|---|---|---|---|---|---|
| | GNSN | CON | GNSN | CON | General | Concessional |
| 1991-92 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 | 1.0000 |
| 1992-93 | 1.0051 | 0.9987 | 0.9783 | 1.0087 | 1.0155 | 1.0097 |
| 1993-94 | 1.0104 | 0.9952 | 0.9976 | 1.0342 | 1.0224 | 1.0097 |
| 1994-95 | 1.0185 | 0.9930 | 0.9894 | 1.0440 | 1.0346 | 1.0097 |
| 1995-96 | 1.0454 | 1.0054 | 0.9790 | 1.0564 | 1.0709 | 1.0291 |
| 1996-97 | 1.1423 | 1.1096 | 0.8919 | 1.0263 | 1.1923 | 1.1456 |
| 1997-98 | 1.2399 | 1.2120 | 0.8349 | 0.9948 | 1.2786 | 1.2427 |
| 1998-99 | 1.2478 | 1.2123 | 0.7897 | 0.9665 | 1.2882 | 1.2427 |
| 1999-00 | 1.2572 | 1.2275 | 0.7413 | 0.9428 | 1.3074 | 1.2621 |
| 2000-01 | 1.2964 | 1.2817 | 0.6998 | 0.9215 | 1.3586 | 1.3204 |
| 2001-02 | 1.3836 | 1.3537 | 0.6568 | 0.9011 | 1.4161 | 1.3786 |
| 2002-03 | 1.4291 | 1.3978 | 0.6416 | 0.8954 | 1.4544 | 1.4175 |
| 2003-04 | 1.4681 | 1.4349 | 0.6292 | 0.8910 | 1.4960 | 1.4563 |
| 2004-05 | 1.6130 | 1.6000 | 0.5872 | 0.8695 | 1.6718 | 1.6311 |
| 2005-06 | 1.8021 | 1.7731 | 0.5390 | 0.8378 | 1.8572 | 1.8058 |

**Figure 7.4    PBS price indexes, copayment categories**
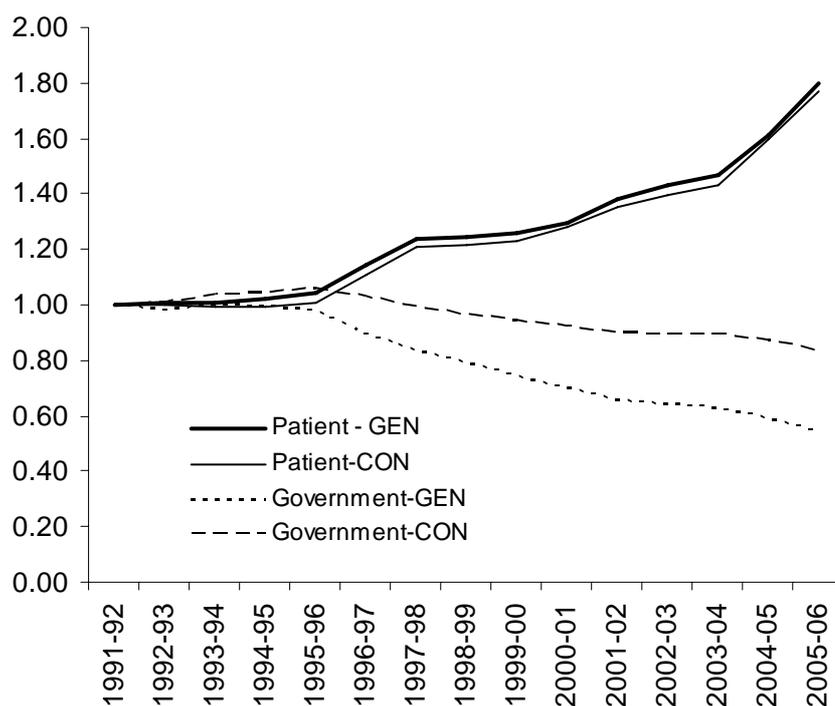


Table 7.9 also includes for reference the average annual general and concessional copayments expressed as indexes. It demonstrates that the patient price indexes follow almost identical courses. The changes in patient prices indicated in Table 7.9 are much larger than those for the overall patient price index given in Table 7.8 which implies an increase of only 13.0% over the period. The difference between the two

results is partly because the overall index includes the FREE category which by definition shows no price change over the period.

By contrast with the patient indexes, the government price indexes are markedly different between the two patient categories. They imply that the prices paid by the Government for medicines consumed by GNSN patients fell by 46.1% between 1991-92 and 2005-06. For CON patients the fall was only 16.2% or just a bit more than the 13.1% implied by the overall index in Table 7.8.

The reason for this disparity is that the government pays much less of the dispensed price for GNSN than CON patients and therefore saves proportionally more from a fall in prices. Consider for example a medicine without a premium which has a dispensed price of $50.00 and this falls by 10% to $45.00. Then at the 2007 general and concessional copayment levels of 30.70 and 4.90, the government prices paid for GNSN and CON patients are initially $19.30 ($50.00 - $30.70) and $45.10 ($50.00 - $4.90). These fall to $14.30 and $40.10 if the copayments are unchanged or by 25.9% and 11.1% respectively.

The quantity measures used in the calculations of these prices indexes are simply the total cost in each category divided by the number of scripts times the maximum quantity for the item. For GNSN patients for instance the total expenditure (Patient Cost plus Government Cost) for each item is divided by the number of scripts for GNSN patients for that item times the item's maximum quantity.

If the price is calculated for each patient category by dividing the total expenditure by the quantity measure this can be used to derive price and quantity indexes for each category. Here the price is not split between patient and government but reflects the dispensed price for each category. The quantity indexes so calculated show how demand for each category has grown over time. The price and quantity indexes are reported in Table 7.10 and the two quantity indexes are charted in Figure 7.5.

**Table 7.10    Price and quantity indexes, copayment categories**

|         | GNSN Price | GNSN Quantity | CON Price | CON Quantity |
|---------|-----------|---------------|-----------|--------------|
| 1991-92 | 1.0000    | 1.0000        | 1.0000    | 1.0000       |
| 1992-93 | 0.9904    | 1.2258        | 1.0068    | 1.1913       |
| 1993-94 | 1.0033    | 1.3911        | 1.0273    | 1.3750       |
| 1994-95 | 1.0023    | 1.6725        | 1.0352    | 1.5495       |
| 1995-96 | 1.0071    | 1.8785        | 1.0475    | 1.7373       |
| 1996-97 | 0.9882    | 2.1452        | 1.0363    | 1.8222       |
| 1997-98 | 0.9819    | 2.1546        | 1.0223    | 1.9590       |
| 1998-99 | 0.9523    | 2.4557        | 0.9973    | 2.1789       |
| 1999-00 | 0.9193    | 2.6903        | 0.9778    | 2.4644       |
| 2000-01 | 0.8980    | 3.0662        | 0.9640    | 2.7295       |
| 2001-02 | 0.8847    | 3.2835        | 0.9516    | 3.0076       |
| 2002-03 | 0.8830    | 3.5285        | 0.9499    | 3.1712       |
| 2003-04 | 0.8816    | 3.8822        | 0.9487    | 3.4310       |
| 2004-05 | 0.8773    | 4.1048        | 0.9406    | 3.6379       |
| 2005-06 | 0.8721    | 4.1914        | 0.9227    | 3.8108       |

**Figure 7.5    PBS quantity indexes, copayment categories**
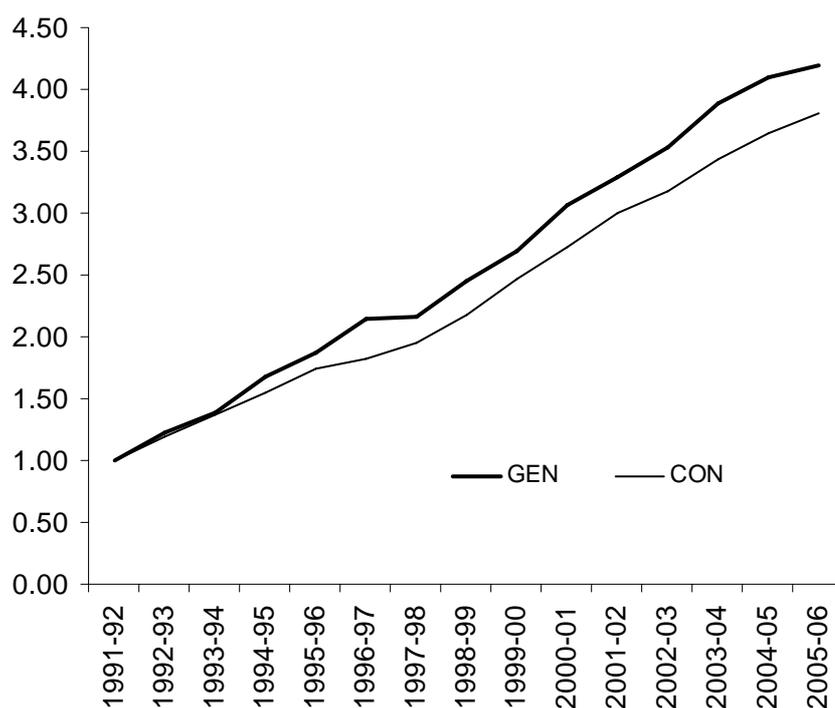


For GNSN patients the quantity of PBS medicines consumed was 4.19 higher in 2005-06 than it was in 1991-92, while for CON patients it was somewhat less at 3.81 times. This broadly in line with the overall growth in quantity shown by the quantity index reported in Table 6.7 in Chapter 6 which has a value of 4.22.

This growth has however been subject to some shocks which are more evident for GNSN patients than CON patients. Figure 7.5 displays clearly the slowdown in growth for GNSN patients in 1997-98 and in 2005-06 and to a lesser extent for CON patients. The major increases in the copayments in January 1997 and January 2005 are likely to have played a part in changing demand although the greater response by GNSN patients suggest that the absolutes value of the change may be more important than the relative change. In January 2005 both copayments rose by 21% but the actual increase for GNSN patients was $4.90 versus $0.80 for CON patients.

The influence of prices on quantities can be explored further using the weighted correlation coefficients between price and quantity relatives. In Chapter 6, these were calculated as part of the Bortkiewicz decomposition of the Paasche/Laspeyres ratio but there the context was an analysis of total PBS expenditure based on the dispensed price. Not surprisingly this showed little if any relationship between price and quantity relatives for most years because patients are not exposed to the dispensed price. If the analysis focuses instead on the two patient categories and uses the relevant price paid by the patient then the price and quantity relatives might be expected to show a greater degree of relationship. Table 7.11 shows the weighted correlation coefficients of the price and quantity relatives underlying the calculation of the GNSN and CON patient price indexes in Table 7.9.

**Table 7.11    Price and quantity relatives, weighted correlation coefficients**

|         | GNSN patient price | CON patient price | Dispensed price |
|---------|-------------------|------------------|-----------------|
| 1991-92 |                   |                  |                 |
| 1992-93 | 0.0065            | -0.0159          | -0.0148         |
| 1993-94 | -0.0090           | 0.0017           | -0.0310         |
| 1994-95 | -0.0125           | -0.0989          | -0.1176         |
| 1995-96 | -0.0107           | -0.0268          | -0.0393         |
| 1996-97 | 0.3518            | 0.0692           | -0.1067         |
| 1997-98 | -0.2631           | -0.2184          | -0.0594         |
| 1998-99 | -0.0148           | -0.0083          | 0.0172          |
| 1999-00 | -0.1513           | 0.0030           | 0.0506          |
| 2000-01 | 0.0489            | 0.0022           | 0.0273          |
| 2001-02 | -0.0893           | -0.0706          | -0.1035         |
| 2002-03 | -0.1295           | -0.1018          | -0.0336         |
| 2003-04 | -0.1037           | -0.1911          | -0.0247         |
| 2004-05 | 0.0522            | 0.0737           | -0.0021         |
| 2005-06 | -0.4707           | -0.2641          | 0.0385          |

It also reproduces the correlation coefficients from Table 6.8 as a comparison. In about half the years, the absolute value of the correlation coefficients for GNSN patients is less than 0.1, but in three years – 1996-97, 1997-98 and 2005-06 the value is above 0.25 and is particularly strong in 2005-06. The anomaly in these results is the value for 1996-97 which is positive when the relationship between price and quantity relatives is expected to be negative. There are obviously other forces at work in this year. By contrast, the relationship for CON patients is generally weaker and the correlation coefficient is only higher than 0.2 in two years – 1997-98 and 2005-06.

## 7.5 Summary

A decomposition of PBS expenditure shows that the overall impact of PBS pricing procedures has caused prices to fall from year to year. Although not shown here, a visual examination of prices for individual PBS items over the period provides strong reinforcement for this conclusion with most prices showing no change over extended periods of time and with some significant falls for some items (such as those discussed in Chapter 4). Very few items show any significant increase in prices. The overall effect is to produce the moderate average reductions demonstrated by the price indexes. Although small, the contribution of these price falls can lead to significant changes in expenditure as shown by the results using the Bennett indicators rather than the Fisher indexes.

Those medicines that fall within WAMTC groups account for most of the fall in prices prior to the changes in PBS policy in August 2005, illustrating the importance of this mechanism in determining PBS prices.

The predominant driver of the increase in PBS expenditure is the strong growth in demand demonstrated by the quantity index, reinforced by the steady addition of new medicines to the PBS formulary. It is argued that the similarity between the Fisher index and the TPD index means that the total PBS expenditure series can be deflated by the Fisher price index to give a "real" expenditure series.

The finding on the relative contribution of prices and demand to PBS expenditure is mirrored in similar decompositions undertaken in other countries, with the notable

exception of the United States. Some of these studies argue for a further "hidden" price effect arising from the shift to higher-priced newer medicines. Because the PBS listing and pricing procedures are based on incremental cost-effectiveness analysis, this effect can be interpreted in the PBS context as an increase in the quality of medicines and the quantity index taken as a quality-adjusted measure of the consumption of PBS medicines. Because prices have fallen slightly over time, the whole increase in PBS expenditure over the period 1991-92 to 2005-06 (which is essentially the same as the change in the quantity index) can be taken as a measure of the increase in benefit received by Australians from the consumption of PBS medicines.

The derived price approach enables the calculation of price indexes for pharmacists and suppliers and a comparison of the two illustrates how the price relationships embodied in the Community Pharmacy Agreements negotiated by the Government lead to different impacts on the remunerations of these two sectors of the industry. One of the key differences is that the price received by the pharmacist is adjusted in part for inflation unlike the price received by wholesalers and manufacturers.

Price and quantity indexes can also be estimated for different categories of patients and for the Government. Patients have been faced with rising prices for PBS medicines and the price paid by Government has tended to fall faster than the dispensed price. This demonstrates again how the Government has used copayments to shift the burden of PBS expenditure increasingly to patients.

The correlation between price and quantity relatives for the two patient categories suggests a significant influence of the patient price on demand for PBS medicines.

# Chapter 8
# The Demand for PBS Medicines

## 8.1 Introduction

The Bortkiewicz decomposition of the Paasche/Laspeyres ratio for the different categories of patients set out in the previous chapter suggested an association between changes in patient prices and changes in the consumption of PBS medicines as measured by the correlation between the price and quantity relatives. The purpose of this chapter is to explore this relationship more fully by estimating demand functions for different categories of PBS patients. This enables the influence of prices on demand for medicines to be quantified as well as the impact of other factors such as income, restriction levels and safety net limits to be assessed.

An important consideration in estimating equations based on observed values for quantity and prices in markets is to what extent the data results from demand factors alone or from the interaction of both demand and supply factors. For PBS medicines, suppliers effectively enter a contract with the Government to provide sufficient medicines at the listed price to meet demand. The amount supplied is therefore not dependent on the price so the supply schedule is horizontal. In a very few instances suppliers have withdrawn medicines when they can no longer agree with the Government about the price but this still means the supply schedule is horizontal while the medicine is listed on the PBS. As noted in Chapter 3, a few suppliers have entered into risk-sharing agreements which specify that once a threshold demand has been reached there is some adjustment in remuneration typically by a reduction in a price. However in most cases the threshold is not reached so the provisions are not invoked. In any case the causation is from consumer demand to price whereas the usual assumption about the supply schedule is that changes in price lead to changes in supply behaviour. In these conditions the supplier still agrees to provide medicines at the new price to meet the demand. For these reasons, there can be considerable confidence that equations estimated with observed market data are demand functions.

The following section is taken up with a brief review of demand models and concludes that a simplified model of demand for PBS medicines can be adopted because the operations of the PBS make certain of the considerations considered important in the literature, such as the estimation of cross-price elasticities unnecessary.

The next section presents a review of four previous studies of the demand for PBS medicines concentrating on the estimates of elasticities with respect to prices (typically the copayments) and of income.

This is followed by a section reporting the results of regression analysis of the demand for PBS medicines by four categories of PBS patients, namely the two types of patients split into the two safety net categories. These patient categories are therefore:


- General non-safety net (GNSN)
- General safety net (GSN)
- Concessional non-safety net (CNSN)
- Concessional safety net (CSN)


The CON category from the previous chapter has been separated into its GSN and CNSN constituents while the CSN category is the same as the FREE category. This classification into four categories enables the influence of the safety net limits to be better assessed and shows how the different patient categories react to changes in the factors influencing demand. It should be recognised that GSN and CNSN patients both face the same concessional copayment but will have different aggregate patient prices because the influence of the premium will vary due to the two patient categories having different consumption patterns. For CSN patients there will be no price effect. The results of some regressions are discussed in the chapter but are not reported in the tables. These results are available from the author.

## 8.2 Demand models

The starting point for most expositions of demand analysis is the Marshallian demand function which relates an individual's consumption of a particular good to the price of the good (its own price), the prices of other goods, and income, namely

$$q_i = f(M, \bar{p}) \tag{8.1}$$

where $q_i$ is the amount of good $i$ consumed, $M = \sum_{i=1}^{n} p_i q_i$ is the consumer's income, and $\bar{p}$ is a vector of prices of both good $i$ and competing goods.

The difficulty with estimating a set of demand equations of the form (8.1) is that the vector of prices for competing goods is large making it virtually impossible to estimate both the own and cross-price elasticities, even if individuals are aggregated. To make the task more tractable, the consumer's purchases are segregated into groups with discrete budgets and while there is substitution of products within groups there is little if any substitution among groups. This means that the demand function for a particular product can be specified with a limited number of competing products and all other products can be ignored.

There are a number of competing functional forms for equation (8.1) but as Rosenthal et al (2003) observe "none has yet been shown to be superior in estimating demand models in markets for prescription drugs" (p 9).

The most common approach is to estimate the demand function for a particular good or set of goods on a stand-alone basis without reference to the demand for other goods and without trying to make the results compatible with the theory of consumer demand. The most common specification for equation (8.1) is the double logarithmic form

$$\log q_i = \alpha_i + \beta_i \log M + \sum_{j=1}^{n} \gamma_{ij} \log p_i + \sum_{k=1}^{m} \delta_{ik} \log z_{ik} \tag{8.2}$$

where $z = [z_k]$ is a vector of $m$ other variables that influence the demand for good $i$. One of the attractions of this form is that the coefficients of the variables are elasticities, so that $\beta_i$ is the income elasticity of demand, $\gamma_{ii}$ is the own price

elasticity, $\gamma_{ij}$ is the cross price elasticity with respect to good $j$, and $\delta_{ik}$ is the elasticity with respect to the $k$'th other factor.

It is not possible to ensure that the double logarithmic form (8.2) will produce estimates of the coefficients that will conform to the restrictions on parameters suggested by consumer demand theory, namely adding-up, homogeneity, symmetry and negativity.

Because of this a number of approaches have been developed which attempt to either ensure or impose these restrictions or at least test their validity. Clements, Selvanathan and Selvanathan (1996) provide a relatively recent review of these alternative demand systems and discuss various functional forms and their derivations. Deaton and Muellbauer (1980a) also summarise the literature to that date. The description below draws mainly on these two sources.

One of the earliest approaches was the *linear expenditure system* (LES) of Stone (1954) in which the equation for the i'th product is

$$p_i q_i = p_i \gamma_i + \beta_i (M - \sum_{j=1}^{n} p_j \gamma_i) \tag{8.3}$$

where $\beta_i > 0$ and $\gamma_i < q_i$ are constants.

While straightforward to use, the LES specification has a number of drawbacks, including the fact that the income elasticity for necessities rises with income, while the income elasticity of luxuries falls.

The *Rotterdam model* was developed by Barten (1964) and Theil (1975) and in its finite form is given by

$$\overline{w}_{it} \Delta \log q_{it} = \theta_i \Delta \log Q_t + \sum_{j=1}^{n} v_{ij} (\Delta \log p_{jt} - \Delta \log P'_t) \tag{8.4}$$

where the average budget share is $\overline{w}_{it} = \dfrac{w_{it} + w_{it-1}}{2}$,

$\Delta$ is the difference operator defined as $\Delta x_t = x_t - x_{t-1}$,

$Q_t$ is defined as the consumer's real income ie $Q_t = \dfrac{M_t}{P_t}$, or $logQ_t = \log M_t - \log P_t$,

$\log P = \displaystyle\sum_{j=1}^{n} w_j \log p_j$ is the Divisia price index, and

$\Delta \log P'_t = \displaystyle\sum_{i=1}^{n} \theta_i \Delta \log p_{it}$ .

Equation (8.4) can be expressed in a somewhat simpler form as

$$\bar{w}_{it} \Delta \log q_{it} = \theta_i \Delta \log Q_t + \sum_{j=1}^{n} \pi_{ij} \Delta \log p_{jt} \tag{8.5}$$

The *Almost Ideal Demand System* (AIDS) was developed by Deaton and Muellbauer (1980b) and has the form

$$w_i = \alpha_i + \beta_i \log\left(\frac{M}{P}\right) + \sum_{j=1}^{n} \gamma_{ij} \log p_j \tag{8.6}$$

but now $P$ has a more complicated form given by

$$\log P = \alpha_0 + \sum_{k=1}^{n} \alpha_k \log p_k + \frac{1}{2}\sum_{k=1}^{n}\sum_{j=1}^{n} \gamma_{kj}^{*} \log p_j \log p_k$$

Deaton and Muellbauer suggest that in most circumstances it is possible to replace $P$ by an appropriate price index such as the Divisia index given above. The first difference form of (8.6) is

$$\Delta w_i = \beta_i \Delta \log\left(\frac{M}{P}\right) + \sum_{j=1}^{n} \gamma_{ij} \Delta \log p_j \tag{8.7}$$

Recognising that $Q = \dfrac{M}{P}$, this can be rewritten as

$$\Delta w_i = \beta_i \Delta \log Q + \sum_{j=1}^{n} \gamma_{ij} \Delta \log p_j \tag{8.8}$$

Comparing equations (8.5) and (8.8) shows that in first difference form the Rotterdam and AIDS models differ just in the form of the dependent variable. For the Rotterdam model the dependent variable is the difference in the logs of quantities weighted by value share while for the AIDS model it is just the value share.

In summary then there are a number of ways of specifying demand functions where either the quantity demanded or the share in expenditure is expressed as a function of income and own and competing good prices[i].

When applied to the demand for PBS medicines, these equations can be simplified to a great extent by recognising that the only "own price" that will have any influence on the patient's demand for a particular medicine is the relevant copayment for that class of patient and any premium that may be added by the manufacturer to the medicine. It has been shown earlier that the combination of copayment and premium is highly correlated with just the copayment itself which therefore means that all own prices must be highly correlated with competing prices – an outcome almost guaranteed by the operation of reference pricing within the PBS. The consequence is that only one price is required in the demand equation, namely the own price which is just the copayment plus premium (or the copayment by itself).

## 8.3 Previous studies of the demand for PBS medicines

Estimates of the impact of changes in copayments and other factors on the demand for PBS medicines have been undertaken by other researchers, notably Harvey (1984), Bureau of Industry Economics (BIE) (1985), Johnston (1990) and McManus et al (1996). Typically these studies concentrate on periods when there have been significant changes in the copayments.

Harvey (1984) provides estimates of both price and income elasticities for general patients firstly for the period 1967-68 to 1979-80 using annual data and secondly using monthly data for two periods – 1969-70 to 1971-72 and 1974-75 to 1976-77.

For his first set of estimates he specifies two forms of the demand equation a log-log version

$$\log GR_{it} = a_1 \log PR_t + a_2 \log WR_t + a_3 \log DR_t +$$
$$(1 + r_i) + a_5 \log ADDR_{it} + a_6 \log DELR_{it} + u_{it}$$

(8.9)

and a log-linear version

$$\log GR_{it} = a_1 \Delta P_t + a_2 \Delta W_t + a_3 \Delta D_t + a_4 +$$
$$a_5 \log ADDR_{it} + a_6 \log DELR_{it} + e_{it} \tag{8.10}$$

where $GR_{it}$ is the ratio of per capita use of general prescriptions at time t and t-1 for the i'th therapeutic group, $PR_t$ is the ratio of deflated patient contributions, $WR_t$ is the ratio of deflated AWE, $DR_t$ is the ratio of the ratio of doctors per 100,000 population and $ADDR$ and $DELR$ are terms to account for the addition and deletion of new medicines.

Harvey uses annual data on the number of prescriptions for general patients for 19 broad therapeutic groups for the years 1968-69 to 1979-80. He presents results based on using all the data within a single equation but for different intervals within the overall period. For the log-log specification all coefficients on the price variable are insignificant and are mostly insignificant for the doctor ratio variable. The income elasticity however is positive, generally significant and varies between 1.5 and 2.5. The log-linear version produces similar outcomes although the income elasticity is smaller and less significant, the price elasticity is somewhat more significant but has t-values less than or equal to 1.5, and the doctor variable generally has the wrong sign.

In a third set of estimates Harvey uses monthly prescription data on 13 medicines in four therapeutic groups for two periods July 1970 to June 1973 and July 1974 to June 1977 and for all months combined. He estimates equations for each medicine separately and for each of the four groups. Here however the equation is specified in levels form unlike the ratio form used in the previous analysis. Looking at the results for all months there are negative and significant elasticities for price for 7 of the 13 medicines, a positive and significant coefficient for the income elasticity for 1 medicine and a positive and significant coefficient for the doctor variable for 4 medicines. Where significant the price elasticity was in the range -0.1 to -0.2. For the four groups the price elasticity was negative and significant for 2 groups (diuretics and urinary antiseptics but not tetracyclines or penicillins) in the range -0.08 to -0.14.

In summary the evidence for a significant copayment elasticity is poor at the overall level and mixed at the detailed medicine level. Where present it lies in the range -0.1

to -0.2. By contrast the income elasticity is evident at the aggregate level but not at the detailed level and the doctor variable generally performs poorly.

The BIE (1985) estimates the demand for total PBS prescriptions per capita for non-pensioners using a simple linear equation with the copayment and average weekly earnings (AWE) as explanatory variables along with two different measures of doctor-patient contacts. Both the copayment and AWE are expressed in real terms and annual data from 1959-60 to 1980-81 is used. Based on the coefficients obtained the BIE estimate the elasticity with respect to the copayment as either -0.17 or -0.25 and the income elasticity as "around 3" (p85).

Johnston (1990) examines the effect of the doubling of the general copayment from $5 to $10 that occurred in November 1986 along with the introduction of the safety net. At this time pensioners continued to receive medicines free so the safety net of 25 prescriptions applied only to general and concessional patients. For both safety net groups medicines were then free – the copayment for general safety net patients was only introduced in 1991. At the same time the concessional copayment was raised from $2.00 to $2.50 but Johnston ignores this in his analysis. The doubling of the general copayment effectively introduced the problem that purchases of PBS medicines with prices below the general copayment level by general non-safety net patients were not recorded. Prior to that, according to Johnston, "in practice very few prescriptions dispensed to general patients attracted a charge of less than $5.00". To simplify his analysis, Johnston only considers the demand by general patients for medicines costing more than $10. This comprises some 340 items from a total of around 1200 at that time. He uses two sets of data – the first is for the four months from May to August in 1986 and 1987, i.e. before and after the increase in copayment, while the second is for the 24 months from May 1987 to April 1989. It should be noted that there was a further increase in the general copayment to $11 in July 1988 which is not considered.

Because the data on prescription use by safety net patients provided to him does not distinguish between former general and concessional patients Johnston uses the second dataset to estimate for each item how many general patient prescriptions fell into the safety net category after adjusting for the increase in demand by safety net

patients paying a lesser copayment. Using these estimates he adjusts the data for the first dataset and estimates an equation relating the number of adjusted prescriptions in 1987 to actual prescriptions in 1986. Based on this he estimates a very significant fall of 26.6% in general patient prescriptions due to the doubling of the general copayment, or an (uncompensated arc) elasticity of -0.47 for medicines costing more than $10. Using the second dataset he estimates the increase in general safety net patient use as 64% when moving from the copayment of $10 to zero, or an arc elasticity of -0.24. The elasticities are "uncompensated" because the procedure does not allow the calculation of an income elasticity.

McManus et al (1996) examine the impact on prescription use of the change in the general copayment from $11 to $15 in November 1990 (an increase of 36.4%) along with the introduction of a copayment of $2.50 for pensioners. The concessional copayment was unchanged. They also consider the effect on Repatriation patients of the introduction of a $2.50 copayment in January 1992. For both pensioners and Repatriation patients a compensating pharmaceutical allowance equal to 52 copayments per year was added to pensions. Unlike the other studies, McManus et al use the data on total community use based on the DUSC dataset described in Appendix A. This includes a component estimated from a survey of pharmacies for general non-safety net usage of medicines with a price below the general copayment. The data is monthly from July 1989 to September 1994 for the analysis of the demand for general prescriptions and from July 1987 to September 1994 for the Repatriation patients. Again there are further changes to general and concessional copayments and safety net levels during the period which are not considered within the analysis.

McManus et al define two categories of medicines – the first is "essential" medicines in 12 therapeutic groups primarily used for treating chronic conditions such as hypertension while the second consists of medicines in 9 therapeutic groups for "discretionary" conditions such as antihistamines. While the description is a little unclear, they appear to estimate equations for the two types of medicines where the dependent variable is the level of prescriptions and the explanatory variables are the underlying trend prior to change in the copayment, change in prescriptions after change in the copayment, the underlying trend after change and a "pulse" term to control for an anticipatory increase in prescriptions just prior to the change. Based on

the coefficients obtained, they find that community prescriptions for "discretionary medicines" were 24.8% lower than might have been expected without any change in the copayment, while the change for "essential" medicines was 18.1%. They also report that regression results for 9 of the 12 essential therapeutic groups estimated individually showed similar results to the aggregate results. They do not provide similar results for the Repatriation patients, although they report decreases in the level of prescriptions for both "essential" and "discretionary" categories.

This review of four studies provides mixed evidence of the impact of copayments on consumption of medicines although all find some effect at least within certain categories of medicines. Harvey, BIE and Johnston are necessarily restricted to estimating copayment elasticities for general patients and report values from -0.1 to -0.47 with most estimates being in the range -0.2 to –0.25. McManus et al do not report elasticities and do not distinguish between general and concessional patients, but find a differential response for categories of medicines. Only Harvey and BIE attempt to estimate an income elasticity and the values for this range between 1.5 and 3. None of the studies includes restriction levels or other influences except for the number of doctors which proves to be irrelevant.

## 8.4 Econometric analysis of the demand for PBS medicines

In undertaking an analysis of the demand for PBS medicines decisions must be made about a number of factors that will influence the scope and nature of the project. These largely revolve around the level of aggregation for the analysis, the choice of variables to include, and the specification of the equation.

At one extreme it is possible to envisage separate equations being estimated for each PBS item using the quantity and price data used in the index calculations. This is impractical for reasons other than the amount of resources required to do it. At most the number of annual observations available is 15 while for a majority of items the actual number will be significantly less with many having only a handful of observations. This means that it would be difficult to obtain meaningful estimates for the coefficients of variables within these equations.

The items within specific ATC3, ATC4, ATC5, and RPGs will often be close substitutes so research interest has usually concentrated on estimating the demand for the group as a whole and then separately estimating shares of medicines within the group. This approach has been adopted by most of the sectoral studies cited in Section 5.6 in Chapter 5. The challenge with estimating demand equations for suitably defined groups of medicines is how to construct the aggregate quantity variable and the difficulties associated with that have been discussed in Chapter 5. One way is to use the number of units for each medicine and aggregate them using the Defined Daily Dose equivalences from the WHO Collaborating Centre but as noted in Chapter 5 for some groups of medicines these are not defined. An alternative is to calculate quantity indexes based on the items within a group and use this as the quantity measure. While aggregation will result in more groups having a larger number of observations, there will still be relatively recent groups of medicines that will have significantly fewer observations than might be desired. Even if the chosen aggregation level is ATC3, this would still involve estimating over 70 equations.

Beyond a certain level of aggregation (such as ATC3 or ATC4) however the degree of substitutability among medicines diminishes sharply and it is not obvious what a quantity measure based on either DDDs or an index would be measuring.

A detailed analysis of the demand for groups of PBS medicines is beyond the scope of this thesis so two relatively simple approaches are used to gain some insights into the impact of various factors on the demand for PBS medicines by different types of patients.

The first approach is based on three alternative measures of the total quantity of PBS medicines consumed using annual data for the years from 1991-92 to 2005-06. The first quantity measure is the total number of units (such as tablets, capsules etc) of medicine calculated by multiplying the number of scripts at the item level by the maximum quantity for that item in the particular year and then summing across items. The second measure is the quantity index calculated for the relevant patient group and the third is the total expenditure for the patient category deflated by the price index for that category. This latter measure therefore includes the net new items which are excluded when calculating the quantity index. Based on the argument put forward in

Chapter 7, these last two quantity measures are quality-adjusted indicators of consumption.

The explanatory variables considered consist of measures of price and income, as well as three other potential influences on demand: the number of PBS medicines (molecules) available in a particular year, measures of restriction levels and the effect of safety net limits. Two variants of the price variable are tested – the relevant patient price index which includes the effect of both the relevant copayment and any price premium, and just the copayment itself. Any difference in the results using these two alternative price measures should therefore reflect the influence of the price premium. In the absence of income variables specific to the different patient categories, the candidates for the income variable are the level of household disposable income, and the level of household consumption expenditure both being deflated by the deflator for household consumption expenditure. Data on household disposable income and consumption expenditure were obtained from RBA (2007c). A third income variable was considered, namely average weekly earnings deflated by the deflator for household consumption expenditure but this proved significantly inferior to the other measures in initial results and was discarded. The number of medicines available is measured by the number of molecules listed on the PBS in each year. Restriction levels are measured using the proportion of PBS items in a particular year that fall into the three restriction categories – "Authority required" (A), "Restricted benefit" (R) and "Unrestricted" (U). Finally the safety net limits are expressed as the number of copayments required to reach the safety net limit within a particular year.

The second approach adopted for demand estimation uses the same set of variables and data but the observations are defined at the item level rather than being aggregated to the whole of PBS level. This provides many more observations and degrees of freedom.

There are other factors that are likely to influence the demand for PBS medicines such as the growth in the number of patients in each patient category and the amount of promotional activity undertaken by pharmaceutical companies but in the absence of data for each year in the period of analysis it was not possible to include these within the regression analysis.

In summary the variables considered for the aggregate equations are

$qu_{tc}$        the number of units in year t for patient category c

$qi_{tc}$        the quantity index in year t for patient category c

$qe_{tc}$        deflated PBS expenditure in year t for patient category c, converted to an index

$pp_{tc}$        the patient price index in year t for patient category c

$cop_{tc}$        the copayment in year t for patient category c

$incd_t$        household disposable income divided by deflator for household consumption expenditure in year t

$cond_t$        real household consumption expenditure in year t

$mol_t$        the number of PBS medicines (molecules) available in year t

$cclm_t$        the number of concessional copayments to reach the concessional safety net limit in year t

$gclm_t$        the number of general copayments to reach the general safety net limit in year t

$Ap_t$        the proportion of items with an "Authority required" restriction level in year t

$Rp_t$        the proportion of items with a "Restricted benefit" restriction level in year t

For the equations estimated using the detailed item level data the variables are as indicated above except for

$qu_{itc}$        the number of units of item i in year t for patient category c

$pp_{itc}$        the patient price for item i in year t for patient category c

$A_{it}$        a dummy variable indicating whether item i had an "Authority required" restriction level in year t or not

$R_{it}$        a dummy variable indicating whether item i had a "Restricted benefit" restriction level in year t or not

$ATC1_{kit}$        a dummy variable indicating whether item i had an ATC1 code of k in year t or not

$ATC3_{kit}$        a dummy variable indicating whether item i had an ATC3 code of k in year t or not

$ATC4_{kit}$        a dummy variable indicating whether item i had an ATC4 code of k in year t or not

$ATC5_{kit}$        a dummy variable indicating whether item i had an ATC5 code of k in year t or not

The regression results reported in the next section are only for the logarithmic version of the demand equation similar to equation (8.2) above in which all the variables are expressed in logarithmic form except for the dummy variables and the restriction variable. By and large, estimating linear equations with the variables untransformed gives similar if slightly inferior results so these are not reported. An "$l$" in front of a variable indicates the natural logarithm.

### 8.4.1 Results for General Non-Safety Net (GNSN) patients

The results of estimating equations for demand for PBS medicines by the GNSN category of patients are given in Tables 8.1 to 8.7. Firstly Table 8.1 reports those results for the logarithmic form of the equation with the number of units as the dependent variable. Here the equations are specified as the classical demand function with just a price and income variable.

**Table 8.1     GNSN patient demand results, lqu (1)**

| Equation | 1 | | 2 | | 3 | | 4 | |
|---|---|---|---|---|---|---|---|---|
| Dep. variable | lqu | | lqu | | lqu | | lqu | |
| | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat |
| constant | -17.313 | -3.2 | -16.579 | -2.5 | -13.086 | -2.7 | -9.968 | -1.6** |
| lpp | -1.208 | -3.7 | | | -1.367 | -3.9 | | |
| lcop | | | -1.120 | -2.9 | | | -1.095 | -2.5 |
| lincd | 2.947 | 6.9 | 2.890 | 5.5 | | | | |
| lcond | | | | | 2.643 | 6.8 | 2.395 | 4.9 |
| | | | | | | | | |
| Adjusted $R^2$ | 0.940 | | 0.924 | | 0.939 | | 0.911 | |
| D-W | 1.276 | | 1.081 | | 1.022 | | 0.824 | |

The best results are obtained with the patient price index as the price variable and household disposable income as the income variable (equation 1). However using household consumption expenditure gives very similar results in terms of equation fit and significance of coefficients. Using the copayment as the price variable results in somewhat poorer fit statistics although the price and income coefficients are still significant. The patient price performs better than the copayment in terms of fit and significance and the elasticity with respect to the patient price is higher than with respect to the copayment. However this difference is not large and implies a price elasticity in the range -1.4 to -1.1. The implied income elasticity is in the range 2.9 to 2.4.

It is clear from the Durbin-Watson statistics that the specification of the equation can be improved by the addition of further explanatory variables. The difficulty is that the process of adding more variables reduces the already small number of degrees of freedom. Experimentation with the candidates for inclusion demonstrated that the number of molecules gives the best results, so the results reported in Table 8.2 show the regression results from adding this variable to those in Table 8.1.

**Table 8.2**     **GNSN patient demand results, lqu (2)**

| Equation | 1 | | 2 | | 3 | | 4 | |
|---|---|---|---|---|---|---|---|---|
| **Dep. variable** | **lqu** | | **lqu** | | **lqu** | | **lqu** | |
| | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat |
| constant | -17.176 | -6.2 | -18.733 | -5.5 | -13.552 | -4.3 | -13.250 | -3.3 |
| lpp | -1.293 | -7.7 | | | -1.296 | -5.5 | | |
| lcop | | | -1.352 | -6.7 | | | -1.208 | -4.3 |
| lincd | 1.664 | 5.4 | 1.612 | 4.7 | | | | |
| lcond | | | | | 1.417 | 3.6 | 1.114 | 2.5 |
| lmol | 2.534 | 5.9 | 2.886 | 6.0 | 2.488 | 4.1 | 3.040 | 4.2 |
| | | | | | | | | |
| Adjusted $R^2$ | 0.984 | | 0.980 | | 0.974 | | 0.963 | |
| D-W | 2.051 | | 2.168 | | 1.385 | | 1.494 | |
| ADF | -3.573 | | -2.755 | | -3.160 | | -3.088 | |
| Prob. | 0.025 | | 0.094 | | 0.049 | | 0.051 | |

It can be seen that adding the number of molecules improves the fit of the equations in terms of adjusted coefficient of determination and the Durbin-Watson statistic. Furthermore all coefficients are significant with the expected signs. Again the patient price index and household disposable income provide the best combination. The implied price elasticities are largely unchanged in the range -1.2 to -1.4 but the implied income elasticities are halved to be in the range 1.1 to 1.7. The elasticity of demand with respect to the number of medicines available demonstrates the largest effect ranging from 2.5 to 3.0.

Aside from the limited number of observations, the analysis of the demand for PBS medicines is restricted by the high degree of collinearity among the dependent and independent variables as demonstrated by the correlation coefficients in Table 8.3. All variables with the exception of the restriction and safety net variables show strong time trends and there are also strong correlations among the income, price and number of molecules variables. This multicollinearity means that the standard errors for the coefficients in the results quoted are likely to be overestimated and hence the t-statistics are underestimated. It becomes harder to judge the significance of coefficients if an attempt is made to add further explanatory variables which are also collinear with the other explanatory variables.

**Table 8.3        Correlation coefficients among variables**

|        | lqu   | lqi   | lqe   | lpp   | lcop  | lincd |
|--------|-------|-------|-------|-------|-------|-------|
| lqu    | 1.000 | 0.983 | 0.979 | 0.863 | 0.878 | 0.944 |
| lqi    | 0.983 | 1.000 | 0.998 | 0.935 | 0.945 | 0.983 |
| lqe    | 0.979 | 0.998 | 1.000 | 0.943 | 0.951 | 0.987 |
| lpp    | 0.863 | 0.935 | 0.943 | 1.000 | 0.998 | 0.974 |
| lcop   | 0.878 | 0.945 | 0.951 | 0.998 | 1.000 | 0.978 |
| lincd  | 0.944 | 0.983 | 0.987 | 0.974 | 0.978 | 1.000 |
| lcond  | 0.940 | 0.980 | 0.986 | 0.977 | 0.979 | 0.996 |
| lmol   | 0.960 | 0.986 | 0.989 | 0.956 | 0.965 | 0.978 |
| ap     | 0.748 | 0.833 | 0.852 | 0.941 | 0.922 | 0.902 |
| lgclm  | 0.865 | 0.839 | 0.813 | 0.682 | 0.714 | 0.761 |
| ltime  | 0.974 | 0.977 | 0.966 | 0.868 | 0.886 | 0.932 |

|        | lcond | lmol  | ap    | lgclm | ltime |
|--------|-------|-------|-------|-------|-------|
| lqu    | 0.940 | 0.960 | 0.748 | 0.865 | 0.974 |
| lqi    | 0.980 | 0.986 | 0.833 | 0.839 | 0.977 |
| lqe    | 0.986 | 0.989 | 0.852 | 0.813 | 0.966 |
| lpp    | 0.977 | 0.956 | 0.941 | 0.682 | 0.868 |
| lcop   | 0.979 | 0.965 | 0.922 | 0.714 | 0.886 |
| lincd  | 0.996 | 0.978 | 0.902 | 0.761 | 0.932 |
| lcond  | 1.000 | 0.982 | 0.915 | 0.741 | 0.923 |
| lmol   | 0.982 | 1.000 | 0.850 | 0.809 | 0.957 |
| ap     | 0.915 | 0.850 | 1.000 | 0.456 | 0.720 |
| lgclm  | 0.741 | 0.809 | 0.456 | 1.000 | 0.899 |
| ltime  | 0.923 | 0.957 | 0.720 | 0.899 | 1.000 |

Nonetheless it is worthwhile to see the effect that these variables might have if they replace the number of molecules variable in the equation with patient price and household income as the other explanatory variables. The only version of the restriction variable that produces meaningful results is the proportion of items with an "Authority required" restriction and the equation using this variable is given in Table 8.4. The restriction variable has the expected sign implying that an increase will lead to a fall in demand but the coefficient is not significant and the patient price variable also becomes insignificant at the 5% level. The fit statistics are also poorer.

The equation which includes the number of copayments required to meet the general safety net limit is somewhat stronger and the coefficient is both significant and has the expected sign. This is because an increase in the number of copayments means that more patients stay within the general non-safety net category adding to demand within that category. Results using other combinations of price and income produce similar results although coefficients in some cases are more significant and fit statistics

improved. However the best results are still obtained with the number of molecules as the other explanatory variable.

**Table 8.4      GNSN patient demand results, lqu (3)**

| Equation | 1 | | 2 | | 3 | | 4 | |
|---|---|---|---|---|---|---|---|---|
| Dep. variable | lqu | | lqu | | lqu | | lqu | |
| | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat |
| constant | -15.594 | -3.1 | -7.300 | -2.5 | -9.795 | -1.9* | 5.728 | 3.3 |
| lpp | -0.747 | -1.9* | | | -0.897 | -3.1 | | |
| lincd | 2.818 | 7.1 | 2.165 | 9.4 | 2.278 | 5.3 | 1.015 | 6.3 |
| Ap | -0.895 | -1.9* | -1.474 | -3.6 | | | | |
| lgclm | | | | | 0.291 | 2.7 | 0.423 | 3.3 |
| | | | | | | | | |
| Adjusted $R^2$ | 0.950 | | 0.939 | | 0.960 | | 0.932 | |
| D-W | 1.343 | | 1.119 | | 1.907 | | 1.356 | |

Given the correlations among the variables and with the time trend it is not surprising that most of the variables are non-stationary when tested for a unit root using the Augmented Dickey-Fuller (ADF) test. In the equations in Table 8.2, the Durbin-Watson statistics are high compared to the adjusted coefficient of determination which does not suggest a spurious regression according to the rule of thumb suggested by Granger and Newbold (Gujarati 2003). Nonetheless the reported equations were tested for cointegration by testing their residuals for stationarity again using the ADF test (as suggested by Gujarati). Cointegration means that the equation represents a valid long-run relationship among the variables and this is demonstrated by the ADF test statistics. To test for short-run disequilibrium the Error Correction Mechanism (ECM) approach is used which involves estimating the equation in first difference form and including as a further variable the lagged estimated residuals from the original equation. The coefficient on this latter variable indicates how quickly the short-run disequilibrium returns to long-run equilibrium.

Table 8.5 reports the results of estimating such ECM equations which parallel those in Table 8.2.

**Table 8.5    GNSN patient demand results, lqu, ECM**

| Equation | 1 | | 2 | | 3 | | 4 | |
|---|---|---|---|---|---|---|---|---|
| Dep. variable | $\Delta$ lqu | | $\Delta$ lqu | | $\Delta$ lqu | | $\Delta$ lqu | |
| | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat |
| constant | 0.014 | 0.5 | -0.011 | -0.5 | 0.009 | 0.2 | -0.007 | -0.2 |
| lpp | -1.224 | -5.7 | | | -1.094 | -3.9 | | |
| lcop | | | -1.048 | -4.9 | | | -0.822 | -2.6 |
| lincd | 1.205 | 2.1 | 1.414 | 2.6 | | | | |
| lcond | | | | | 1.012 | 1.2 | 0.936 | 1.0 |
| lmol | 2.476 | 4.2 | 3.220 | 5.2 | 2.469 | 3.5 | 3.041 | 3.5 |
| residual term | -1.007 | -2.9 | -1.324 | -4.2 | -0.837 | -2.2 | -1.008 | -2.7 |
| | | | | | | | | |
| Adjusted $R^2$ | 0.805 | | 0.813 | | 0.731 | | 0.643 | |
| D-W | 2.195 | | 1.797 | | 2.063 | | 1.730 | |

Comparing equation 1 in both tables shows that the coefficients on the patient price and the number of molecules are largely unchanged but the income term becomes weaker and less significant. With the copayment replacing the patient price, the price elasticity falls a little, and the income and number of molecules terms become stronger and more significant. With household consumption expenditure as the income term the results are less satisfactory although the price and number of molecules variables are still significant. The implied price elasticities are somewhat less than in the previous equations. The coefficients on the lagged residuals term are large and significant implying a significant period of adjustment from short-term disequilibrium to longer term equilibrium.

If the quantity index is used as the dependent variable rather than the number of units, the results are broadly similar to those just reported in terms of both fit statistics and coefficients on variables. The price, income and number of molecules variables are significant with the expected signs on the coefficients. The implied price elasticities are somewhat less but closer together in the range -1.2 to -1.0. Both the elasticities with respect to income and the number of molecules are significantly higher being in the range from 1.8 to 2.7 and 3.5 to 4.0 respectively. The larger elasticities when the quantity index is used as the dependent variable rather than the number of units may indicate that the elasticities are expressing both a quantity and a "quality" component in the response of patients to changes in the explanatory variables. Table 8.6 reports the preferred equation and its ECM equivalent

**Table 8.6       GNSN patient demand results, lqi**

| Equation | 1 | | 2 | |
|---|---|---|---|---|
| **Dep. variable** | **lqi** | | $\Delta$ **lqi** | |
| | Coeff | t-stat | Coeff | t-stat |
| constant | -55.573 | -10.9 | 0.091 | 2.6 |
| lpp | -1.143 | -3.7 | -1.096 | -4.1 |
| lincd | 2.683 | 4.7 | 0.866 | 1.2 |
| lmol | 3.480 | 4.4 | 1.722 | 1.9 |
| residual term | | | -0.740 | -2.7 |
| | | | | |
| Adjusted $R^2$ | 0.988 | | 0.604 | |
| D-W | 2.050 | | 2.019 | |
| ADF | -4.391 | | | |
| Prob | 0.005 | | | |

The ADF test on the residuals of the equation indicates a cointegrating relationship but the coefficients on the income and number of molecules variables in the ECM equation lose significance with the main explanation for short-run disequilibrium being the change in prices. Although not reported, substituting either the restriction or the safety net limit variable for the number of molecules gives significant coefficients of the expected sign for these variables but in combination with the price variables produces insignificant coefficients for the latter. Again the best results come from using the number of molecules variable with the price and income variables.

If the deflated PBS expenditure series is used as the quantity measure for the dependent variable, the difference in regression outcomes is enhanced. The coefficients on the income and number of molecules variables increase further although the price elasticities remain with a range of -1.2 to -1.3. The ADF tests indicate the variables are cointegrated and the ECM equations show significant coefficients on the price and number of molecules variables but the income term is not significant. The preferred equation and its ECM equivalent are given in Table 8.7. As the dependent variable includes net new items in addition to the common items as well as the possible "quality" component this may explain the greater response of patients as measured by the higher elasticities for income and the number of molecules.

**Table 8.7    GNSN patient demand results, lqe**

| Equation | 1 | | 2 | |
|---|---|---|---|---|
| **Dep. variable** | **lqe** | | **Δ lqe** | |
| | Coeff | t-stat | Coeff | t-stat |
| constant | -67.370 | -13.4 | 0.107 | 3.6 |
| lpp | -1.208 | -3.9 | -1.322 | -5.3 |
| lincd | 3.240 | 5.8 | 1.004 | 1.5 |
| lmol | 4.235 | 5.4 | 2.574 | 3.5 |
| residual term | | | -0.768 | -3.4 |
| | | | | |
| Adjusted $R^2$ | 0.993 | | 0.730 | |
| D-W | 1.987 | | 2.636 | |
| ADF | -3.572 | | | |
| Prob | 0.022 | | | |

To this point, regression results have been reported for aggregate analysis based on 15 annual observations. An alternative approach using quantity and price data for each PBS item within the dataset can be used to estimate the demand equation for each patient category. Here a quasi-panel approach is adopted with the dependent variable being the number of units of item i in year t and the equation specified as follows

$$q_{it} = \alpha + \beta p_{it} + \gamma M_t + \delta c_t + \chi \sum_{r=1}^{R} RES_{it}^r + \eta \sum_{k=1}^{K} ATC_{it}^k + u_{it} \tag{8.11}$$

In contrast to the aggregate approach there is only one measure of quantity and that is the number of units for the item in a specific year, measured as the number of scripts times the average maximum quantity. This is the same quantity measure used in deriving the price and quantity indexes. Two price variables are considered. The first is the patient price derived by dividing the patient cost by the quantity measure and again this is the raw data used in the calculation of the price and quantity indexes. The second price considered is the average copayment for the year and is hence the same for all items in that year. As previously, two income variables are considered – household disposable income and household consumption expenditure – and these are also the same for each item in a particular year. The *c* variable represents the number of copayments required to reach the safety net limit which varies by year but not by item. A set of dummy variables are used to account for the restriction status (*RES*) of the item and another set of dummy variables are used to control for the ATC code of the item. The values of both of these dummy variables can vary among items and from year to year. As with the equations at the aggregate level, only results for the

logarithmic version are reported as these are generally superior to those using untransformed variables.

The dataset for the regression analysis is formed by "stacking" the block of observations for one year on top of the following year. Data is therefore ordered first by item then by year. The data is not a complete panel because there are not observations for all items in all years. However it is possible to organize the data as a balanced panel within the EViews software package (Quantitative Micro Software 2007) with the missing observations acknowledged as such and ignored in the analysis. Organising the data in this way has the advantage of enabling time-ordered diagnostics to be computed even though the regression analysis is based just on OLS without any panel effects being specified. These are accounted for in part by the dummy variables.

Table 8.8 reports the results of estimating equation (8.11) with the patient price as the price variable and household income as the income variable.

Substituting the copayment and household consumption expenditure produces similar results although the overall fit is worse. The only difference among equations 1-5 in Table 8.8 is that the ATC code dummy variables are defined at successively higher ATC levels beginning with no ATC dummy variables, then those defined at ATC1, ATC3, ATC4 and ATC5 levels.

It is obvious from Table 8.8 that as the ATC codes become more specific to the actual item the fit of the equations improves considerably at least when measured by the adjusted $R^2$. The coefficient on the patient price variable is relatively unchanged and is in the range -1.4 to -1.2. However the coefficient on the income variable reduces with higher levels of ATC code and becomes insignificant at the ATC5 level. The coefficient of the number of copayments to reach the general safety net limit is significant and has the expected sign but also reduces as ATC level increases. The only restriction variable that has any impact is the dummy variable for "Authority required" or not and while significant has an unexpected positive sign except at ATC5 when the sign becomes negative.

**Table 8.8  GNSN patient demand results, item level data, n=18005**

| Equation | 1 | | 2 | | 3 | | 4 | |
|---|---|---|---|---|---|---|---|---|
| Dep. variable | lqu | | lqu | | lqu | | lqu | |
| | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat |
| constant | -17.413 | -6.4 | -14.641 | -5.6 | -10.604 | -4.3 | -8.217 | -3.4 |
| lpp | -1.363 | -103.4 | -1.251 | -84.3 | -1.218 | -76.7 | -1.233 | -74.8 |
| lincd | 1.783 | 7.1 | 1.464 | 6.1 | 0.963 | 4.3 | 0.830 | 3.8 |
| lgclm | 1.057 | 4.9 | 1.085 | 5.3 | 0.887 | 4.6 | 0.684 | 3.8 |
| A | 0.513 | 9.3 | 0.706 | 13.2 | 0.625 | 11.1 | 0.359 | 6.2 |
| ATC level | | | ATC1 | | ATC3 | | ATC4 | |
| | | | | | | | | |
| Adjusted $R^2$ | 0.381 | | 0.437 | | 0.511 | | 0.560 | |
| D-W | 0.115 | | 0.127 | | 0.147 | | 0.166 | |

| Equation | 5 | | 6 | | 7 | |
|---|---|---|---|---|---|---|
| Dep. variable | lqu | | lqu | | lqu | |
| | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat |
| constant | 3.592 | 1.3 | 2.675 | 1.6 | -1.133 | -0.6 |
| lpp | -1.274 | -73.7 | -1.275 | -74.7 | | |
| lcop | | | | | -1.614 | -10.5 |
| lincd | -0.085 | -0.4 | | | | |
| lgclm | 0.519 | 3.2 | 0.468 | 4.1 | 0.570 | 3.2 |
| A | -0.460 | -6.9 | -0.460 | -6.9 | -0.457 | -6.0 |
| ATC level | ATC5 | | ATC5 | | ATC5 | |
| | | | | | | |
| Adjusted $R^2$ | 0.644 | | 0.644 | | 0.535 | |
| D-W | 0.201 | | 0.201 | | 0.156 | |
| Pedroni test | 11/11 | | 9/11 | | 9/11 | |

Omitting the income variable gives equation 6 as the preferred equation in Table 8.8 and the Pedroni Residual Cointegration Test within EViews indicates that the variables (excluding the ATC dummy variables) for this equation are cointegrated. Table 8.8 also shows the results if the copayment is substituted for the patient price. In this latter case, although all variables have significant coefficients, the overall fit of the equation has diminished.

The demand elasticities of the patient price and the copayment implied by these equations are close to those values derived from the aggregate equations.

### 8.4.2 Results for Concessional Non-Safety Net (CNSN) patients

When equations are estimated explaining the demand for PBS medicines by Concessional Non-Safety Net (CNSN) patients with (the logarithm of) the number of

units as the dependent variable, the outcomes are similar to those for General Non-Safety Net patients in that the price and income variables are significant and the fit statistics quite similar. The number of molecules variable is significant when household disposable income is the income variable but not for household consumption expenditure. However the implied price elasticities are less than half those for GNSN patients and are in a much tighter range from -0.43 to -0.47. Similarly the income elasticities are almost half those for GNSN patients in the range 0.64 to 0.90. The elasticity for the number of molecules ranges between 0.53 and 0.73. The ADF test statistics indicate cointegrating relationships among the variables and the corresponding short-term ECM equations give broadly similar results although those including household consumption expenditure perform poorly. Replacing the number of molecules by the restriction variable leads to poorer results although the variable itself has a significant coefficient of the expected sign when the income variable is household consumption expenditure. Similarly the number of copayments to reach the safety net limit performs poorly as an explanatory variable. Equation 1 in Table 8.9 reports the preferred equation with patient price, household disposable income and number of molecules as explanatory variables.

If the quantity index or deflated PBS expenditure is used as the dependent variable the results again mirror the experience with GNSN patients. There is an improvement in fit statistics and an increase in the values of the coefficients on the price, income and number of molecules variables. With the quantity index equations the price and income elasticity ranges are -0.76 to -0.86 and 2.11 to 2.41 respectively while the range for the elasticity for the number of molecules increases dramatically to 2.41 to 2.87. With deflated PBS expenditure as the dependent variable the ranges are even higher at -0.73 to -0.94 for the price elasticity and 2.63 to 2.77 and 2.48 to 3.24 for the income and number of molecules elasticities. The preferred equations for both variants of the demand equation are given as equations 2 and 3 in Table 8.9.

**Table 8.9** **CNSN patient demand results**

| Equation | 1 | | 2 | | 3 | |
|---|---|---|---|---|---|---|
| **Dependent variable** | **lqu** | | **lqi** | | **lqe** | |
| | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat |
| constant | 7.184 | 6.1 | -47.184 | -15.7 | -53.375 | -13.5 |
| lpp | -0.439 | -6.2 | -0.756 | -4.2 | -0.731 | -3.1 |
| lincd | 0.895 | 6.3 | 2.404 | 6.6 | 2.717 | 5.7 |
| lmol | 0.533 | 2.6 | 2.698 | 5.2 | 3.053 | 4.5 |
| | | | | | | |
| Adjusted $R^2$ | 0.981 | | 0.994 | | 0.993 | |
| D-W | 1.122 | | 2.001 | | 1.100 | |
| ADF | -5.543 | | -4.312 | | -2.697 | |
| Prob. | 0.006 | | 0.007 | | 0.105 | |

Using the detailed data on units and prices for CNSN patients, the demand equations results are somewhat different from those for GNSN patients. While the patient price is strongly significant, the copayment performs poorly as the price variable. The income variable is significant at all ATC levels including ATC5 but the number of concessional copayments to reach the safety net limit is always insignificant. By contrast, including dummy variables for the "Authority required" and Restricted Benefit" restriction classifications produces strongly significant coefficients with the expected signs at all ATC levels and the effect is much stronger for the "A" items than for the "R" items. In general the fit off the equation improves as the ATC level increases. The implied price elasticity for the preferred equation at the ATC5 level is -1.39 and this is significantly higher than suggested by the aggregate equations but very close to that for GNSN patients (Table 8.10).

**Table 8.10** **CNSN patient demand results, item level data, n=23612**

| Dependent variable | lqu | |
|---|---|---|
| | Coeff | t-stat |
| constant | -24.476 | -2.0 |
| lpp | -1.395 | -95.6 |
| lincd | 1.223 | 8.2 |
| lcclm | 4.038 | 1.2 |
| A | -1.877 | -27.2 |
| R | -0.622 | -11.5 |
| ATC level | ATC5 | |
| | | |
| Adjusted $R^2$ | 0.627 | |
| D-W | 0.099 | |
| Pedroni tests | 9/11 | |

### 8.4.3 Results for General Safety Net (GSN) patients

While the regression analyses of the demand for PBS medicines by patients within the general and concessional non-safety net categories produce robust results and significant estimates for elasticities, the results for patients within the two safety net categories are much weaker.

For General Safety Net (GSN) patients the only significant variables are income and the copayment limit in equations estimated using aggregate data. Patient price, copayment, the number of molecules and restriction levels all produce insignificant coefficients. The best regression result is shown as equation 1 in Table 8.11 with the household disposable income and the number of copayments to reach the general safety net limit as explanatory variables, with the latter variable lagged by one year. The fit statistics of the equation is much poorer than those for the previous two patient categories. The income elasticity is in the range 1.15 to 1.38 and the coefficient on the lagged copayment limit is significant and has the expected sign, indicating a reduced demand when the copayment is increased as more patients remain within the general non-safety net category. The ADF tests indicate a cointegrating relationship.

**Table 8.11    GSN patient demand results**

| Equation | 1 | | 2 | | 2 | |
|---|---|---|---|---|---|---|
| Dependent variable | lqu | | lqi | | lqe | |
| | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat |
| constant | 4.398 | 1.1 | -40.852 | -10.0 | -45.615 | -10.8 |
| lincd | 1.377 | 3.6 | 3.461 | 9.3 | 3.846 | 10.1 |
| lgclm(-1) | -0.907 | -3.2 | -0.698 | -2.5 | -0.731 | -2.6 |
| | | | | | | |
| Adjusted $R^2$ | 0.475 | | 0.911 | | 0.924 | |
| D-W | 2.462 | | 2.481 | | 2.473 | |
| ADF | -4.385 | | -4.493 | | -4.455 | |
| Prob. | 0.006 | | 0.005 | | 0.005 | |

The equations with the quantity index and deflated PBS expenditure as dependent variables show similar outcomes although there is a big jump in the fit statistics (equations 2 and 3 in Tables 8.11). As with the other patient categories the coefficient on the income variable increases markedly and the coefficient on the copayment limit becomes somewhat smaller in absolute terms.

Using item level data for quantity and price, the results are quite different. In this circumstance all the variables are significant and have their expected signs at all ATC levels. The preferred equation given in Table 8.12 which includes ATC5 dummy variables has an implied patient price elasticity of -1.37 and this is very close to that for the same equation for CNSN patients.

**Table 8.12      GSN patient demand results, item level data, n=21470**

| Dependent variable | lqu | |
| --- | --- | --- |
| | Coeff | t-stat |
| constant | -16.463 | -8.0 |
| lpp | -1.371 | -105.0 |
| lincd | 1.722 | 11.0 |
| lgclm | -0.706 | -5.4 |
| A | -1.428 | -23.2 |
| R | -0.457 | -9.6 |
| ATC level | ATC5 | |
| | | |
| Adjusted $R^2$ | 0.659 | |
| D-W | 0.188 | |
| Pedroni tests | 9/11 | |

It should be remembered that GSN and CNSN patients both pay the same concessional copayment so the patient price series in both cases will be very similar. The income coefficient is also significant at ATC5 level although somewhat higher in value than for CNSN patients. Both the "A" and "R" restriction dummy variables are significant, have the expected signs and the same sort of disparity in value. For GSN patients however the number of copayments to reach the safety net limit is significant and negative. This is the mirror of the positive coefficient for GNSN patients. Again like the GNSN patients, replacing the patient price by the copayment gives significant results although poorer overall fit. It makes very little difference if household consumption expenditure is used as the income variable.

### 8.4.4 Results for Concessional Safety Net (CSN) patients

For the equations explaining demand for PBS medicines by Concessional Safety Net (CSN) patients only the income variable proves to be significant at the aggregate level. Because there is no copayment for CSN patients there is no price variable to be used in the demand equations. While the lagged copayment limit has the expected negative sign in the preferred equation with units as the dependent variable, it is still

insignificant at the 5% level (equation 1 in Table 8.13). Despite this however, the overall fit for the equations is quite good, perhaps reflecting a strong time trend within the data. The ADF test statistic point to a cointegrating relationship although the ECM equations are dominated by the ECM term. The implied income elasticity is 1.58. Similar results are obtained with the quantity index or deflated PBS expenditure as the dependent variable and again the coefficient on the income term becomes much larger (equations 2 and 3 in Table 8.13).

**Table 8.13    CSN patient demand results**

| Equation | 1 | | 2 | | 3 | |
|---|---|---|---|---|---|---|
| Dependent variable | lqu | | lqi | | lqe | |
| | Coeff | t-stat | Coeff | t-stat | Coeff | t-stat |
| constant | 37.293 | 1.8 | -28.403 | -1.7 | -25.982 | -1.4 |
| lincd | 1.576 | 15.4 | 4.008 | 21.6 | 4.281 | 21.5 |
| lcclm(-1) | -9.311 | -1.8 | -5.547 | -1.2 | -7.034 | -1.4 |
| | | | | | | |
| Adjusted $R^2$ | 0.954 | | 0.979 | | 0.979 | |
| D-W | 1.592 | | 1.564 | | 1.450 | |
| ADF | -2.771 | | -4.717 | | -4.269 | |
| Prob. | 0.010 | | 0.000 | | 0.000 | |

For equations using data defined at the item level, the regression results show no significance for either the income term or for the copayment limit term although both have the expected signs (Table 8.14). The only significant explanatory variables are the "A" and "R" restriction dummy variables and again they have the expected sign and the disparity between their coefficients is the same as that seen for both GSN and CNSN patients.

**Table 8.14    CSN patient demand results, item level data, n=22248**

| Dependent variable | lqu | |
|---|---|---|
| | Coeff | t-stat |
| constant | 12.492 | 0.9 |
| lincd | 0.182 | 1.0 |
| lcclm | -2.767 | -0.7 |
| A | -1.523 | -18.7 |
| R | -0.379 | -5.9 |
| ATC level | ATC5 | |
| | | |
| Adjusted $R^2$ | 0.496 | |
| D-W | 0.101 | |
| Pedroni tests | 10/11 | |

## 8.5 Summary of econometric analysis

The results quoted in the previous section show that the demand for PBS medicines is significantly influenced by two of the policy instruments controlled by the Government. On the one hand demand increases more than proportionately to the steadily increasing number of medicines made available through the operation of the PBS listing procedures. As the PBAC makes available more choice among medicines to treat particular diseases and introduces medicines for diseases previously untreated or poorly treated, doctors prescribe these for their patients reducing the burden of disease. On the other hand demand is reduced when Governments increase the amount patients are required to pay for these medicines and to a lesser extent when manufacturers change the premium they add to the base dispensed price.

For General Non-Safety Net (GNSN) patients the patient price elasticity is in the range -1.1 to -1.4, while for Concessional Non-Safety Net (CNSN) patients it is significantly lower in the range -0.5 to -0.9. The situation is less clear with General Safety Net (GSN) patients although analysis using detailed data suggests an elasticity of -1.4. The demand elasticities with respect to either the patient price or the copayment are significantly higher than those found in previous studies of the demand for PBS medicines. They are however similar to recent estimates made by Berndt, Danzon and Kruse (2007) who report own-price elasticities in the range -0.75 to -1.1 based on an analysis using IMS health data from 1992 to 2003 across 15 countries, not including Australia.

The income elasticity is generally significant but there is more variability in the estimates depending on how the dependent variable is defined and at what level the analysis is undertaken. The elasticity is higher if the quality-adjusted quantity variables are used rather than the number of units for all categories of patients. The elasticity with respect to the number of molecules also shows the same tendency to increase. For most of the regression analyses the elasticities with respect to income and the number of molecules is significantly higher than one. The estimates show significant contributions to the demand for PBS medicines from rising incomes and as the number of medicines available on the PBS increases.

There is further evidence that when the Government imposes an "Authority required" restriction level on a PBS item this restricts demand for that item. Other restriction levels seem not to have this effect.

The level of the copayment set by the Government has the dual effect of both reducing demand because of its price effect and of shifting the share of the cost to the patient and away from the Government. Changes to the safety net limit however shift demand within a patient category between those covered by the safety net and those not covered. Increases in the safety net limit reduce demand within the safety net category and again lead to shifts in the shares of cost borne by patients and the Government.

While these effects are generally true for all PBS patients, there are significant differences among the patient categories. General patients display a greater reaction to changes in the patient price than do concessional patients. One explanation for this may lie in the types of medicines consumed by both groups. If concessional patients have a higher proportion of chronic conditions or conditions displaying symptoms then changes in prices may have less influence on their purchasing decisions. If general patients have more acute conditions or asymptotic conditions they may be more influenced by changes in prices. It should be remembered however that the concessional copayment is less than a sixth the value of the general copayment and this may not be fully accounted for in the regression results. The difference in conditions experienced by general and concessional patients may also explain their differential responses to the number of molecules and income.

The demand by general patients also seems to be more sensitive to changes in the safety net limit than is the demand by concessional patients. This may simply reflect the fact that the safety net limit for concessional patients changed very little for most of the period.

For both general and concessional patients, the responsiveness of patients to changes in the explanatory variables as measured by the elasticities increase when different measures of quantity are used. Moving from the number of units to the quantity index may be adding a "quality" factor to the quantity measure and the responsiveness of

patient could be due to this. With the deflated expenditure as quantity measure, the influence of net new items is also incorporated again with a further response from patients.

Estimating equations using price and quantity data defined at the aggregate level clearly demonstrates the importance of the number of molecules listed ion the PBS, while using data defined at the detailed item level enables the influence of both restriction levels and safety net limits to be better understood.

[i] An alternative specification of the demand equation (8.1) is to make no assumption about the underlying functional form but to express the percentage change in quantity as a linear function of the percentage changes in the dependent variables. The argument for this (eg Tran Van Hoa 2004) relies on the following relationships among the partial and complete differentials (as given in Allen (1972) for instance)

$$dq = \left(\frac{\delta q}{\delta M}\right) dM + \sum_{i=1}^{n} \left(\frac{\delta q}{\delta p_i}\right) dp_i \tag{1}$$

Dividing through by q and rearranging the remaining terms gives

$$\frac{dq}{q} = \frac{M}{q} \left(\frac{\delta q}{\delta M}\right) \frac{dM}{M} + \sum_{i=1}^{n} \frac{p_i}{q} \left(\frac{\delta q}{\delta p_i}\right) \frac{dp_i}{p_i} \tag{2}$$

$$\frac{dq}{q} = \left(\frac{\delta q}{\delta M} \Big/ \frac{q}{M}\right) \frac{dM}{M} + \sum_{i=1}^{n} \left(\frac{\delta q}{\delta p_i} \Big/ \frac{q}{p_i}\right) \frac{dp_i}{p_i} \tag{3}$$

$$\frac{dq}{q} = \beta \frac{dM}{M} + \sum_{i=1}^{n} \gamma_i \frac{dp_i}{p_i} \tag{4}$$

where $\beta$ and $\gamma_i$ are the income and price elasticities. This can be rewritten with as

$$\dot{q} = \beta \dot{M} + \sum_{i=1}^{n} \gamma_i \dot{p}_i \tag{5}$$

where the form $\frac{dq}{q}$ is interpreted as the percentage change in q, namely $\dot{q} = (q_t - q_{t-1})/q_{t-1}$ and similarly for the other variables.

Estimating demand equation for PBS medicines using this specification produces results very similar to the Error Correction Mechanism results reported for the logarithmic specification. For this reason no separate results are given for this alternative specification.

# Chapter 9

# Conclusions

## 9.1 Introduction

The purpose of this thesis has been to investigate the contribution to the growth in expenditure on PBS medicines from three inter-related sources: (i) the steady accumulation within the PBS formulary of new medicines to treat an expanding range of diseases and conditions, (ii) the operation of the processes within the PBS for determining the prices of medicines and their conditions of listing and (iii) the strong demand by patients for PBS medicines. In doing so it uses three analytic techniques: trend analysis presented in both tabular and graphic form, expenditure decomposition techniques based on index and indicator numbers, and econometric analysis. It addresses some key aspects of decomposition analysis including the treatment of new and disappearing goods and the potential bias arising from changing market shares among substitutable medicines. The way pharmaceutical markets are defined is important in understanding how they operate and in guiding the analysis and interpreting the findings.

The preceding chapters have shown how the Government, to a greater or lesser degree, affects each of these factors through its control of the policy settings within the PBS. It also influences how much of the cost of the PBS is borne by itself and by the various classes of patients. Through its control of price setting and its negotiations with pharmacists it also has a major influence over the incomes of suppliers, wholesalers and pharmacists.

This concluding chapter summarises the findings of the main body of the thesis in the light of the Commonwealth Government's National Medicines Policy, which has as one of its objectives to ensure "timely access to the medicines that Australians need, at a cost individuals and the community can afford".

## 9.2 The contribution from new medicines

To meet its objective of providing "access to the medicines that Australians need", the Government through the PBS has enabled a steady increase in the number of medicines available through the Scheme. The average addition of 25 new medicines per year offset by 14 exiting medicines has seen a growth in the stock of PBS medicines from 535 in June 1992 to 687 in June 2007, an increase of 152 or 28%. This has lead to both an expansion in the choice of medicines within well-established disease treatment markets and better pharmaceutical options for diseases which were previously poorly treated or untreated. Because these medicines have been subject to a thorough therapeutic and economic evaluation by the TGA and the PBS, this represents an unambiguous increase in the contribution by medicines to the alleviation of the burden of disease in Australia.

The publicity surrounding the rapid growth in expenditure following the listing of certain new medicines in 2000-01 and the projections of long-term future costs made by the Treasury and Productivity Commission created the climate for significant changes within the PBS. One of these seems to have been a significant reduction in the number of new medicines listed over the following years. Over the five years to 2005-06 the average number of new listings was 20.8 compared to 29.6 over the previous five years. However the number of new listings increased to 27 in 2006-07 and to 27 in 2007-08. This may reflect an increasing willingness to accommodate more new medicines as a quid pro quo for the pharmaceutical industry accepting the price reduction policies that began to take effect in late 2005.

The analysis of PBS approvals over the period 1991-92 to 2006-07 quoted in Chapter 1 based on CSES (2007a) and Sweeny (2007b) shows an increase in the average length of time between regulatory approval of a medicine, whether by the FDA, the EMEA or the TGA, and its subsequent listing on the PBS. While not conclusive, this could be taken as further evidence of intervention by the Government to delay the introduction of new medicines. However establishing this definitively would require further research. The average lag from FDA approval to PBS listing is around 18 to 24 months and in recent years has been closer to 60 months. The time taken from

approval by the TGA to PBS listing is 9 to 12 months and reached 36 months in 2005-06.

To some extent then the outcomes of the PBAC listing process and subsequent Government decision-making may be seen as a conflict between the objective of providing "access to the medicines that Australians need", the objective of ensuring this is done in a "timely" manner, and the objective of doing this "at a cost … the community can afford". While the cost of the PBS was growing at rates well above the growth of GDP the number of new medicines being listed was reduced. At the same time the length of time taken to list new medicines increased. However once the concern about cost diminished the number of new medicines rebounded.

Despite the concern about cost and the time taken to list new medicines, a comparison with the numbers of new medicines approved by the FDA and EMEA indicates that by and large most significant new medicines eventually do become available to patients in Australia through the PBS. There is some evidence that the proportion of new medicines that are novel is falling perhaps reflecting the diminishing productivity of the development pipeline. Over the five years to 2006-07 the average number of novel medicines listed was 4.4 versus 5.2 for the previous five year period. "Access" to PBS medicines seems to becoming increasingly restricted, with about two thirds of new medicines having an "Authority required" status on initial listing. Over the most recent five years the percentage of new listings with an "Authority required" status was 66.2% on average compared to 46.3% in the previous five years.

The econometric analysis suggests that every additional medicine will add between $13 million and $15 million on average to PBS expenditure although there will be considerable variation from medicine to medicine. Further to this, expenditure will increase at about twice the rate of the increase in the number of medicines.

In summary
- The average addition of 25 new medicines per year represents an unambiguous increase in the contribution by medicines to the alleviation of the burden of disease in Australia;

- There was significant reduction in the number of new medicines listed after 2000-01 but the increase in 2006-07 and 2007-08 reflects an increasing willingness to accommodate more new medicines as a quid pro quo for the pharmaceutical industry accepting the price reduction policies that began to take effect in late 2005;

- Nonetheless the lag between approval overseas and PBS listing is significant and increasing over recent years; and

- The proportion of new PBS listings with an "Authority required" status is also increasing demonstrating the Government's increased use of this policy setting to control demand.

## 9.3 Price determination and its effects

### PBS pricing and listing procedures

Since 1993 the Government has required that all major submissions for listing a medicine on the PBS be accompanied by an economic analysis which forms the basis for the determination of the price of the new medicine and includes an assessment of its net impact on PBS expenditure. The economic analysis provides evidence about the efficacy, safety and cost of the new medicine compared to a comparator – typically the leading pharmaceutical treatment for the disease already listed on the PBS. A majority of successful submissions (65-75%) are made on the basis of a cost-minimisation argument, namely that the new medicine provides similar benefits to the comparator and is priced accordingly. A minority of submissions seek a significant price premium over the comparator by presenting a cost-effectiveness case demonstrating superior efficacy and/or safety. The probability of success for cost-minimisation analyses is around 95% but only 30% for cost-effectiveness submissions.

Cost-minimisation medicines form Reference Pricing Groups (RPG) (or therapeutic relativity groups) in which medicines with a common comparator have their prices set together with the comparator. Price changes for one member of the groups flow through to all other members of the group. Some RPGs for more popular medicines are subject to a more rigorous regular price review through the Weighted Average Monthly Treatment Cost (WAMTC) process. Medicines within these groups have

dominated PBS expenditure although that influence has begun to wane. While RPGs accounted for over two thirds of PBS expenditure in 2005-06, the peak of their importance was in the late 1990s and their share of the PBS has declined steadily since then, in part due to market saturation for some of the main RPGs and through the influence of falling prices. Similar declines in importance are evident for WAMTC groups for the same reasons.

The operation of this reference pricing procedure effectively discourages any significant price differential among brands of the same medicine. If a supplier offers a lower price for a brand this automatically becomes the base price for all other brands thus providing no price advantage within the market. Originator suppliers have been reluctant to add a brand premium and most that do are about 7 % of the base price on a weighted average basis. If anything this margin has diminished over recent years.

The inability of generic brand suppliers to gain a significant price advantage in the market has led them to offer pharmacists discounts from the official wholesale PBS prices. Despite this the generic share within the PBS is smaller than in markets such as the United States and the United Kingdom and the rate at which generics gain market share is rather slow. Off-patent medicines are responsible for about 43% of PBS expenditure and within this market originator brands claim 55% with competing brands having 45%. Overall competing brands made up 14.4% of PBS expenditure in 2005-06.

To recoup the costs associated with the development of a new medicine, suppliers are granted patent protection affording a period of market exclusivity for that particular medicine and enabling prices to be charged that a significantly higher than the marginal unit cost of supply. Normally the expiry of patent protection enables generic suppliers to enter the market at prices closer to the marginal unit cost of supply. The introduction of the mandatory 12.5% price reduction policy in August 2005 was a recognition by the Government that this mechanism has been virtually non-existent within the PBS. The examination of 112 patent expiries from August 1991 to July 2005 showed that only 46 attracted competing brands for at least one of the formulations of the medicine. There were only a handful of these medicines where the

new entrant may have offered a lower price than the prevailing price at the time and for most of these the price reduction was less than 15%.

The introduction of this new policy highlights the limitations of reference pricing. While cost-effectiveness analysis is internally consistent and delivers rational relative price outcomes, it does not provide a mechanism for determining the absolute level of prices because the price of the comparator can be arbitrarily determined. There is no guarantee that the price obtained by originators from the PBS is adequate to meet a proportionate contribution to a fair rate of return on the investment made in bringing the medicine to market.

In summary
- The probability of success for cost-minimisation analyses is around 95% but only 30% for cost-effectiveness submissions
- Cost-minimisation medicines make up the majority of new listings and form Reference Pricing Groups (RPG) in which medicines with a common comparator have their prices set together with the comparator. Price changes for one member of the groups flow through to all other members of the group.
- The operation of this reference pricing procedure effectively discourages any significant price differential among brands of the same medicine
- The introduction of the mandatory 12.5% price reduction policy in August 2005 was a recognition by the Government that patent expiry followed by generic entry had had virtually no impact on prices within the PBS.

## Price changes

A decomposition of PBS expenditure demonstrates that prices for PBS medicines fell by 9.7% over the period 1991-92 to 2005-06 or by 0.7% per year on average. Until August 2005, the PBS price setting procedures provided little opportunity or reason for the price of a PBS medicine to change from its initial listing price. Visual inspection of the prices of PBS items during the period confirms the impression that the prices of most PBS items hardly changed at all, the prices of medicines within WAMTC groups fell periodically and any other price movements were due to changes in restriction status or exceptional circumstances peculiar to a particular medicine.

Patent expiry flowed by entry of competing generic brands did not contribute significantly to overall price changes except in a few instances. Price-volume agreements appear to have had little if any effect on prices to date.

Alternative decomposition techniques produce very similar results when applied to PBS expenditure. Standard index number formulae behave as expected with superlative indexes producing values that track between the Laspeyres and Paasche indexes as upper and lower bounds to a true cost-of-living index. Despite theoretical arguments in favour of one formula over the others, the Fisher, Tornqvist, Walsh and Vartia price indexes have values very close to each. Similarly the equivalent quantity indexes are very similar except for the Tornqvist quantity index, which is sensitive to extreme values as predicted.

Any bias arising from the exclusion of new and disappearing items from standard index formulae is minimised through chaining. The Time Product Dummy (TPD) regression technique is an alternative approach to calculating indexes utilising all price and quantity information. Somewhat remarkably it produces results very similar to the standard formulae such as the Fisher index at least using data defined at the PBS item level. This close agreement among indexes excluding and including new and disappearing items suggest that there is no bias arising from this source and that a Fisher price index can be used to deflate all PBS expenditure not just expenditure on PBS items common to adjacent years. The TPD technique involves large numbers of dummy variables and there appears to be a limit to the number which can be accommodated before serious problems arise in the manipulation of arrays. For the PBS the technique works well at the item level but not at the unique brand level. It also works less well if used to calculate quantity indexes.

The PBS data available enables prices and quantities to be defined in two ways. The first of these - the derived price approach - is easier to use and underpins most of the results presented in the thesis. The second is the derived quantity approach which has claims to be superior as it employs actual prices rather than unit values but is harder to use. It is the only way however to calculate indexes of prices received by suppliers and pharmacists because the derived price approach is limited to using data at the retail level. Again indexes calculated using the two approaches produce similar results

with data defined at the PBS item level giving confidence in the accuracy of the indexes for suppliers and pharmacists. There is however some divergence when indexes are calculated at the unique brand level.

While the dispensed price fell by 9.7% between 1991-92 and 2005-06, the prices received by suppliers whether manufacturers, importers or wholesalers fell by 17.0% on average, or by about 1.3% per year. By contrast the margin received by the pharmacist rose by 18.7% or 1.2% per year. The differing experiences of suppliers and pharmacists arose from the five-yearly Community Pharmacy Agreements negotiated between the Government and the Pharmacy Guild. The formula linking the price paid by the pharmacist for PBS medicines to the dispensed price has two components – a percentage markup on the wholesale price and a dispensing fee. The dispensing fee rose by 44% over the period because it was adjusted for inflation at least for part of the time. This increase was offset by the decline in wholesale prices to give the 18.7% overall increase. Prices received by suppliers did not include an inflation adjustment. Suppliers have relied therefore on selling increasing volumes of medicines to maintain revenue and profits in the face of declining prices.

In summary
- Prices for PBS medicines fell by 9.7% over the period 1991-92 to 2005-06 or by 0.7% per year on average. Over the same period the CPI rose by 43% or by 2.5% per annum on average. Adjusting the PBS dispensed price for the CPI shows a decline of 36.2% in the "real" dispensed price or -3.3% per annum on average.
- Most of the price decline was due to falls in the prices of medicines within WAMTC groups rather than from generic entry after patent expiry. Other price movements were due to changes in restriction status or exceptional circumstances peculiar to a particular medicine. Price-volume agreements appear to have had little if any effect on prices to date.
- Pharmaceutical prices in other jurisdictions have shown similar trends under the influence of reference pricing and Government control with the notable exception of the United States which constitutes about half the global market for medicines. Prices in the United Sates have shown positive increases with a slight margin above the general rate of inflation.

- All standard superlative index number formulae produce very similar results as does the Time Product Dummy technique which makes use of all data available. This close agreement among indexes excluding and including new and disappearing items suggest that there is no bias arising from this source.

- The prices received by suppliers, whether manufacturers, importers or wholesalers, fell by 17.0% on average, or by about 1.3% per year. By contrast the margin received by the pharmacist rose by 18.7% or 1.2% per year. The differing experiences of suppliers and pharmacists arose from the five-yearly Community Pharmacy Agreements negotiated between the Government and the Pharmacy Guild which ensured that the pharmacist margin had an adjustment for inflation and this did not apply to prices received by suppliers.

## 9.4 Demand for medicines

### Decomposition of PBS expenditure

The contribution to the growth in PBS expenditure from changes in prices, quantities and new and disappearing items can be estimated using standard price and quantity indexes. Standard index formulae omit new items for the first year after entry but incorporate their influence in subsequent years. Although their importance varies from year to year, on average the annual contribution of net new items was 2.1% compared to the overall average growth in PBS expenditure of 12.3%. As noted earlier the average annual change in prices was a fall of 0.7% while the quantity consumed of items common to adjacent years was 10.9% per year on average.

The growth in PBS expenditure was therefore dominated by the strong increase in the consumption of medicines reinforced by the continual addition of new medicines.

While price and quantity indexes decompose the value ratio and hence show this picture in percentage change terms, price and quantity indicators decompose the difference in values from one year to the next and show the changes in absolute terms. Bennett price and quantity indicators clearly demonstrate that, while the percentage changes in prices may have been small, they resulted in significant reductions in PBS expenditure in some years and particularly in 2005-06 after the mandatory 12.5% price reduction policy was introduced. The quantity indicator reinforces the picture of

the strong contribution from consumer demand. Indicators are also useful in showing the contributions to expenditure from groups of medicines. It is clear that the change in PBS expenditure due to prices can largely be accounted for in most years by the fall in prices of WAMTC medicines with some additional contribution from other members of RPGs. The WAMTC procedure for determining prices therefore is probably the main reason for the change in expenditure due to changes in prices within the PBS over the period from 1991-92 to 2005-06. Generally speaking, the contribution to growth in demand from WAMTC medicines as shown by the quantity indicator has been less dominant, although still significant in most years, and medicines within other RPGs have made a greater contribution.

As indicators are as easy to calculate as indexes and they provide an additional dimension to the interpretation of change within the PBS, their use should be encouraged.

In summary
- The major contribution to the growth in PBS expenditure came from consumer demand for PBS medicines which grew by 10.9% per year on average, with net new items adding a further 2.1% and prices falling 0.7%, based on standard analysis using chained Fisher indexes.
- Bennett price and quantity indicators demonstrate that, while the percentage changes in prices may have been small, without these decreases PBS expenditure would have been significantly higher in some years and particularly in 2005-06 after the mandatory 12.5% price reduction policy was introduced.
- These indicators are useful in showing the contributions to expenditure from groups of medicines. It is clear that the change in PBS expenditure due to prices can largely be accounted for in most years by the fall in prices of WAMTC medicines with some additional contribution from other members of RPGs.

## Costs borne by patients and the Government

While decomposition techniques can provide an insight into the factors contributing to growth in expenditure they can also be used to show how this cost is shared among the payers. General patients within the PBS currently pay a fixed copayment of $31.30 per prescription (plus any price premium if the supplier has added one) while concessional patients pay $5.00 plus any price premium. Safety net provisions ensure that once general patients spend more than a certain amount ($1141.80) their copayment falls to the concessional level. Similarly for concessional payments: once they have spent $290.00 their medicines thereafter are free.

Patients therefore do not face the dispensed price when acquiring PBS medicines but a patient price made up of the copayment and possibly a price premium. By changing the values of the copayment and the safety net limits the Government has systematically shifted the cost of the PBS from itself to patients. From July 1991 to June 2007 the general and concessional copayments effectively doubled. In real terms the general copayment rose from 3.1% to 3.5% of average weekly earnings (AWE) and the concessional copayment from 0.5% to 0.6%. For general patients the safety net limit rose from 61.2% to 123.5% of AWE while the concessional copayment increased from 26.6% to 32.0%. The Government then has concentrated on shifting more of the cost to general patients by increasing the copayment and making it harder to reach the safety net limit. The change for concessional patients has been less severe perhaps because the number of people in this category is growing more slowly. The econometric analysis suggests that an increase of 10% in the number of copayments necessary to reach the safety net limit will reduce the number of general safety net cardholders by 24.4% and the number of concessional safety net cardholders by 55.6%. The announced policy of increasing the safety net limit by the value of two copayments per year will therefore have a very significant impact on the numbers of patients eligible to obtain PBS medicines at reduced cost and represents a major shift in the proportion of PBS cost borne by patients rather than the Government.

Each patient category pays a patient price made up of the copayment and any price premium added by the supplier. The Government pays the difference between this price and the dispensed price. These "patient" and "Government" prices can be

expressed as price indexes and show that over the period from 1991-92 to 2005-06 the patient price rose by about 75-80% for both categories of patients. The Government price on the other hand fell by about 13% or somewhat more than the overall dispensed price. The quantity indexes for general patients confirms the picture of stronger growth in demand by general patients than by concessional patients and their profiles over time clearly show the influence of changes in copayments and in safety net limits on the amount of medicines consumed.

The systematic increase in the real value of copayments and safety net limits and the consequent increase in the share of cost borne by patients brings out the inherent conflict within a policy that seeks to provided "[access to medicines]… at a cost individuals and the community can afford". At least it focuses on what the word "afford" means in this context.

In summary
- By changing the values of the copayment and the safety net limits the Government has systematically shifted the cost of the PBS from itself to patients. In real terms the general copayment rose from 3.1% to 3.5% of average weekly earnings (AWE) and the concessional copayment from 0.5% to 0.6% from July 1991 to June 2007. For general patients the general safety net limit rose from 61.2% to 123.5% of AWE while the concessional copayment increased from 26.6% to 32.0%.
- The econometric analysis suggests that an increase of 10% in the number of copayments necessary to reach the safety net limit will reduce the number of general safety net cardholders by 24.4% and the number of concessional safety net cardholders by 55.6%.
- Over the period from 1991-92 to 2005-06 the patient price index rose by about 75-80% for both general and concessional patients. The Government price index on the other hand fell by about 13% or somewhat more than the overall dispensed price fall of 9.7%.

## Demand for PBS medicines

Aside from influencing the distribution of expenditure, changes in the patient price, copayments and safety net limits also influence the demand for PBS medicines and hence the overall level of PBS expenditure. Econometric estimation of demand functions for PBS medicines by each of the four categories of patients – general and concessional patients and their two safety net components – shows the clear influence of increase in the patient price on demand. In this context the patient price which incorporates the price premium performs better than the copayment by itself.

The results quoted in Chapter 8 show that the demand for PBS medicines is significantly influenced by two of the policy instruments controlled by the Government. On the one hand demand increases more than proportionately to the steadily increasing number of medicines made available through the operation of the PBS listing procedures. As the PBAC makes available more choice among medicines to treat particular diseases and introduces medicines for diseases previously untreated or poorly treated, doctors prescribe these for their patients reducing the burden of disease. On the other hand demand is reduced when Governments increase the amount patients are required to pay for these medicines and to a lesser extent when manufacturers change the premium they add to the base dispensed price.

For General Non-Safety Net (GNSN) patients the patient price elasticity is in the range -1.1 to -1.4, while for Concessional Non-Safety Net (CNSN) patients it is significantly lower in the range -0.5 to -0.9. The situation is less clear with General Safety Net (GSN) patients although analysis using detailed data suggests an elasticity of -1.4. The demand elasticities with respect to either the patient price or the copayment are significantly higher than those found in previous studies of the demand for PBS medicines. They are however similar to recent estimates made by Berndt, Danzon and Kruse (2007) who report own-price elasticities in the range -0.75 to -1.1 based on an analysis using IMS health data from 1992 to 2003 across 15 countries, not including Australia.

The income elasticity is generally significant but there is more variability in the estimates depending on how the dependent variable is defined and at what level the

analysis is undertaken. The elasticity is higher if the quality-adjusted quantity variables are used rather than the number of units for all categories of patients. The elasticity with respect to the number of molecules also shows the same tendency to increase. For most of the regression analyses the elasticities with respect to income and the number of molecules are significantly higher than one and closer to two. The estimates show significant contributions to the demand for PBS medicines from rising incomes and as the number of medicines available on the PBS increases.

Employing two basic estimation strategies – using aggregated and item level data – enables the impact of the "Authority required" restriction level to be estimated as well as changes in safety net limits, although the latter are more important in shifting demand among patient categories.

The demand analysis results highlight how demand is driven by the increasing choice arising from an expanded formulary and rising incomes offset by the Government's ability to raise patient prices and to dampen demand through restriction levels and changes to safety net limits. To the extent that patients are discouraged from buying medicines or abandon existing treatments because of price increases, this represents a real reduction in patient welfare and raises fundamental issues about how copayments should be regarded.

## 9.5 Market definition and bias in decomposition

A theme underlying the analysis in this thesis is that the way pharmaceutical markets are defined has an important bearing on how the analysis is framed and how the results are interpreted. It is suggested that most medicines are suited for treating only a very narrow range of diseases and that the PBS can be seen as a collection of separate pharmaceutical treatment markets. One way of defining these markets is to use the Anatomical Therapeutic Classification (ATC) managed by the WHO which uses five levels of classification for medicines. The analysis in this thesis and elsewhere indicates that pharmaceutical treatment markets can best be specified by the ATC system at the ATC4 and ATC5 code levels. The ATC system however is not definitive and further research is required on how the pharmaceutical markets within

the PBS should be defined, building on the current incomplete coverage given by the Reference Pricing Groups.

How these markets are defined provides a limit to the extent of any bias that arises when the decomposition of PBS expenditure is undertaken using standard index number formulae. Griliches and Cockburn (1994) identified the bias that arises when indexes are calculated assuming different brands of the same medicine are separate goods. The bias occurs if market shares change among these brands and their prices differ. One way of dealing with this bias is to aggregate brands and use the resulting average prices in the calculations. This results in an "objective" index which ignores consumer preferences for brands. A comparison of the resulting "objective" index with the original index provides an indication of the maximum size of the bias.

This argument is generalised firstly to the case of changing market shares among different strengths and form of the same medicine, then to medicines with similar characteristics, then to different generations of medicines. It is argued that it becomes increasingly difficult to find appropriate factors beyond Defined Daily Doses to convert these medicines into equivalents which can be aggregated. The main problem is finding suitable factors to adjust for differences in quality.

Despite these limitations price indexes were calculated for PBS expenditure at the brand level, item level, molecule/ATC level (ie at AT7 level), and at ATC5 and ATC4 levels. The last two ATC code levels are proxies for medicines that are close substitutes for each other and for medicines of different generations in the same treatment market.

The price indexes calculated at brand and item level are very similar, providing strong evidence for the absence of the Griliches-Cockburn bias at the brand level. Indexes are also quite similar at the item level, molecule/ATC level and ATC5 level. These outcomes can largely be explained by the operation of reference pricing within the PBS, which compresses differences among the prices of medicines within the same treatment market and ensures that the prices of these medicines move in similar ways.

An index calculated at the ATC4 level diverges significantly from all these other indexes implying an increase in prices over the period in contrast to the decreases suggested by the other indexes. However an index calculated at this level is unreliable because of the conceptual and practical difficulties of aggregating data and adjusting for quality differences among medicines. This quality difference becomes particularly acute at the ATC4 level. At the ATC5 level many of the medicines being aggregated are within the same RPG while at the ATC4 level different RPGs are being aggregated. The further examination of indexes at the ATC level might best be undertaken by case studies of particular pharmaceutical markets properly defined and by the use of appropriate quality adjustment factors.

Various authors have sought to find within the decomposition of pharmaceutical expenditure an additional price effect beyond that revealed by the standard price index formulae. They accept that the price index provides an accurate account of the changes in pharmaceutical prices but have argued that the shift to newer medicines with higher prices induces the generalised Griliches-Cockburn bias. The difference between the quantity index calculated either directly or indirectly by deflating expenditure and some measure of usage such as doses or defined daily doses is attributed in part or in whole to this disguised price effect. Superficially the divergence between the PBS price index at the ATC4 level and at other levels provides some evidence for this, despite the reservations about the difficulties involved, in particular whether the alternative usage measure is valid. If there is nonetheless an effect at the ATC4 level it is due in part to price differences firstly among rather than within RPGs and secondly to price differences among RPGs and medicines listed on a cost-effectiveness basis which are not members of RPGs.

Any disguised "price" effect is likely to be minimal within a decomposition of expenditure of PBS medicines. New PBS medicines are listed at a price determined either on a cost-minimisation basis, so that the price of the new medicines is set to produce the same therapeutic outcome as the comparator, or on a cost-effectiveness basis where the price of the new medicine is set according to the incremental benefit derived from the new medicine. Given that the initial price is set in this way and that the prices of medicines treating the same conditions subsequently move in the same way, any "price" effect arising from a shift from, say, the comparator to the new

medicine is fully accounted for in the quantity index as a "quality" effect reflecting the increased treatment benefit received by patients. The quantity index is then a quality-adjusted measure of consumption which avoids the problems inherent in aggregating heterogeneous measures such as prescriptions, units or doses.

Over the period 1991-92 to 2005-06 the PBS grew on average by about 12.3% per annum. The quality-adjusted quantum of PBS medicines consumed by patients increased by the same amount illustrating the benefit derived by patients from PBS medicines. By contrast, prices fell on average by 0.7% per annum or by 3.3% in real terms.

# Appendix A
## Data Sources and Issues

### A1 Introduction

Much of the analysis in this thesis relies on a number of datasets created or compiled by the author at the Centre for Strategic Economic Studies within Victoria University with the assistance of Ms Alison Welsh, Research Officer. This appendix provides an overview of these databases and some of the issues involved in transforming and using the data contained within them. The data is grouped into the following categories

- ATC and DDD information from WHO
- PBS Schedule information
- PBS expenditure and usage data
- Patent data from IMS Health
- Other data

Access to information from IMS Health was kindly provided to the Centre by Mr Tom Oberleiten and Ms Rebecca Foringer from the Merck Co, Whitehouse Station, New Jersey, USA.

### A2 ATC and DDD data from WHO

One of the most widely used systems of categorising medicines in terms of their action and use is the *Anatomical Therapeutic Classification* (ATC), a classification scheme developed and maintained by the World Health Organisation (WHO) Collaborating Centre for Drug Statistics Methodology in Oslo, under which medicines are "divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties". (WHO Collaborating Centre 2007)

The ATC system was developed in the 1970s and is a modification and extension of the classification originally developed by the European Pharmaceutical Market Research Association (EPhMRA). A more detailed discussion of the ATC system and its application to defining pharmaceutical treatments markets is given in Chapter 1.

For medicines with an ATC code, the WHO Centre also publishes a *Defined Daily Dose* (DDD), which it defines as "the assumed average maintenance dose per day for a drug used for its main indication in adults". (WHO Collaborating Centre 2007) In doing so however it recognises that the DDD does "not necessarily reflect the recommended or Prescribed Daily Dose. Doses for individual patients and patient groups will often differ from the DDD and will necessarily have to be based on individual characteristics (e.g. age and weight) and pharmacokinetic considerations".

Despite these drawbacks DDDs can be used when it is desired to aggregate different strengths and forms of a particular medicine. DDDS have also been widely used to produce measures of the use of medicines by aggregating across medicines and treatment markets. The conceptual issues that arise when this is attempted are discussed in Chapter 5.

The WHO Centre does not estimate DDDs for topical products, sera, vaccines, antineoplastic agents, allergen extracts, general and local anaesthetics and contrast media, principally because of the wide ranges of doses that can be used for these products. This limits the extent to which aggregating across medicines and treatment markets is possible.

## A3 PBS Schedule data

The PBS Schedule sets out the terms and conditions under which PBS and Repatriation PBS (RPBS) medicines are made available to patients and pharmacists reimbursed.

The Pharmaceutical Benefits Division within the Department of Health and Ageing maintains a database of all medicines listed on the PBS and other Australian Government pharmaceutical benefit programs. Extracts from this database provide the

content for the *Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners* (PBS Schedule, DoHA 2007j) which is distributed to medical practitioners and pharmacists as a guide to prescribing and dispensing PBS and RPBS medicines. An electronic version of the most recent edition of the Schedule is provided at http://www.pbs.gov.au/html/healthpro/publication/list and from January 2007 the free printed edition was replaced by a subscription-based service.

From August 1991 to June 1995 the Schedule was published in full in April, August and December each year with short amendments showing any changes between these editions in February, June and October. Short amendments were also included with each of the three major editions to include any late changes that had occurred between the printing of the edition and its release date. From August 1995 to August 2004 the Schedule appeared 4 times per year in February, May, August and November with no intermediate amendments. From August 2004 onwards the format reverted to the previous one of 3 editions per year with intermediate amendments.

The CSES database contains monthly information from August 1991, which is the earliest date for which the Schedule is available in electronic form, to the present (March 2007 at time of writing). The Pharmaceutical Benefits Division has provided regular updated editions of the Schedule to interested parties in electronic form when there have been significant changes. Initially coinciding with major editions of the Schedule this service is now provided monthly. This service was the source of information from August 1994 to the present. Following a request by the Centre, the Pharmaceutical Benefits Division provided information in a compatible electronic format for the major editions of the Schedule prior to August 1994. Where necessary, information for months between the major editions of the Schedule was extracted from the printed amendments.

The database comprises some 946 products as 3774 items and 9493 brands for the period from August 1991 to March 2008. These therapeutic products listed on the PBS include medicines, combinations of medicines, and a range of other non-medicine aids and appliances.

Once there is agreement that a new medicine is to be listed on the PBS or RPBS it is assigned an alphanumeric PBS item code of the form *nnnna* where *n* is a digit and *a* is a letter of the alphabet. The PBS item code refers to a unique combination of form, strength and maximum quantity to be dispensed of a particular medicine, along with indications for use and any restrictions, cautions, and notes.

Different item codes are allocated to all the different strengths and forms of a medicine. Each item can consist of a single brand if for instance the medicine is patent-protected or multiple brands if there is more than one supplier. New item codes are used for a medicine with the same strength and form if for instance the indications or pricing conditions differ.

The information accompanying each item code is listed below and is illustrated by the extract from the printed version of the PBS Schedule for December 2006 for the medicine *aciclovir* provided in Table A1 at the end of this appendix.

Aciclovir has two separate item codes for the 200 mg tablet form (1003T, 1007B), two item codes for the 800 mg tablet (1052J, 8234J) and one item code for the ointment form (1002R).

### *Medicine name and ATC code*

In recent editions of the Schedule, medicines and their accompanying items have been organised according to the Anatomical Therapeutic Classification (ATC) described earlier. In general, the name of the medicine given to each item in the Schedule is a close match to that given in the WHO ATC system. However in a number of instances this name has changed over time. The name within the CSES database is the most recent version.

Aciclovir is listed under 2 anatomical main groups

| | |
|---|---|
| J | Antiinfectives for systemic use |
| S | Sensory organs |

The first of these has four items – 1003T, 1007B, 1052J and 8234J, while the second has only one – 1002R.

The subheadings for aciclovir in the first case are

| | |
|---|---|
| J05 | Antivirals for systemic use |
| J05A | Direct acting antivirals |
| J05AB | Nucleosides and nucleotides excl. reverse transcriptase inhibitors |
| J05AB01 | ACICLOVIR |

and for the second case

| | |
|---|---|
| S01 | Ophthalmologicals |
| S01A | Antiinfectives |
| S01AD | Antivirals |
| S01AD03 | ACICLOVIR |

While the printed version of the Schedule does not include the actual ATC code, the electronic version does. The WHO Centre changes the ATC classification codes from time to time, so the entries in the CSES database are regularly updated with the most recent code.

Different ATC codes for the same medicine point to separate markets for this medicine. For instance the market for the supply of tablets of aciclovir to treat genital herpes covered by the items 1003T, 1007B, 1052J and 8234J (ie ATC code J05AB01) is quite distinct to the market for supplying an eye ointment for the treatment of herpes simplex keratitis covered by item 1002R (ie ATC code S01AD03).

In identifying and analysing the markets for PBS medicines therefore, it is important to know which ATC code is applicable for the medicine being considered

Some PBS products such as blood glucose indicators are not medicines and do not have an ATC code. For a few other medicines, including those listed as extemporaneous preparations it has not been possible to find an appropriate ATC code.

### Restrictions, notes and cautions

Each item on the PBS is classified according to a restriction level.

| | |
|---|---|
| Authority required | – the doctor must seek approval from Medicare Australia before prescribing |
| Restricted benefit | – the medicine must only be prescribed for specific therapeutic uses as indicated in the Schedule |
| Unrestricted | – there are no restrictions on the therapeutic use |

For aciclovir, the tablet forms have an "authority required" restriction while the eye ointment is only a "restricted benefit".

Some items have notes accompanying their listing which provide additional advice and guidance. This is the case for items 1003T, 1007B and 1052J but not for item 8234J. Less often, some items carry cautions about their use, principally warning of the possibility of dangerous side effects.

Restrictions, notes and cautions for an item can change over time. Changes in restriction levels can have important consequences for the size of the market for a medicine and the PBS often lists medicines initially with an "authority required" restriction before downgrading to "restricted benefit" once usage becomes better understood.

### Description, strength and form

Each item carries a description of its strength and form. The common forms of a medicine are tablets, capsules, injections, syrups, powders and eye and ear drops. The strength refers to the amount of active ingredient within the form. Some items occur as combinations of 2 or more medicines and the strength of each is noted separately.

In addition to strength and form, some descriptions also note how much of the medicine is provided in total. For instance the eye ointment form of aciclovir (item 1002R) comes as a tube containing 4.5g with 30 mg of active ingredient per gram. This means a tube contains 135 mg of aciclovir.

### Maximum quantity, repeats and pack size

Each item specifies a maximum quantity a doctor can prescribe on the one prescription. In addition the listing specifies how many times (repeats), if any, the pharmacist may issue this amount against the same prescription. In the data reported on the PBS however each repeat is treated as a separate prescription.

For the 200 mg tablet form of aciclovir, item 1003T allows a maximum of 50 tablets per prescription with no repeats, while item 1007B allows up to 90 tablets with 5 repeats.

For most items on the PBS the maximum quantity is the same as the size of the pack provided by the manufacturer. However for some items, the maximum quantity is a multiple, or (rarely) a fraction, of the pack size.

For aciclovir item 1003T, the supplier GenRx has a pack size of 50 while the other suppliers have pack sizes of 25. In the printed version of the Schedule, an asterisk next to the dispensed price indicates the pack size is different to the maximum quantity. In the electronic version pack size is provided as a separate field.

While the maximum quantity is the same for all brands within an item, the pack size can vary from manufacturer to manufacturer.

For most items listed on the PBS the description of the item remains essentially unchanged over time in terms of the strength, form and amount of the medicine being described. For the few items where this is not the case, significant changes in description occur in two ways. For a handful of items the strength of the medicine changes, and it has been necessary to adjust both the maximum quantity and the pack size of the item to ensure that the item has a consistent description over time. If for instance the description indicates a change in strength from 220 mg to 250 mg, the earlier maximum quantity and pack size values are multiplied by 220/250.

In the second case, the change in description indicates a change in the way the amount of medicine provided is recorded. Most items on the PBS show the strength and form

of the medicine, eg "Tablet 200 mg" and the maximum amount field shows the number of units provided, eg "90", indicating that for this item the prescriber can prescribe 90 of the 200mg tablets. An alternative convention used for some items is to include the number of units within the description, eg "Tablet 200 mg, 90" and show the maximum amount as "1". If the alternative convention is used consistently over time this does not affect the use of items for a variety of analyses of the data. However for some items within the Schedule the description has shifted from one convention to the other. This creates a significant problem and needs to be addressed. For the CSES database the most recent convention is adopted and the maximum quantity and pack size fields adjusted to be in line with this convention. For instance if the earlier description is "Tablet 200 mg, 90", and this changes to "Tablet 200 mg", the earlier maximum quantity is changed from "1" to "90". Similar changes are made to the pack size field if necessary.

In the example of aciclovir, the maximum quantity for PBS item code 1007B is now shown as 90 and the description as "Tablet 200 mg". From July 1991 to July 1996 however, the maximum quantity was given as 1 and the description as "Tablet 200 mg, 90". The maximum quantity was therefore changed to 90 for the earlier period.

If a particular kind of analysis makes it necessary to aggregate different strengths of the same medicine or to combine different medicines, it is important to ensure that the same convention is used for all forms and strengths of the medicines that enter into these analyses. The CSES database therefore includes fields that list form, strength and amount separately.

### *Brand name and manufacturer*

Within each item there may be multiple suppliers providing different brands. Generally this occurs when a medicine loses patent protection and competitors enter the market. However it can also occur when two or more companies jointly develop and/or market a medicine.

Along side each brand the manufacturer's 2 digit code is provided. CSES maintains a database of codes and manufacturer names based on DoHA information.

For item 1007B for instance there are 8 manufacturers

AF    Alphapharm Pty Limited

CH    Chem mart Pty Limited

GK    GlaxoSmithKline Australia Pty Ltd

GM    Genepharm Pty Ltd

GX    GenRx Pty Ltd

HX    Hexal Australia Pty Ltd

RA    Ranbaxy Australia Pty Limited

TW    Terry White Chemists

However Chem mart, GenRx, and Terry White Chemists are all banner group names within Mayne Pharma and cannot be regarded as separate competitors.

The original brand for item 1007B is *Zovirax 200 mg*, but over the period from 1991 to 2006, the following manufacturers have provided this brand.

BW    Wellcome Australia Pty Ltd A subsidiary of Glaxo Wellcome Australia

GK    GlaxoSmithKline Australia Pty Ltd

GW    Glaxo Wellcome Australia Ltd

This is essentially the same company but the name changes reflect both mergers within the pharmaceutical industry and changing supply arrangements in Australia.

To allow for these changes, the CSES database records the original manufacturer code and name and the most recent parent or ultimate manufacturer code and name. This is discussed further in Chapter 6.

### *Prices and premiums*

The printed version of the Schedule reports for each brand within an item, the dispensed price for maximum quantity, ie the retail price, and any brand premium. If the maximum quantity is different to the pack size, the price of the pack (including markup but not dispensing fees) is reported in Section 3 of the Schedule.

The electronic version of the Schedule reports, inter alia, the following

- Manufacturer's dispensed price for maximum quantity, ie the retail price including any premium
- Commonwealth dispensed price for maximum quantity, ie the base retail price without any premium
- Brand premium
- Therapeutic premium or Special Patient Contribution
- Manufacturer's price to pharmacist (for manufacturer's pack), ie the price paid by the pharmacist for the manufacturer's pack, including any premium
- Commonwealth price to pharmacist (for manufacturer's pack), ie the base price paid by the pharmacist for the manufacturer's pack, without any premium

The PBS determines first the Commonwealth price to pharmacist (for manufacturer's pack). On the basis of this the Commonwealth dispensed price for maximum quantity is calculated using a standard formula, setting out a margin to be added to the pharmacist price plus any dispensing fees, after adjusting for any difference between maximum quantity and pack size.

If any of the suppliers within a particular item wish to add a further premium (to be paid by the patient) this is added to the Commonwealth dispensed price to obtain the manufacturer's dispensed price. The manufacturer's price to pharmacist is then calculated by applying the formula in reverse. A brand premium can be added by a manufacturer, usually the company supplying the original brand, where there are multiple suppliers within an item. Therapeutic premiums can be added for some groups of medicines.

The formula determining the dispensed price is set out within the 5-yearly Community Pharmacy Agreements is discussed further in Chapter 2, as are the different types of premiums.

For item 1003T, the Commonwealth price to pharmacist for a standard pack of 25 tablets is $38.25 for all manufacturers except GX, for which it is $76.51 for a pack of 50 tablets. The formula for calculating the Commonwealth dispensed price for maximum quantity in this case is

(Commonwealth price to pharmacist for manufacturers pack) *times* (maximum quantity divided by pack size) *times* markup *plus* dispensing fee, or

$38.25x(50/25)x1.1+$5.15 =$89.30 for all except GX

and

$76.51x(50/50)x1.1+$5.15 = $89.31 for GX

For item 1003T, the markup is 10% and the dispensing fee is $5.15 and all brands are given the Commonwealth dispensed price for maximum quantity of $89.31

The originator company GlaxoSmithKline Australia (GK) elected to add a premium of $5.78 making its dispensed price equal to $95.09. In this case the manufacturer's dispensed price is same as the Commonwealth dispensed price except for GK.

The manufacturer's price to pharmacist for GK is therefore

($95.09-$5.15)/(2x1.1) = $40.88

or $2.63 higher than the Commonwealth price to pharmacist.

## *Medicine type*

The electronic version of the Schedule also classifies each item according to the program to which it belongs within the PBS. Medicine types current at August 2007 were

CI          Colostomy and Ileostomy Associations
CS          Section 100 (Chemotherapy Special Benefits)

| CT | Section 100 (Chemotherapy Scheme) |
|----|-----------------------------------|
| DB | Emergency Drug (Doctors' Bag) Items |
| DS | Dental (Special Pharmaceutical Benefits) |
| DT | Dental |
| GE | General |
| GH | Section 100 (Growth Hormone) |
| HS | Section 100 (Highly Specialised Drugs) |
| IF | Section 100 (IVF/GIFT Treatment) |
| MD | Section 100 (Opiate Addiction Treatment) |
| MF | Section 100 (Botulinum Toxin Program) |
| PL | Palliative Care |
| PQ | Paraplegic and Quadriplegic Associations |
| R1 | Repatriation Pharmaceutical Benefits |
| SA | Section 100 (Special Access Scheme) |
| SB | Special Pharmaceutical Benefits |
| SY | Section 100 (Special Authority Items) |

### *Listing dates*

The CSES database lists for each item and brand combination the date of the edition of the Schedule in which it was first listed and the last date of listing if no longer on the PBS.

In addition to the information available directly from the Schedule, other information has been added to the database for each item and brand combination.

### *Patent status*

The patent status of each PBS and RPBS medicine was assessed using a number of sources, principally the IMS Health Lifecycle *Patent Focus* database for November 2004 described below. This database was interrogated for each medicine and the patent expiry date determined. In many cases multiple entries with different patent expiry dates are given for a particular medicine so care was taken to identify where patent expiry dates differed for different forms of the medicine and match these to specific items in the Schedule database.

It was possible to allocate a patent date in this way to about half of all the medicines in the PBS Schedule database. For the other medicines, some are listed in the *Patent Focus* database but are identified as either

- An old medicine, typically with a patent application date prior to 1960
- A naturally occurring or synthetic chemical which cannot be patented

These medicines were assumed to have a patent status similar to those whose patent had expired by 1991.

Those medicines not listed on *Patent Focus* were classified in a number of ways. There is a handful of PBS and RPBS products that are not medicines, such as blood glucose indicators and these were also assumed to have a status similar to those whose patent had expired by 1991.

Each remaining medicine was checked to see if it was listed in the December 1975 edition of the Schedule and if so its patent, if any, was assumed to have expired by 1991. The few medicines not classified in any of the above ways were assumed to have had patents expired by 1991.

The tablet form of aciclovir (items 1003T, 1007B, 1052J and 8234J – ATC J05AB01) has a patent expiry date of 2/09/1995 while the eye ointment form (item 1002R – ATC S01AD03) has an expiry date of 17/07/2006. This explains why there are multiple suppliers of the tablet and only one supplier of the eye ointment.

### *Supplier status*

Determining the supplier status for different brands within an item is important in assessing the overall level of competition in the PBS and estimating the impact of entry of competitors after patent expiry. As noted earlier, competition occurs within markets defined by the medicine and an ATC code, so assigning supplier status needs to occur at this level.

In determining supplier status for these medicine/ATC combinations the following procedure was used.

Firstly CSES identified all those chemical/ATC combinations that were only provided by the same single supplier (based on the ultimate supplier code and name) across the whole period. The supplier in this case is either the company that developed the medicine (the originator) or a licensee of the originator. For instance aciclovir/S01AD03 has only ever been provided by GlaxoSmithKline Australia despite its changes of name over time.

Secondly those combinations that were provided by only one supplier at any one time were identified. In this case both the ultimate supplier and another supplier had been involved at various times. In most cases, this situation arose because the ultimate supplier transferred the rights to the medicine to the other supplier. Typically an originator company will license the brand name often to an Australian company such as Sigma or Arrow. The South African company Aspen is also an important licensee for the PBS. Continuity of brand name was the main determinant of this status. An example of this is the peptic ulcer treatment nizatidine (*Tazac*) supplied by Eli Lilly as originator up to May 2003 and by Aspen since then.

Some medicines are developed and marketed by more than one originator. Irbesatan for instance is supplied by both Bristol-Myers Squibb Australia (as *Avapro*) and Sanofi-Synthelabo Australia (as *Karvea*). In addition there were a handful of medicines that were codeveloped by originators but then licensed to other suppliers (usually by one of the developers) in the same way as described above for single supplier medicines.

These categories essentially consist of either a single supplier or joint suppliers that do not compete with each other on a price basis.

Most of the remaining medicine/ATC combinations have multiple suppliers at least one of which can be characterised as a "generic" competitor, ie as a supplier that is not the originator(s) or a licensee of the originator(s). These combinations were carefully examined and their suppliers were classified as either originator or as a

competitor. For aciclovir/ J05AB01, GK was designated the originator and the other suppliers (Alphapharm, Arrow, Douglas, Hexal, Mayne, and Novartis) were designated as competitors.

For a few combinations (12) it was not possible to identify which supplier was the originator or competitor. Usually this was because they involved medicines that have been on the market for a long time.

### Therapeutic group

The prices of many medicines on the PBS are determined by reference to the base price of a therapeutic group to which the medicine belongs.

New medicines are usually listed on the PBS on a "cost-minimisation" or "cost-effectiveness" basis. If the listing is on a cost-minimisation basis the medicine becomes part of a therapeutic group and the prices of all the medicines in the group are determined together. A description of the basis for most medicines listed on the PBS in recent years is provided in the Therapeutic Relativity Sheets (DoHA 2007k). Since the introduction of the mandatory 12.5% price reduction policy from August 2005, the Department has published a regularly updated list of Reference Pricing Groups (RPG) and their constituent medicines to coincide with the major editions of the Schedule (DoHA 2007i). This document was used to assign an RPG code to every entry in the CSES database where possible. In addition those medicines listed on a cost-effectiveness basis were tagged as such.

## A4 PBS expenditure and usage data

Data on PBS transactions are available from the monthly returns submitted by community pharmacists to Medicare Australia as the basis for reimbursement. These returns specify, for each medicine contained on a prescription written by a doctor, the total cost of supplying that medicine and the cost recovered from the patient (ie the copayment and any premium or Special Patient Contribution (SPC)). Both the brand and the PBS item code are recorded for each PBS medicine supplied by the pharmacist, as well as the patient status (ie general, concessional, safety net etc). Summaries of the data collected from pharmacists are available on-line at the PBS and

RPBS item code level from the Medicare Australia web site (Medicare Australia 2007). The Department of Health and Ageing also publishes summary data in its *Expenditure and Prescriptions* report (DoHA 2006c)

The principal deficiency in the data is that pharmacists do not submit a return to Medicare Australia when the cost of supplying the medicine is fully recovered from the patient. This only occurs for transactions involving general non-safety net patients when the dispensed price is lower than or equal to the general copayment plus any premium if relevant. All transactions are recorded for concessional and safety net patients, because the formula for calculating the dispensed price always ensures that the dispensed price is above the concessional copayment level (because the pharmacist's dispensing fee is always greater than the concessional copayment). For general non-safety net patients, transactions with prices above the general copayment level plus any premium will be recorded, while those with prices less than or equal to the copayment plus any premium will not be recorded.

The Drug Utilisation Subcommittee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) has attempted to remedy this situation by collating information on PBS prescriptions priced under the general patient copayment and on private prescriptions.The source for this information is a survey carried out by the Pharmacy Guild of around 150 pharmacies. The information collected is published as *Australian Statistics on Medicine* (DoHA 2007a) and is available from 1992 to 2005.

In this publication, data is presented on the number of scripts and total cost (government cost plus patient cost) for PBS and RPBS medicines. For non-PBS medicines and PBS prescriptions priced under the general patient copayment, the number of scripts is reported but not their cost and the two categories are not separately identified. In addition information is presented at the PBS item level rather than at the brand level. The publication also estimates the defined daily dose per day per 1000 of population for each medicine.

CSES has developed an annual dataset at the national level for the financial years 1991-92 to 2005-06 based on the data collected by Medicare Australia. This consists of annual financial year data provided by the Department of Health and Ageing for

the period 1991-92 (ie the year ending 30 June 1992) to 2001-02 and monthly data provided by Medicare Australia for the period July 2002 to June 2006. For each combination of item code and manufacturer code, the dataset contains information on the number of scripts, the cost to the patient, and the cost to the government cross-classified by patient category. The fields are therefore

Patient type

PBS item code

Manufacturer code

Scripts

Patient cost

Government cost

The monthly data from Medicare Australia from July 2002 also includes RPBS items and use by RPBS cardholders of PBS items.

The original data includes entries where the supplier code is not known and these entries have been distributed among the supplier codes present in the period according to their share of scripts with known suppliers. The unknown supplier codes typically make up less than 5% of total item expenditure.

While most PBS medicines are provided through community pharmacies on a prescription written by a doctor, Section 100 of the Health Act makes allowance for other ways in which PBS medicines can be made available. These Section 100 medicines are grouped into special programs namely

- Chemotherapy
- Growth Hormone
- Highly Specialised Drugs
- IVF/GIFT Treatment
- Opiate Addiction Treatment
- Botulinum Toxin Program
- Special Access Scheme
- Special Authority Program

Detailed data on the Botulinum Toxin Program, Growth Hormone, IVF/GIFT Treatment, Opiate Addiction Treatment, and the Special Access Scheme are not available. These programs are described in Chapter 1.

Information on the Chemotherapy Program and Special Authority Program are provided through Medicare Australia in the usual way.

The Highly Specialised Drugs (HSD) Program is by far the largest of these Section 100 programs and provides medicines that can only be administered in hospitals. When administered in a private hospital, these medicines are provided through a community pharmacy associated with the hospital. Use of these medicines in private hospitals is therefore recorded through Medicare Australia. Over 90% of Section 100 medicines however are provided through public hospitals. State Governments seek compensation directly from the DoHA for the cost of providing these medicines and this cost is not recorded by Medicare Australia.

The Highly Specialised Drugs section within the DoHA collects and disseminates statistics on expenditure and quantities of those PBS items that fall within the Highly Specialised Drugs program. The HSD section combines data for both public and private hospitals so that total usage can be known for each HSD item and this information has been provided on an annual financial year basis from 1992-93 to 1994-95 and quarterly since then. This data for HSD items has been incorporated into the CSES database and replaces the private hospital data from Medicare Australia.

For private hospitals, the HSD section provides data on scripts, dispensed quantity, patient cost and government cost for each PBS item code. For public hospitals data is provided on total cost, and the number of packs consumed of each PBS item code. Separate data on private and public hospitals has only been available since mid way through 2000-01.

In estimating patient and government cost for each Section 100 PBS item, it is assumed that all cost in public hospitals is government cost and to this is added the data on government cost in private hospitals. Patient cost is assumed to be zero from

1992-93 to 1999-2000 and equal to patient cost in private hospitals thereafter. Patient cost represents about 1% of total cost in private hospitals. Scripts are calculated by converting packs in public hospitals into a script equivalent and adding this to the number of scripts in private hospitals.

The expenditure and usage data has a number of aspects that require further comment.

### *Outliers*

Inspection of the data shows that although a particular combination of item code and manufacturer code is no longer be listed on the PBS after a certain date, expenditure may be recorded in some months and years after that date.

This can occur for a number of reasons.

Firstly the data provided by Medicare Australia is based on claims submitted by pharmacists at the time they are processed by Medicare Australia. Claims processed in a particular month will include transactions undertaken in that month but can also include transactions from previous months. In most cases there is only a short lag between transaction date and processing date but there are some instances where the lag is considerable.

The second reason is that while a brand from a supplier with a certain manufacturer code may no longer be listed on the PBS Schedule, it may still be within a pharmacist's inventory and will therefore appear in transactions beyond the date when no longer listed. Note that this can occur even if the processing date coincides with the transaction date. Thirdly there may be errors arising from incorrect descriptions of transactions by pharmacists or errors arising when claims are processed.

The relative importance of these reasons for expenditure being recorded in periods when the Schedule indicates it should not be are unknown.

However, the value of these outlier transactions is typically very small – less than 0.05% of the previous period's value – so it is important that their omission or

inclusion have negligible effect on any analysis where this data is used. In particular, the presence of these outliers can effect the treatment of new and disappearing goods in the calculation of price and quantity indexes.

## *Overlapping manufacturer codes*

One of the difficulties encountered when using PBS data is overlapping manufacturer codes for the same brand in a particular time period. The example of aciclovir discussed earlier indicated that the "Zovirax" brand had been successively supplied as follows

| Code | Company name | Period |
|------|--------------|--------|
| BC | Wellcome Australia Pty Ltd | July 1991 to October 1996 |
| GW | Glaxo Wellcome Australia | November 1996 to July 2002 |
| GK | GlaxoSmithKline Australia | August 2002 to the present |

As these are essentially the same company under different names supplying the same product it makes sense to treat them as identical.

Both the PBS expenditure and usage dataset and the PBS Schedule dataset are defined in terms of the combination of item and manufacturer code. If the data is left in this raw form in essentially treats the combination of item and code as different brands and therefore as different goods when used in index or other analyses.

The issue in index analysis is that this introduces an artificial "new and disappearing goods" problem each time the manufacturer code changes for the same brand. The solution is to construct time series data at the level of item and unique brand.

For many items there has only ever been the same manufacturer supplying the brand so there is no need to make any adjustment. For the bulk of the remainder this problem is relatively straightforward for the PBS Schedule data because there is a clean switch from one period to the next when the manufacturer code changes. The task then is to splice the data for the different manufacturer codes from the different periods into one series.

For a handful of items however the situation is more complicated principally because the combination of item and manufacturer code can refer to a different brand at different periods of time. This mainly occurs when subsidiaries of the same company with different codes swap responsibility for providing the brand. Each of these instances needed to be identified and an algorithm developed to properly allocate the right manufacturer code to the right brand in a particular time period.

For the PBS expenditure data there is an added complication arising from the use of annual data. If there is a switch of manufacturer codes during the course of the year, expenditure can be recorded for both codes in the same year. For those instances described in the paragraph above where the same manufacturer code refers to different brands, this means having to allocate the expenditure data proportionally to the two brands.

## A5 IMS Health patent data

The IMS Lifecycle product contains three data sets which are regularly updated. Copies of this product were provided by Merck Co, the latest edition of which was for November 2004 (IMS Health 2004b).

The Patent Focus database provides information on the patent status of medicines sold in a particular market, including patent expiry dates. The Research Focus database provides information on the progress of research projects involving pharmaceutical companies, while the Market Launch database gives details on the characteristics of medicines in each particular market.

## A6 Other data

The following information on medicines was also accessed

- Sales and usage data for England - Data on annual sales of pharmaceutical in England for the years 1991 to 2004 were obtained from the Prescribing Support Unit within the Department of Health (2007). Data for 2005 and 2006 was obtained from the National Health Service Information Centre (National Health Service 2007).

- MIMS – an electronic database of medicines currently available in Australia, updated monthly. MIMS provides a range of detailed pharmacological data on medicines including brand name, supplier, chemical composition, indications, adverse events, and dosing instructions (CMPMedica Australia 2007).

- eTG - an electronic database updated quarterly providing therapeutic guidelines to doctors for most conditions encountered by GPs (Therapeutic Guidelines Limited 2007).

## Table A1  Aciclovir - extract from PBS Schedule, December 2006

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty | No of Rpts | Premium $ | Dispensed Price for Max Qty $ | Maximum Recordable Value for Safety Net $ | Proprietary Name and Manufacturer | |
|------|------|------|------|------|------|------|------|------|
| | **ANTIVIRALS FOR SYSTEMIC USE (J05)** | | | | | | | |
| | **Direct acting antivirals (J05A)** | | | | | | | |
| | **• Nucleosides and nucleotides excl. reverse transcriptase inhibitors (J05AB)** | | | | | | | |
| | **ACICLOVIR (JO5AB01)** | | | | | | | |
| | **Authority required** | | | | | | | |
| | **Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment.** | | | | | | | |
| | **NOTE:** | | | | | | | |
| | **Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.** | | | | | | | |
| 1003T | Tablet 200 mg | 50 | .. | .. | *89.31 | 29.50 | a Acihexal<br>a Acyclo-V 200<br>a Lovir | HX<br>AF<br>GM |
| | | | | .. | 89.31 | 29.50 | a GenRx Aciclovir | GX |
| | | | | B5.78 | *95.09 | 29.50 | a Zovirax 200 mg | GK |
| | NOTE:<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Authority required** | | | | | | | |
| | **Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.** | | | | | | | |
| | **NOTE:** | | | | | | | |
| | **Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.** | | | | | | | |
| 1007B | Tablet 200 mg | 90 | 5 | .. | 159.12 | 29.50 | a Acihexal<br>a Acyclo-V 200<br>a Chem mart Aciclovir<br>a GenRx Aciclovir<br>a Lovir<br>a Ozvir<br>a Terry White Chemists Aciclovir | HX<br>AF<br>CH<br>GX<br>GM<br>RA<br>TW |
| | | | | B4.28 | 163.40 | 29.50 | a Zovirax 200 mg | GK |
| | **Authority required** | | | | | | | |
| | **Treatment of patients with herpes zoster within 72 hours of the onset of the rash;**<br>**Herpes zoster ophthalmicus.** | | | | | | | |
| | **NOTE:** | | | | | | | |
| | **Aciclovir is effective only if commenced within 72 hours of onset of rash.**<br>**Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.** | | | | | | | |
| 1052J | Tablet 800 mg | 35 | .. | .. | 191.68 | 29.50 | a Acihexal<br>a Acyclo-V 800<br>a GenRx Aciclovir<br>a Lovir | HX<br>AF<br>GX<br>GM |
| | | | | B2.09 | 193.77 | 29.50 | a Zovirax 800 mg | GK |
| | **NOTE:**<br>**No applications for repeats will be authorised.** | | | | | | | |
| | **Authority required** | | | | | | | |
| | **Patients with advanced HIV disease (CD4 cell counts of less than 150 million per litre).** | | | | | | | |
| 8234J | Tablet 800 mg | 120 | 5 | .. | 590.20 | 29.50 | a Acihexal<br>a Acyclo-V 800<br>a Lovir | HX<br>AF<br>GM |
| | | | | B7.19 | 597.39 | 29.50 | a Zovirax 800 mg | GK |
| | **OPHTHALMOLOGICALS (S01)** | | | | | | | |
| | **Antiinfectives (S01A)** | | | | | | | |
| | **• Antivirals (S01AD)** | | | | | | | |
| | **ACICLOVIR (S01AD03)** | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | **Herpes simplex keratitis** | | | | | | | |
| 1002R | Eye ointment 30 mg per g (3%), 4.5 g | ‡1 | .. | .. | 22.82 | 23.81 | Zovirax | GK |

Notes

An asterisk (*) against the dispensed price of a benefit indicates that the manufacturer's pack does not coincide with the maximum quantity.

A double dagger ( ‡ ) in the maximum quantity column indicates an item for which the maximum quantity has been specially determined to correspond to the manufacturer's pack and the manufacturer's standard pack should be prescribed and supplied. For any item where a maximum quantity greater than 1 is marked with a double dagger ( ‡ ), that maximum quantity should be prescribed and supplied.

'a' located immediately before brand names of a particular strength of an item indicates that the sponsors of these brands have submitted evidence that they have been demonstrated to be bioequivalent or therapeutically equivalent, or that justification for not needing bioequivalence or therapeutic equivalence data has been provided to and accepted by the Department. It would thus be expected that these brands may be interchanged without differences in clinical effect. For other brands of an item, i.e., those not indicated as above, it is either unknown whether or not they are equivalent, or else the sponsors of these brands have requested that an indication of equivalence NOT be shown.

'B' located immediately before an amount in the premium column indicates a brand premium which applies to that particular brand of the item.

Source: DoHA (2007j), December 2006

# Appendix B

## Index and Indicator Price and Quantity Formulae

**Index Number Formulae**

| | Price Index | Quantity index |
|---|---|---|
| Laspeyres | $$P^t = \dfrac{\sum\limits_{i=1}^{n} p_i^t q_i^0}{\sum\limits_{i=1}^{n} p_i^0 q_i^0}$$ | $$Q^t = \dfrac{\sum\limits_{i=1}^{n} q_i^t p_i^0}{\sum\limits_{i=1}^{n} q_i^0 p_i^0}$$ |
| Paasche | $$P^t = \dfrac{\sum\limits_{i=1}^{n} p_i^t q_i^t}{\sum\limits_{i=1}^{n} p_i^0 q_i^t}$$ | $$Q^t = \dfrac{\sum\limits_{i=1}^{n} q_i^t p_i^t}{\sum\limits_{i=1}^{n} q_i^0 p_i^t}$$ |
| Fisher | $$P^t = \sqrt{\dfrac{\sum\limits_{i=1}^{n} p_i^t q_i^0 \; \sum\limits_{i=1}^{n} p_i^t q_i^t}{\sum\limits_{i=1}^{n} p_i^0 q_i^0 \; \sum\limits_{i=1}^{n} p_i^0 q_i^t}}$$ | $$Q^t = \sqrt{\dfrac{\sum\limits_{i=1}^{n} q_i^t p_i^0 \; \sum\limits_{i=1}^{n} q_i^t p_i^t}{\sum\limits_{i=1}^{n} q_i^0 p_i^0 \; \sum\limits_{i=1}^{n} q_i^0 p_i^t}}$$ |
| Walsh | $$P^t = \dfrac{\sum\limits_{i=1}^{n} p_i^t \sqrt{(q_i^t q_i^0)}}{\sum\limits_{i=1}^{n} p_i^0 \sqrt{(q_i^t q_i^0)}}$$ | $$Q^t = \dfrac{\sum\limits_{i=1}^{n} q_i^t \sqrt{(p_i^t p_i^0)}}{\sum\limits_{i=1}^{n} q_i^0 \sqrt{(p_i^t p_i^0)}}$$ |
| Tornqvist | $$P^t = \prod_{1}^{n} \left( \dfrac{p_i^t}{p_i^0} \right)^{\frac{1}{2}\left(s_i^t + s_i^0\right)} \text{ or}$$ $$\ln P^t = \sum_{i=1}^{n} \dfrac{1}{2}\left(s_i^t + s_i^0\right)\ln\left(\dfrac{p_i^t}{p_i^0}\right)$$ | $$Q^t = \prod_{1}^{n} \left( \dfrac{q_i^t}{q_i^0} \right)^{\frac{1}{2}\left(s_i^t + s_i^0\right)} \text{ or}$$ $$\ln Q^t = \sum_{i=1}^{n} \dfrac{1}{2}\left(s_i^t + s_i^0\right)\ln\left(\dfrac{q_i^t}{q_i^0}\right)$$ |
| Vartia | $$P^t = \prod_{1}^{n} \left( \dfrac{p_i^t}{p_i^0} \right)^{w_i^t} \text{ or}$$ $$\ln P^t = \sum_{i=1}^{n} w_i \ln\left(\dfrac{p_i^t}{p_i^0}\right)$$ where $$w_i = \dfrac{\left(v_i^t - v_i^0\right)\big/\left(\ln v_i^t - \ln v_i^0\right)}{\left(\sum\limits_{i=1}^{n} v_i^t - \sum\limits_{i=1}^{n} v_i^0\right)\Big/\left(\ln\left(\sum\limits_{i=1}^{n} v_i^t\right) - \ln\left(\sum\limits_{i=1}^{n} v_i^0\right)\right)}$$ | $$Q^t = \prod_{1}^{n} \left( \dfrac{q_i^t}{q_i^0} \right)^{w_i^t} \text{ or}$$ $$\ln Q^t = \sum_{i=1}^{n} w_i \ln\left(\dfrac{q_i^t}{q_i^0}\right)$$ |

## Indicator Number Formulae

| | Price indicator | Quantity indicator |
|---|---|---|
| Bennet | $I^t = \dfrac{1}{2}\left(\displaystyle\sum_{i=1}^{n}\left(q_i^0 + q_i^t\right)\left(p_i^t - p_i^0\right)\right)$ | $V^t = \dfrac{1}{2}\left(\displaystyle\sum_{i=1}^{n}\left(p_i^0 + p_i^t\right)\left(q_i^t - q_i^0\right)\right)$ |
| Montgomery | $I^t = \displaystyle\sum_{i=1}^{n} w_i \ln\left(\dfrac{p_i^t}{p_i^0}\right)$ <br> where <br> $w_i = \dfrac{v_i^t - v_i^0}{\ln v_i^t - \ln v_i^0} = \dfrac{p_i^t q_i^t - p_i^0 q_i^0}{\ln\left(p_i^t q_i^t\right) - \ln\left(p_i^0 q_i^0\right)}$ | $V^t = \displaystyle\sum_{i=1}^{n} w_i \ln\left(\dfrac{q_i^t}{q_i^0}\right)$ |

# Appendix C

## Estimation of the Time Product Dummy Regression Equation

The weighted time product dummy equation is given by

$$w_{ij} \ln(p_{ij}) = \sum_{t=1}^{T} w_{ij} \alpha_t D_{it} + \sum_{k=1}^{K} w_{ij} \gamma_k D_{ik}^* + e_{ij} \tag{1}$$

where

$p_{ij}$ is price for product i =1 to K at time j = 1 to T

$D_{it}$ is the time dummy variable for time t,

= 1, when j = t;

= 0 otherwise

$D_{ik}^*$ is the product dummy variable for product k,

= 1, when i = k;

= 0 otherwise

$$v_{ij} = \frac{V_{ij}}{\sum_{i=1}^{K} V_{ij}} = \frac{p_{ij} q_{ij}}{\sum_{i=1}^{K} p_{ij} q_{ij}} \quad \text{ie product i's share of total value in time j}$$

$w_{ij}$ is the square root of $v_{ij}$

The estimated values of $\beta = \begin{pmatrix} \alpha \\ \gamma \end{pmatrix}$ are given by

$$\hat{\beta} = \left( X'X \right)^{-1} X'y \tag{2}$$

where $X$ is a matrix of observations of the explanatory variables, $X'$ is the transpose of $X$, and $y$ is a vector of observations of $w_{ij} \ln(p_{ij})$.

The price index at time t with time 0 as base is given by

$$\exp\left( \frac{\hat{\beta}_t}{\hat{\beta}_0} \right) \tag{3}$$

Statistical packages like SPSS, Stata and EViews have difficulty handling linear regressions when the number of explanatory variables gets beyond 500-1000. In the application considered in Chapter 6, T = 15 and K = 3244 giving 3239 explanatory

variables for equation (1). This implies inverting a matrix in equation (2) of dimensions 3239 x 3239.

This appendix illustrates how the weighted time product dummy regression can be undertaken for these larger numbers of explanatory weighted dummy variables using *Scilab*, a software package for performing operations on large matrices and vectors. A procedure for the simpler unweighted case is set out in Rao (2004).

To illustrate how the values of $\hat{\beta}$ are obtained, the calculations are shown for the case of 4 products and 3 time periods. It is assumed that observations are ordered first by product and then by time, so $y$ and $X$ are

$$
y = \begin{bmatrix}
w_{11}\ln(p_{11}) \\
w_{12}\ln(p_{12}) \\
w_{13}\ln(p_{13}) \\
w_{21}\ln(p_{21}) \\
w_{22}\ln(p_{22}) \\
w_{23}\ln(p_{23}) \\
w_{31}\ln(p_{31}) \\
w_{32}\ln(p_{32}) \\
w_{33}\ln(p_{33}) \\
w_{41}\ln(p_{41}) \\
w_{42}\ln(p_{42}) \\
w_{43}\ln(p_{43})
\end{bmatrix}
\qquad
X = \begin{bmatrix}
w_{11} & 0 & 0 & w_{11} & 0 & 0 & 0 \\
0 & w_{12} & 0 & w_{12} & 0 & 0 & 0 \\
0 & 0 & w_{13} & w_{13} & 0 & 0 & 0 \\
w_{21} & 0 & 0 & 0 & w_{21} & 0 & 0 \\
0 & w_{22} & 0 & 0 & w_{22} & 0 & 0 \\
0 & 0 & w_{23} & 0 & w_{23} & 0 & 0 \\
w_{31} & 0 & 0 & 0 & 0 & w_{31} & 0 \\
0 & w_{32} & 0 & 0 & 0 & w_{32} & 0 \\
0 & 0 & w_{33} & 0 & 0 & w_{33} & 0 \\
w_{41} & 0 & 0 & 0 & 0 & 0 & w_{41} \\
0 & w_{42} & 0 & 0 & 0 & 0 & w_{42} \\
0 & 0 & w_{43} & 0 & 0 & 0 & w_{43}
\end{bmatrix}
$$

To avoid perfect multicollinearity (note sum of first 3 columns of $X$ is same as sum of last 4 columns and is the weights vector) and hence $X'X$ being singular, the first time dummy variable (column 1 of $X$) is omitted. This is equivalent to putting $\hat{\beta}_0$ equal to 1 in equation (3) above. The calculated price indexes will therefore all have the first year as the base period.

Then $X'X$ in equation (2) is

$$X'X = \left[\begin{array}{cc|cccc} \sum_k v_{k2} & 0 & v_{12} & v_{22} & v_{32} & v_{42} \\ 0 & \sum_k v_{k3} & v_{13} & v_{23} & v_{33} & v_{43} \\ \hline v_{12} & v_{13} & \sum_t v_{1t} & 0 & 0 & 0 \\ v_{22} & v_{23} & 0 & \sum_t v_{2t} & 0 & 0 \\ v_{32} & v_{33} & 0 & 0 & \sum_t v_{3t} & 0 \\ v_{42} & v_{43} & 0 & 0 & 0 & \sum_t v_{4t} \end{array}\right]$$

or

$$X'X = \left[\begin{array}{cc|cccc} 1 & 0 & v_{12} & v_{22} & v_{32} & v_{42} \\ 0 & 1 & v_{13} & v_{23} & v_{33} & v_{43} \\ \hline v_{12} & v_{13} & \sum_t v_{1t} & 0 & 0 & 0 \\ v_{22} & v_{23} & 0 & \sum_t v_{2t} & 0 & 0 \\ v_{32} & v_{33} & 0 & 0 & \sum_t v_{3t} & 0 \\ v_{42} & v_{43} & 0 & 0 & 0 & \sum_t v_{4t} \end{array}\right]$$

where $v_{ij} = w_{ij}{}^2$ and $\sum_k v_{kj} = 1$

This matrix can be represented as a partitioned matrix

$$X'X = \left[\begin{array}{c|c} I & V' \\ \hline V & Z \end{array}\right]$$

where $I$ is the identity matrix of dimensions T-1 x T-1 (2 x 2 in the example). $V$ is matrix of dimensions K x T-1 (4 x 2) where the elements are just the value shares defined earlier. $Z$ is a diagonal matrix of size K x K (4 x 4) where the elements on the main diagonal are the sums across the T time periods of the value share for a particular product and the off-diagonal elements are zero.

In the application considered, $I$ is of dimensions 14 x 14, $V$ is 14 x 3244 and $Z$ is 3244 x 3244.

Now $X'y$ in equation (2) is

$$
\begin{bmatrix}
0 & w_{12} & 0 & 0 & w_{22} & 0 & 0 & w_{32} & 0 & 0 & w_{42} & 0 \\
0 & 0 & w_{13} & 0 & 0 & w_{23} & 0 & 0 & w_{33} & 0 & 0 & w_{43} \\
w_{11} & w_{12} & w_{13} & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 \\
0 & 0 & 0 & w_{21} & w_{22} & w_{23} & 0 & 0 & 0 & 0 & 0 & 0 \\
0 & 0 & 0 & 0 & 0 & 0 & w_{31} & w_{32} & w_{33} & 0 & 0 & 0 \\
0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 & 0 & w_{41} & w_{42} & w_{43}
\end{bmatrix}
\begin{bmatrix}
w_{11}\ln(p_{11}) \\
w_{12}\ln(p_{12}) \\
w_{13}\ln(p_{13}) \\
w_{21}\ln(p_{21}) \\
w_{22}\ln(p_{22}) \\
w_{23}\ln(p_{23}) \\
w_{31}\ln(p_{31}) \\
w_{32}\ln(p_{32}) \\
w_{33}\ln(p_{33}) \\
w_{41}\ln(p_{41}) \\
w_{42}\ln(p_{42}) \\
w_{43}\ln(p_{43})
\end{bmatrix}
$$

$$
=
\begin{bmatrix}
\sum_k v_{k2}\ln p_{k2} \\
\sum_k v_{k3}\ln p_{k3} \\
\sum_t v_{1t}\ln p_{1t} \\
\sum_t v_{2t}\ln p_{2t} \\
\sum_t v_{3t}\ln p_{3t} \\
\sum_t v_{4t}\ln p_{4t}
\end{bmatrix}
$$

which is a vector with K+2 rows, or 3246 rows in the application.

It is relatively straightforward within a spreadsheet program such as Excel to form the matrices $I$ and $V$ and the vector $X'y$ and to read them into *Scilab*. The matrix $Z$ can be formed within *Scilab* from a vector consisting of its main diagonal elements and it is also a relatively simple task to construct and read this into *Scilab*. These can be combined to form the matrix $X'X$ which can then be inverted and multiplied by the vector $X'y$ to obtain the vector of coefficients $\hat{\beta}$. The standard errors of these coefficients are the square roots of the main diagonal elements of the inverted matrix and these can be read out of *Scilab* as a vector. The vector of coefficients can be used to estimate the residuals and hence the standard error of estimate and the adjusted coefficient of determination.

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