Technical Barriers to Trade for the importation of Australian Veterinary Biological Vaccines to the European Union

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Abstract

Technical barriers to trade are product health and safety related regulations imposed by governments to restrict or control the inflow and outflow of particular products. This thesis begins with a brief review of governments' sovereign rights in the context of international standards to be adopted in restricting or controlling market access to specific products.

This is followed by an analysis of the multilateral regulatory environment under the World Trade Organisation's (WTO) agreements, with particular emphasis on GATT (1994) Article XX and the Agreements on Sanitary and Phytosanitary Measures and the Technical Barriers to Trade. This analysis aims to assist a better understanding of the new global trade order under the WTO regime as it deals with the contradiction between safety concerns versus market access and trade liberalisation.

The thesis then examines in detail the various European Union (EU) regulations as they relate to veterinary biological vaccines and the requirements for Australian products to be allowed into EU markets. The bureaucratic requirements of such regulations appear to protect domestic producers from foreign competition, by, at the very least, frustrating market access through a myriad of committees and technical requirements designed to retard market penetration. The EU regulations, therefore, appear to have negatively impacted on trade flows.

The Australian market is typically oligopolistic in structure and significant foreign take-over of domestic production in the 1990's, has reduced Australia's ownership in domestic production of veterinary biological vaccines. Given this circumstance it is unlikely that the Australian government would invest significant resources investigating the likelihood of a challenge to the EU through the WTO dispute mechanism.

Table of Contents

ABSTRACT ..... **III**

LIST OF TABLES ..... **VII**

LIST OF FIGURES ..... **VIII**

CHAPTER 1. INTRODUCTION AND RESEARCH CONTEXT **1**

1.1 THE RESEARCH CONTEXT 2
1.2 BACKGROUND INFORMATION AND LITERATURE REVIEW 3
1.2.1 Review of Literature on Administrative and Technical Barriers *5*
1.3 METHODOLOGY AND TECHNIQUES 7
1.4 THE RELEVANCE OF THIS RESEARCH 9

CHAPTER 2. ..... THE WORLD TRADE ORGANISATION AND THE MULTILATERAL REGULATORY ENVIRONMENT **14**

2.1 OVERVIEW 14
2.2 A BRIEF INTRODUCTION TO THE WTO 14
2.3 THE GENERAL PROVISIONS OF THE GATT 1994 16
2.3.1 Article III and National Treatment *16*
2.3.2 Article XX and Product Health and Safety: An Exception to the Rule *16*
2.4 THE AGREEMENT ON SANITARY AND PHYTOSANITARY MEASURES (SPS) 18
2.4.1 The Base Standards *19*
2.4.2 Science and Protection or Market Access Impediments? *20*
2.4.3 The 'Consumer Concerns' Standard *22*
2.4.4 Justifiable Action Within the Scope of the SPS Agreement *23*
2.5 THE TECHNICAL BARRIERS TO TRADE AGREEMENT (TBT) 25
2.5.1 The TBT and National Treatment *26*
2.5.2 SPS and TBT Agreements: A Comparative Analysis *28*
2.6 A BRIEF OVERVIEW OF THE AUSTRALIAN CONTEXT 30
2.7 SUMMARY AND CONCLUSIONS 34

CHAPTER 3. THE EUROPEAN UNION REGULATORY FRAMEWORK **36**

3.1 INTRODUCTION 36
3.2 THE EU AND ITS INSTITUTIONAL STRUCTURES 37
3.2.1 The EU Decision-Making Bodies *37*
3.2.2 EU Legislative Forms *38*
3.3 THE REGISTRATION METHODS 41
3.3.1 National Registration (NR) *42*
3.3.2 Decentralised Registration (DR) *43*
3.3.3 Centralised Registration (CR) *45*
3.4 THE EU REGISTRATION REQUIREMENTS 46
3.4.1 Context *46*
3.4.2 National Registration (NR) *48*
3.4.2.1 Strategic Considerations 49
3.4.2.2 Country Choice 50
3.4.3 Decentralised Registration (Mutual Recognition) (MR) *53*
3.4.3.1 MR Recognition Issues 55
3.4.4 Centralised Registration (CR) *57*
3.4.4.1 Part A Products 58
3.4.4.2 Part B Products 60
3.4.4.3 Satisfying the Innovation Requirement 61
3.5 AN ASSESSMENT OF THE RAMIFICATIONS OF MULTIPLE PATHWAYS 63
3.6 SUMMARY 67

CHAPTER 4. BARRIERS IMPLICIT IN THE APPLICATION PROCESS **70**

4.1 INTRODUCTION 70
4.2 THE REGISTRATION FORM (THE DOSSIER) 70
4.2.1 Labelling *71*

4.2.2 Product Release Control Testing *74*
4.2.3 Product Application Fees and Plant Inspections *75*
4.2.4 Mutual Recognition Treaties and GMP Certification *76*
4.3 APPLICATION ASSESSMENT HURDLES 77
4.3.1 Dossier Validation *79*
4.3.2 Trial Data Assessment *79*
4.3.3 Data Confidentiality *80*
4.4 OBTAINING MARKETING AUTHORISATIONS IN THE UK: A CASE STUDY 82
4.5 CONCLUSION 85

CHAPTER 5. ..... AN ECONOMIC AND TRADE FLOW ANALYSIS OF THE IMPACT OF EU REGULATIONS 87

5.1 INTRODUCTION 87
5.2 AN ECONOMIC ANALYSIS OF THE STRUCTURE OF THE EU INDUSTRY: OVERVIEW 87
5.2.1 The Regulation 2309/93 Annex and its Competitive Effects *88*
5.2.2 Likely Pricing Effects of Discouraging Competition *91*
5.2.3 Rationalising the Existence of the Rules *96*
5.3 AN ANALYSIS OF TRADE FLOWS BETWEEN AUSTRALIA AND THE EU 97
5.3.1 Trade Flows by Country *99*
5.3.2 Trade Flows (Export) by State *102*
5.3.3 Aggregate Trade Flow Analysis *106*
5.4 CONCLUSION 111

CHAPTER 6. CONCLUSION 112

6.1 OVERVIEW 112
6.2 THE RESEARCH QUESTION 112
6.3 THE INTERNATIONAL FRAMEWORK 114
6.3.1 Scientific based principles, according to the SPS - but whose science? *115*
6.3.2 TBT versus domestic standards, transparency and fairness *116*
6.4 THE EU REGULATIONS AND THEIR APPLICATIONS 117
6.5 TRADE FLOW EFFECTS OF THE EU REGULATIONS 118
6.6 FINAL CONCLUSIONS 120

7. BIBLIOGRAPHY 122

List of Tables

TABLE 3.1: CHOOSING THE MOST APPROPRIATE REGISTRATION PATHWAY IN THE EU 66
TABLE 4. 1: SUMMARY OF PRODUCT APPLICATION FEES PAYABLE FOR EU REGISTRATION 75
TABLE 5. 1 : AUSTRALIAN IMPORTS AND EXPORTS SUMMARY (1996-2000) IN AUD 98
TABLE 5. 2 : AUSTRALIAN IMPORTS AND EXPORTS SUMMARY (1196-2000) IN AUD 103

List of Tables

TABLE 3.1: CHOOSING THE MOST APPROPRIATE REGISTRATION PATHWAY IN THE EU 66
TABLE 4. 1: SUMMARY OF PRODUCT APPLICATION FEES PAYABLE FOR EU REGISTRATION 75
TABLE 5. 1 : AUSTRALIAN IMPORTS AND EXPORTS SUMMARY (1996-2000) IN AUD 98
TABLE 5. 2 : AUSTRALIAN IMPORTS AND EXPORTS SUMMARY (1196-2000) IN AUD 103

List of Figures

FIGURE 1: EU NATIONAL REGISTRATION PROCEDURE 50
FIGURE 2: EU DECENTRALISED REGISTRATION PROCEDURE (MUTUAL RECOGNITION OF AUTHORISATION GIVEN UNDER NATIONAL PROCEDURE) 55
FIGURE 3: EU CENTRALISED REGISTRATION PROCEDURE 57
FIGURE 4 : UK MARKETING AUTHORISATION PROCEDURE 78
FIGURE 5 : A MONOPOLISTIC COMPETITIVE FIRM IN MARKET BEFORE TRADE OPENS 92
FIGURE 6: A MONOPOLISTIC COMPETITIVE FIRM IN A MARKET AFTER TRADE OPENS 93
FIGURE 7 : SUMMARY OF IMPORTS AND EXPORTS TRADE FLOWS (1996-2000) BETWEEN AUSTRALIA AND THE EU (AUD) 99
FIGURE 8 : AUSTRALIA AGGREGATE IMPORT / EXPORT FLOWS (AUD) 106

1. Introduction and Research Context

Technical barriers to trade are product health and safety related regulations imposed by Governments that have the effect of restricting or imposing conditions on the importation of a particular product. Technical barriers can be classified as having either a *positive* or *negative* policy origin or rationale. Positive barriers are implemented to control the importation of hazardous material, or goods that may pose health and safety risks to consumers. Negative barriers, on the other hand, have a more political function. The underlying purpose of a negative barrier is to provide a non-transparent means of limiting imports of a particular product in order to protect domestic industries from import competition (Evans, 1994, p.60).

The research problem investigated in this thesis involves an analysis of product health and safety standards and regulations that have a justifiably positive rationale on their face, but may in actual fact, be designed to achieve a negative protectionist objective. In an attempt to identify and distinguish between the legitimate and illegitimate use of technical barriers, Article XX of the General Agreement on Tariffs and Trade (GATT 1994) provides that signatories to the WTO Agreement are entitled to take regulatory measures to protect human, animal or plant life or health, provided that the controls are: i) necessary; ii) non-discriminatory as between domestic and imported products; and iii) not disguised as restrictions upon international trade (Patterson, 1990, p.91).

In spite of the constructive and principled approach, the language against misuse contained in Article XX is so vague, or broad, as to be virtually unenforceable. For example, what is "necessary"? What is "arbitrary and unjustified"? What is a disguised restriction to trade"? (Patterson, 1990, p.91)

1.1 The Research Context

There is no argument that national governments have, and should continue to possess, the sovereign right to control the importation of products that pose health and safety risks to its citizens. However, in the context of this research, it is apparent that the European Union's (EU) pharmaceutical registration and certification process for veterinary vaccines appears to have the effect of functioning as a negative technical barrier to trade. In this regard, the EU veterinary vaccines registration and certification process provides an interesting opportunity to examine and demonstrate the very fine line between positive and negative technical barriers to trade. Because the discriminatory aspects of the EU veterinary vaccine registration process are subtle and difficult to identify on the face of the regulations, a detailed analysis of the scheme provides insight into how a complex regulatory scheme can be devised and implemented in a manner that functions as a negative technical barrier to trade. In this context, a broad objective of this thesis is to examine and describe and analyse how the operation and administration of the EU regulatory process constitutes a negative barrier to trade.

Article 2.2 of the WTO Agreement on Technical Barriers to Trade (TBT) states that "Members shall ensure that technical regulations are not prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to international trade." The question that remains unresolved is what constitutes an *obstacle* to international trade within the meaning of the Agreement? Since, Article 2.2 includes a prohibition against the negative administration of the regulatory mechanism, it must be shown that access by non-EU applicants is impeded by the administrative processes.

In this context, the more specific aim of this research is to investigate and analyse the application of the European Union (EU) regulatory regime in respect of

obtaining European market access of veterinary biological vaccines from Australia. This objective will encompass an analytical framework that necessitates:

- A review of EU registration and certification regulations on veterinary biological vaccines;
- A review of the administrative processes surrounding the application of the regulations;
- An analysis of the EU regulations in respect of the World Trade Organisation (WTO) Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT);
- An investigation into the degree to which the bureaucratic application of the EU regulations are used as a negative technical barrier; and
- An analysis of the manner in which market access for Australian veterinary biological vaccines is being restricted by the EU regulations.

Accordingly, the purpose of the research is to assess the effect of the regulations on trade flows, not to examine the causal legalities of the regulations.

1.2 Background Information and Literature Review

Over the past two decades, successive national governments have embarked on economic measures designed to open up access to the Australian market for imports with a view to gaining more favourable reciprocal market access rights to overseas markets. The policy foundation for this initiative was based upon a rationale of reciprocal market access, whereby it was considered that if Australia liberalised its markets, then its trading partners would be compelled to reciprocate and their markets too would be come accessible to Australian products (McMullan, 1995, p.7).

Whilst this approach has had a positive overall effect in opening the Australian economy to foreign competition and expanding overseas market access for some of our

manufactured goods, market access for elaborately transformed manufactures (ETMs) has not expanded to the degree it could be expected (Feaver & Mahmood, 1997, p.42). It appears that the higher the technical composition of a product, the higher the level of regulatory compliance required to satisfy and achieve offshore market access (Wilson, 1996, pp.70-71).

An example of an industry that produces a high-value added product that regularly meets technically-based market access constraints is the veterinary vaccine industry. Australia does have a small (by world standard), but significant (by local standards) veterinary vaccine industry. The Australian industry for veterinary vaccines is oligopolistic with few firms operating in the local manufacture of these products. Foreign enterprises have recognized the strength and competitiveness of the Australian industry in the past decade as evidenced by the acquisition in the early 1990's of a major Australian veterinary vaccine manufacturer (Arthur Webster Pty. Ltd.) by a US firm (American Cyanamid). By global standards, the Australian industry possesses large scale manufacturing facilities which produce to world best practice standards. For example, Australia has the largest single production facility for bacterial veterinary vaccines. Overseas markets are, therefore, necessary for expansion to achieve the increasing returns to scale needed to ensure the on-going viability of this industry.

In a global context, Governments around the world are aware of the importance of the biotechnology industries. Biotechnology has the potential to generate high-value added returns which have the effect of improving national trade balances. Governments are also aware that in the absence of a viable industry, skill and knowledge resources have little alternative but to seek employment elsewhere. The re-allocation of important intellectual capital erodes the possibility of future industry survival, much less successful expansion.

1.2.1 Review of Literature on Administrative and Technical Barriers

In classical economics, competition is the dynamic force that drives economies to achieve higher levels of efficiency. In order to promote economy-wide efficiency, Governments around the world have implemented economic policies designed to remove impediments that unduly restrict competition. Governmental policy, therefore, is an important ingredient in establishing and promoting an economic environment within which competition (and therefore efficiency) can flourish. Unrestricted competition, on the other hand, cannot exist given that Governments are also obliged to safeguard their citizens. In doing so, national governments rely on the notion of sovereignty and the right to choose appropriate protective measures required to provide such safeguards.

The debate on the effects of protective measures is not new. The notion of illegitimate Technical Barriers to Trade (TBT) has received some attention over the past decade as the various governments around the world have come to the realisation that, at times, TBTs are used to artificially deny market access to foreign products.

> Despite the emergence of the World Trade Organisation and multilateral trade agreements like the North American Free Trade Agreement, officials in nations around the globe are lying awake at night devising new and better ways to protect their markets. It is probably fair to say this will always be so. It's up to exporters to recognise non-tariff barriers, which take many forms, including import licenses, import surcharges, centralised distribution systems, quality standards, local content laws, cartels and shipping restrictions... Some trade barriers are designed to jack up your duties or keep your product out altogether (Biederman, 1998, p.33).

It would appear then that TBTs are not unusual, not industry specific and more common than we might imagine in various countries around the world. Baron (1983), for example, identifies Japan as a problem country employing a complex matrix of customs regulations and standards to prevent certain imports. For instance, "American

pharmaceutical companies have been frustrated by Japan's failure to accept the results of key clinical tests performed in the United States" (Baron, 1983, p.11).

Paterson (1990) discusses issues in relation to the international trade of agricultural products and points to the GATT[1] Article XX, as being problematic in terms of protectionism through TBT. As mentional earlier, GATT Article XX specifically provides:

> parties the right to take measures to protect human, animal or plant life or health provided three conditions are met: (1) the measures are necessary; (2) the measures do not arbitrarily or unjustifiably discriminate between countries where the same conditions prevail; and (3) the measures are not disguised restrictions on international trade (Patterson, 1990, p.91).

The problem with Article XX stems from its wording. There is a need to more clearly define what is necessary, arbitrary or justifiable and what constitutes a disguised restriction. Furthermore, clarification of who decides who is right and who is wrong is also required. In this regard, the appropriateness, fairness and equity of standards is illustrated by an assessment of the American Society of Mechanical Engineers (ASME)

> So what is an international standard? ASME believes the true test of an international standard is one that provides for open and nondiscriminatory access to any affected parties, regardless of geographic location, and that meets the needs of the global marketplace (Hamilton, 1997, p.39).

ASME has its own standards and challenges whether alternatives, such as ISO (International Standards Organisation), touted as "international standards" are indeed better then theirs - hence, the debate continues. ASME's position is supported by the Missouri District Export Council (MDEC).

> Access to foreign markets has been overwhelmingly identified as the number one priority of the U.S. exporting community. Restricting that access through nontariff barriers, such as International Standards Organisation (ISO) 9000 regulations and "shifting" European Union

[1] GATT is the General Agreement on Tariffs and Trade 1947 referred to in this article. The later GATT of 1994 establishes the formation of the WTO and does not replace the GATT 1947, but rather exists separately to it.

> directives, has become particularly important for small-and medium-sized exporters (Kisling, 1997, p.23).

Even though MDEC, not surprisingly, shares a patriotic stand with ASME, on favouring US standards, the point made by Kisling is valid for all exporters in all nations, in a climate where, presumably international business wishes to standardise, to achieve greater efficiency, through economies of scale. ASME further recommends that international standards harmonisation should proceed on a sectoral industry basis. This would allow for different standards between pressure equipment and pharmaceuticals for example.

To date, there appears to be a void in the available literature which examines the subject issue of this thesis, although PJB Publications have issued a number of reports, namely:

- Veterinary Vaccines in the EU Markets and Regulations (1994)
- Veterinary Vaccines A World Market Review (1996)
- Animal Pharm's Top 20 (1993).

The above mentioned publications do explain in detail the structure of the world market and to some degree the regulations which exist for EU for veterinary vaccines. These documents are too broad in their coverage, that is, they look at veterinary vaccines as a total group, not biological vaccines per se. None of these publications address the issue of regulatory barriers to trade through the existence, the application, or the administration of regulations. Finally these publications are now out of date due to changes in the EU requirements effective through EU directives which became effective from the beginning of 1998.

1.3 Methodology and Techniques

There is little published literature that examines the specific issues and problems associated with this particular area of study. The majority of available information is

obtained from industry and trade journal articles. In light of this constraint, the substance of this research is more of an applied rather than theoretical nature. Accordingly, the structure and methodology of the analysis is as follows.

After a broad summary and overview of issues in Chapter 1, a more detailed analysis commences in Chapter 2. The objective of Chapter 2 is to identify and examine the relevant international standards and principles that govern the creation and imposition of national health and safety standards. The source of the international principles are, primarily, the several WTO Agreements relating to product health and safety regulations.

After having identified and clarified the structure of the international rules governing the use of technical barriers, Chapters 3 and 4 commences a review of the EU legislation and regulatory scheme that governs the certification and registration process for veterinary vaccines. This is not intended to be a detailed legal analysis, but rather an applied review from a point of statutory compliance required for market access through EEC Directives and similar decrees. Furthermore, each EU member country has local laws, some of which may cause bureaucratic differences in the application of the EU regulations. To the extent possible, the research will also examine the application standards associated with the enactment of the EU regulations at the local level, with a specific focus on how the local bureaucracy carries out its tasks. The EU is a conglomeration of 15 independent member states, all enjoying sovereignty in their own right, but linked by common regulations.

The objective of Chapter 3 and Chapter 4 is to identify whether and how the EU regulatory scheme might function as a negative technical barrier to trade. Having identified the mechanics of the EU regulations, it is then possible to conduct a trade flow, or effects oriented, analysis of the possible impacts of the EU scheme. In Chapter

5, a descriptive analysis of trade flows of veterinary vaccines between Australia and the EU is undertaken to determine the presence of trends in patterns of trade that may show evidence of the negative TBT effect of the EU regulations. To assist in this analysis, detailed trade flow information is presented by product type, price, time period, volume, value and country of origin. Some limitations on this data may exist due to customs classification of the products in question, nevertheless, the data in question provides a rich source of material for research . Chapter 5 is followed by a summary of observations and conclusion.

1.4 The Relevance of this Research

The regulation of the certification and registration processes for veterinary vaccines poses an interesting question of whether the purpose of the EU regulations are intended to protect animal or human health and safety. Although the answer to this question is somewhat rhetorical in that it does not provide any potential legal implications in respect of the GATT (1994) Article XX exemption, it is useful at this stage of the analysis to highlight the close relationship between animal and human health issues.

Diseases of animals have particular ramifications for humans. A surprisingly large number of diseases have been shown capable of crossing the animal to human host barrier. Therefore, cross-infection is possible. One of the two most amazing enigmas of last century are Acquired Immune Deficiency Syndrome/Human Immunodeficiency Virus (AIDS/HIV) and Bovine Spongiform Encephalopathy (BSE) or more commonly known as Mad Cow's Disease and its recent links to a new variant, Creutzfeldt-Jakob Disease (vCJD).

The AIDS/HIV problem came to the fore in the 1980's when cases of kaposi's sarcoma and pneumocystis carinii, particularly in males in the USA, started to manifest

in exponential numbers. What followed was a flurry of world biotechnological activity directed towards, firstly, diagnosing the disease using laboratory devices and, secondly, to isolate the virus, mimic its functions and try to come up with a solution (which to this day still evades us). The role of several governments has been to provide infrastructure by way of care, funding for research and to impose mandatory testing for AIDS/HIV under certain conditions.

One outcome of the AIDS/HIV problem has been the reminder of the opportunities that exist for infections to cross the animal to human host barrier. We have known for some years about some of these diseases. Columella, in 14 AD, in Northern Italy, described a condition of cattle known as "consumption". We now know this is tuberculosis, following the discovery of Robert Koch's tubercule bacillus in 1882. It is also commonly accepted that tuberculosis can quite easily cross from/to cattle and humans and also from/to monkeys and humans. The theory behind AIDS/HIV is that this disease had been around for some time and was probably contracted by humans through the butchering and eating of monkeys in the African continent. Dr Ernie Drucker, Professor of Epidemiology and Social Medicine, Albert Einstein College of Medicine at Montefiore Hospital in the Bronx, New York, recently stated, in relation to the AIDS/HIV origin being from monkeys, that it "seems clear that's where the virus came from. Almost all human viruses crossed over from animal species to humans" (Swan, 2000, p.3).

There are considerable dangers associated with humans and animals sharing the same environment. The risk of disease is one of the major considerations. Animal husbandry methods and hygiene are important. Immunisation to prevent diseases is also important, but equally important is the knowledge that whatever is injected or fed to the animals will not contribute to any other problem, especially when the animals, or their

derivatives are part of the human food chain. Careful controls and regulations are therefore needed and warranted to prevent disasters from happening. In a way the problem with BSE and vCJD appears to have been a blatant disregard for science. As Dr Drucker explains:

> We see other diseases happening all the time, like Mad Cow Disease, which are a product of technologies we didn't really understand the implications of. Cows weren't mean to eat animal protein, they have no mechanism to protect themselves (Swan, 2000, p.5).

The plight caused by vCJD is as yet unknown, simply because the scientific community has not been able to conclusively determine how this disease transmits. The possibilities are that it may be transmitted in sheep, vaccines, blood donations and even some anti-ageing creams (Pearson, 2000, p.59).

Mortality rates are not high as yet, with reports of 80 people dead in the UK, but nobody knows how many people may be carrying the disease (2000a, pp.2-3). Given that the only diagnostic method to confirm infection involves dissection of the brain, it is currently only possible to confirm infection after death. We quite simply do not know what the future has in store. The BSE Advisory Committee stated that the maximum possible number of vCJD victims in the UK had been estimated to be one quarter of a million people (UPI, 2000a, p.3).

Australia, recently has followed the lead of the USA, Canada, Austria and New Zealand in banning acceptance from certain blood donors as a preventative measure. (Cooke, 2000, p.61). A recent U.K. 16 volume report was the result of a judicial inquiry set up in 1997to look at the response of BSE and vCJD. It issued a damning report on the handling of the epidemic by Conservative ministers and their officials. It was alleged in that report that the governments of the time were keen to avoid a health scare and reassure the public that British beef was safe (Pearson, 2000, p.64). Very recently in the continuing saga of the BSE, Britain's Food Standard Agency has called for an urgent

mass screening of the nations' 40 million sheep. The problem is that there is a very similar disease called "scrapie" in sheep which displays similar symptoms to BSE in cows. What is not known is whether scrapie is masking BSE. (UPI, 2000a, p.2). If this is found to be the case, then UK sheep population may no longer be a viable food option for human consumption. The ramifications of the potential depopulation of the UK's sheep stocks (and possibly those of countries where sheep product was sold to) coupled with death of such large numbers of people is almost incomprehensible.

Other diseases which have been known to affect humans, such as Leptospirosis (from cattle) and Erysipelas (from pigs) have not caused such concern. Brucellosis was eradicated in Australia in 1989, but it is reported in 86 countries around the world. Brucellosis is contracted from cattle, sheep, goats and pigs ("WHO Fears Global Crisis from Infectious Disease," 1996, p.45). Anthrax is fatal to humans and may be contracted from cattle, but no major epidemic has been experienced with this disease, probably due to long standing animal husbandry procedures which can be readily implemented, with the benefit of past experience.

From this, it is possible to see the importance of disease control and the need not only for regulations, but an understanding of science and the effects that can happen depending on courses of actions chosen. Although this research tends to focus on economic and regulatory issues, it indirectly addresses issues relating to the production and distribution of medical products that have the potential to mitigate or prevent serious and widespread health and safety issues. The research also highlights how health, safety and welfare concerns that should dominate the composition and administration of the EU regulatory process may be relegated to secondary considerations behind economic and political motives. Finally, this research, in general

terms, serves to highlight the complexity of the issue surrounding the identification and control of negative technical barriers to trade.

2. The World Trade Organisation and the Multilateral Regulatory Environment

2.1 Overview

In Chapter One, the suggestion is made that the regulations enacted by the EU that govern the registration process for the sale of veterinary vaccines appears to discriminate against non-EU registrants. In order to assess whether the EU regulatory scheme is designed to impede trade, the EU regulations must be assessed against the global reference standard. In this case, that standard is a body of rules developed and administered by the WTO.

Accordingly, the broad purpose of this Chapter is to analyse the role of the WTO as the relevant multilateral institution having jurisdiction over the regulation of trade flows and trading relations between countries. A more specific purpose is to begin the process of clarifying the multilateral standard by analyzing the multilateral rules as a means of establishing a benchmark against which the EU regulations and registration process can be compared. To this end, an understanding of the WTO's institutional/regulatory characteristics, as well as the regulatory requirements must be examined.

The structure of this Chapter is as follows. First a brief introduction to the WTO and its more general provisions governing health and safety related issues is undertaken in Part 2.1. A more detailed examination of the specific WTO rules is contained in Parts 2.2 and 2.3. In Part 2.2, the SPS Agreement is examined. These analyses are followed by an examination of how the multilateral framework is applied by domestic regulators in Part 2.4. Finally, a summary and concluding observations are made in Part 2.5.

2.2 A Brief Introduction to the WTO

The WTO is the multilateral regulatory institution created as an outcome of the Uruguay Round of multilateral trade negotiations that took place between 1986 and

1994. The establishment of the WTO represents a 'formalisation' of institutional arrangements which were previously more informally encompassed within the activities of the GATT Secretariat, the body responsible for administering the trade agreements concluded under the auspices of the former General Agreement on Tariffs and Trade (GATT) prior to 1994 (*The WTO and GATT - Are They the Same?,* 2000, p.1).

In addition to administering the WTO trade agreements, the broad functions of the WTO are to handle trade disputes between member states, monitor trade policies, co-operate with other complementary international organizations, provide technical assistance and training for Developing Countries and provide a forum for trade negotiations.

As a result of the Uruguay Round, as well as previous rounds of multilateral trade negotiations, a large body of agreements covering a wide range of trade related matters regulating goods, services, intellectual property, and to a lesser extent investment, have come into existence. These agreements have been devised so as to articulate the principles that govern the WTO's broad objective of providing the vehicle for the global reduction of trade barriers between WTO member states.

There are some 30,000 pages and about 60 agreements making up the complete set of the WTO agreements (*The WTO Agreements,* 2000, p.1). The vast majority of these agreements are not relevant to the question being pursued in this thesis and the examination of each individual agreement is both unnecessary and beyond the scope of this work. Of the agreements under the WTO umbrella, the two of major interest to this thesis are the Agreement on Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT).

2.3 The General Provisions of the GATT 1994

Before analyzing the provisions of the SPS and TBT in greater detail, two general provisions of the GATT (1994) Agreement are of relevance to this analysis. The two provisions provide the foundation principles upon which the more specific obligations contained within the SPS and TBT have been formulated. The purpose of this Part, therefore, is to briefly examine and discuss the relevance of Article III and Article XX of the GATT (1994) Agreement in an effort to explain the basic principles underlying the regulatory framework.

2.3.1 Article III and National Treatment

Article III of the GATT obligates members to provide tax and regulatory treatment for imports that do not place them at a disadvantage relative to domestic products. Under the WTO principle of national treatment, there can be no discrimination between the way similar goods, services and intellectual property owners are treated on the basis of whether they are domestic or foreign.

2.3.2 Article XX and Product Health and Safety: An Exception to the Rule

Although Article III appears clear on the matter of non-discrimination, in addition to establishing the basic principles such as national treatment, the GATT (1994) defines important exceptions to the rules. It has long been argued that certain exceptions to the basic rules are needed to allow member countries the necessary flexibility to enact legislation or regulations that may appear to violate WTO obligations under certain or special circumstances.

Article XX provides a list of exemptions, one of which is Article XX (b) which allows:

> a party to restrict trade in order to protect human, animal or plant life or health, subject to the requirements that such measures are not applied in a manner that would constitute a means of arbitrary or unjustifiable discrimination between countries where the same

> conditions prevail, or a disguised restriction on international trade (Foy, 1992, p.123)

Article XX (b) attempts to distinguish the use of national standards for legitimate national objectives (i.e. protection of human, plant and animal life) as opposed to their use to either gain a competitive advantage or stifle competition by artificially impeding market access.

Implicit within Article XX(b) is the basic mechanism which, on the one hand, permits a government to set its own standards to safeguard its citizens, yet, on the other hand, requires that the safeguards be justifiable. The question as to what constitutes 'justifiable' depends upon a number of factors that act as limitations affecting a government's freedom in setting product standards. The factors are:

- the requirement/recommendation to use international standards
- the mandate for a scientific and economic justification of national standards that effect trade
- the dispute settlement procedures (Foy, 1992, p.124).

Foy goes on to argue that these limitations are necessary because "complete national freedom may lead to protectionism and globally inefficient resource use" (Foy, 1992p. 125).

Because Article XX (b) allows countries to set their own process standards, this has led national authorities in several countries to devise mechanisms for acceptable recognition of each other's standards. For example, this is the case with respect of mutual recognition between Australia and the EU for veterinary biological vaccines. Under these arrangements, authorities will recognise each other's product certifications while simultaneously acknowledging that differences may exist in relation to *good manufacturing practices* (GMP). These differences, whilst being noted, are not

completely accepted and under arrangements currently in place with the EU, the importing country reserves the right to physically inspect before final acceptance of product from that source (Johnson, 2000).

Mutual recognition is not the harmonization of standards. Instead, it is a form of bureaucratic expediency. Rather than develop harmonized standards, the mutual recognition principle enables governments having differing regulatory regimes to recognize each other's standards for the sake of facilitating trade flows. For example, within the EU, a member state is permitted to maintain national standards, but cannot prevent the sale of foreign products within its own boundaries which meet the standards in other EU member states. The only exception to this rule is where it is necessary to protect the public health and the consumer (Stevens, 1993, pp.43-44).

The level of standards will have an effect on trade. High product standards distort trade because they do not allow low cost exporters to have access. Low process standards attract foreign direct investment because it is cheaper to produce and therefore more profit is realised. In an environment where safety is a high priority issue, such as veterinary biological products, there is a need to have high product standards, to ensure that users are safeguarded.

2.4 The Agreement on Sanitary and Phytosanitary Measures (SPS)

Article XX(b) provides a very large loophole which member countries could, potentially, abuse as a justification for imposing discriminatory health and safety standards. In order to add a greater degree of clarity, and some limitations to the nature and breadth of the exception provided by Article XX(b), the Agreement on Sanitary and Phytosanitary Measures (SPS) provides a more detailed, yet basic, statement of principles against which national food safety and animal and plant health standards can be judged.

The SPS Agreement does not provide strict standards. Instead, like other WTO Agreements, the SPS is designed to provide WTO member countries with a great deal of flexibility in setting their own national standards. However, the scope and purpose of these national standards must satisfy minimum threshold tests, which in the case of the SPS, are to be based on science. For example, Article 2.1 of the SPS states that national standards are to be devised and "applied to the extent necessary for the protection of human, animal, plant life or health and should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail" (*Agreement on the Application of Sanitary and Phytosanitary Measures,* 2000, p.2).

2.4.1 The Base Standards

Article 3.4 of the SPS refers to the Codex Alimentarius Commission (CAC) and the International Office of Epizootics (OIE). The OIE is the world organisation for animal health, the veterinary equivalent of the World Health Organisation (WHO). The CAC is the food code produced by the FAO (Food and Agriculture Organisation of the United Nations) and the WHO (World Health Organisation). The CAC has relevance to international trade and its significance was underscored by United Nations Resolution 39/248 in 1985 which states that:

> Governments should take into account the need of all consumers for food security and should support and, as far as possible, adopt standards from the ...Codex Alimentairus (*Understanding the Codex Alimentarius,* 1999, p.1).

What Article 3.4 represents is a mechanism, which by reference, attempts to establish a base standards to reduce the possibility of widely varying standards.
To the extent that variation from the base standard can be expected, Article 3.3 allows members to:

> introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection that would be

> achieved by measures based on the relevant international standards, guidelines, or recommendations , if there is scientific justification .. or in accordance with ... paragraphs 1 through to 8 of Article 5 (*Agreement on the Application of Sanitary and Phytosanitary Measures,* 2000, p.2).

Further to this Article 5.7 states in part:

> In cases where relevant scientific evidence is insufficient, a member may provisionally adopt sanitary or phytosanitary measures on the basis of available information.... Members shall seek to obtain the additional information ... within a reasonable time (*Agreement on the Application of Sanitary and Phytosanitary Measures,* 2000, p.4).

Because Article 3.3 and 3.4 are both framed very broadly, in practice it is clear that they are susceptible to abuse. In recent times, both have been proven contentious in regard to actions taken by members under the guise of "health risks" which will be examined more closely later in this thesis.

2.4.2 Science and Protection or Market Access Impediments?

A country's duty and right to protect its citizens is recognised and supported in both the SPS and TBT Agreements. However, the critical question is whether product standards are enacted as a legitimate means of safeguarding health and safety concerns surrounding a product based on good science, or whether science is abused as an easy excuse to deny market access or to slow market penetration of a competitor.

The issue whether health and safety standards are enacted as a safeguard or market access impediment is examined in a recent article in which the author highlights this tension (Ambrose, 2000, p.861). In it, the infamous US Beef Hormone dispute is examined. The US Beef Hormone dispute is a trade conflict that has affected US/EU trade relations for over twenty years. The dispute very clearly illustrates the shortcomings of science and the tensions arising from differing perspectives and opinions.

The US Beef Hormone dispute centers around prohibitions imposed by the EU upon the importation into the EU of US beef treated with growth hormones. The EU claims that animals treated with such hormones may represent a health risk to its citizens. The US and Canada argue this is not the case and that:

> There is no scientific evidence that the hormones used for growth purposes pose any health risk. In 1995 the EU convened a conference of its own that found no significant evidence of risk from the hormones. ... Moreover, the EU has approved the use of three hormones on beef for therapeutic purposes. The EU - origin beef on which these hormones are used is sold without restriction or labelling requirements within the EU (Ambrose, 2000, p.864).

Both the SPS and TBT Agreements require sound science as the basis for regulations. This principle, however, is opposed by several Member countries. The argument is that the 'sound science rule' prevents them from using the alternative precautionary approach. The precautionary principle application is not denied by the SPS agreement Article 5.7 where there is an opportunity for a member country to adopt provisional trade measures on the proviso that additional information is obtained within a reasonable period of time.

> In Beef Hormones, in discussing the requirements of scientific evidence, the Appellate Body implied that one lone scientist could find a risk in the face of overwhelming scientific evidence demonstrating no risk and the opinion of that lone scientist may still be sufficient to justify imposing a ban on imports. Further, these WTO reports do not assess whether the science to be used is sound (Ambrose, 2000, p.865).

It would appear that all a government need do is to find a scientist prepared to uphold a certain point of view for market access impediments to be implemented under the health risk consideration. However the country imposing restrictive measures must ultimately be able to defend these under dispute charges.

> Perhaps the most controversial aspect of the Appellate Body's findings with respect to these provisions is its treatment of minority scientific opinion.....the Appellate body makes clear that Members are not

> obliged in every case to base their SPS measures on the majority scientific view:
> In most cases responsible and representative governments tend to base their legislative and administrative measures on "mainstream" scientific opinion. In other cases....governments may act in good faith of... divergent opinion coming from qualified and respected sources (Thorn & Carlson, 2000, p.844).

To balance this the Appellate Body has also made it clear that the Member country may well be called upon to defend their regulatory decisions in dispute settlement. To this end, the EU has continued to defend its position in relation to the ban on the US Beef Hormones, citing an opinion from the Scientific Committee of Veterinary Measures Relating to Public Health (SCVPH):

> ... (SCVPH) reiterated its opinion that that the use of hormones as growth promoters in cattle poses a health risk to consumers. Therefore, the (European) Commission proposes to ban indefinitely the use ... also proposes to maintain the current prohibition on five other hormones ... on a provisional basis while it seeks more scientific information... the Commission now considers that the embargo conforms to WTO rules ("Meat Hormones," 2000, p.1).

It would appear that there is an obligation for science and standards to be applied, but with built in flexibility, which may effectively result in market access impediment. The difficulty is in knowing, whether any measures taken are bona fide risk protective, or just a disguise for other motives. Even if a country is found to have transgressed the Agreements, it may be some years before the matter is resolved and during this time the product in question is denied market access.

2.4.3 The 'Consumer Concerns' Standard

Another dimension to the base standards debate is the question of 'consumer concerns'. Whilst the SPS may be well suited to deal with the provision of a broad base standard and assessment principles, it does not provide governments with the power to enact health and safety measures based on perceived or real 'consumer concerns'.

> This is illustrated by the EU's unsuccessful attempt to use the SPS to justify the exclusion from its markets of beef produced using

> hormones. Consumers' non-acceptance of the scientific evidence relating to the safety of beef produced using hormones makes this an issue in the EU (Kerr, 2000, p.106).

The issue to consider is whether governments are imposing SPS measures fairly and equitably, based on scientific argument and objections, or whether the 'consumer concern' is used as an excuse to impede market access. If any measure imposed to stem the free flow of goods is based on the health protection of a country, its citizens, plant and animal life and the environment, then such measures are to be respected. If these measures are introduced with a view to effectively create barriers, then they are to be challenged. Indeed, the US Beef Hormones case is a good illustration of this point. Why was the USA based product kept out of EU markets, particularly as some of the 'undesirable' products were already in use in the EU? Given the loss of the case by the EU, the suggestion may be that motives other than consumer concerns may have been present.

The question that needs to be addressed is whether a government is protecting its citizens (and plant and animal life and the environment), or whether the citizens (and plant and animal life and the environment) are being used as pawns in a game as a means to achieve predetermined outcomes, such as market access retardation or impediment, thereby assisting domestic producers.

2.4.4 Justifiable Action Within the Scope of the SPS Agreement

Governments must therefore balance all concerns and follow their role as a nation's overall protector. In the case of French bans against the import of Canadian asbestos, the WTO ruled that these were valid on health grounds. This ruling was handed down in the full knowledge by the WTO that France's ban had the effect of favouring asbestos replacement products and therefore, in principle, this ban was

breaking trade rules, however the ban was acceptable on safety grounds and thus ultimately prevailed (Koopel, 2000, pp.1-2).

Not all bans, regulations or restrictions reach the WTO. A number of measures put in place by governments under the risk prevention umbrella are not always challenged, such as the decision to ban a particular substance because of potential undesirable effects. Examples of this were the bans instituted in the use of Avoparcin in Australia in 1996. Avoparcin is an antibiotic growth promoter and has been linked to a resistant strain of disease in humans- vancomycin resistant *Enterococcus* (VRE). This disease caused some deaths and the Australian authorities decided to ban this substance. Disquiet about this product were not new at the time, with the Dutch Ministry of Agriculture threatening to bring in legislation to prevent its use, unless the European Commission banned it. Similar bans were already in place in some other EU member states("Australia Bans Avoparcin in Poultry," 1996, p.1).

An example of restrictions on use of a product based on protection of animal health, is provided by the decision of the EU to implement an indefinite ban on the use of Bovine Somatotrophin (BST), which is a hormone injected into cows to increase their milk production. Apparently this ban has been implemented in 1990 and was under review to have it rescinded, but the EU claimed to have scientific evidence, which warranted a need for a ban. Amidst calls of this measure being used as a form of protectionism, David Byrne (European Commissioner for Health and Consumer Protection) said:

> Imports of milk and milk products are unaffected by the ban. The EU has simply given a higher priority to animal health than to lower-cost milk production ("EU Proposes a Ban on BST for Dairy Cows," 1999, p.5).

The question of regulations versus market access also acknowledges the connection between governmental policy setting and market place reaction. A lot of the markets for

the most widely used products have become increasingly global and risk avoidance and containment are among a government's primary considerations. In looking at this facet of the safeguarding role a government plays against the importation of harmful substances, we can note several examples where government intervention is warranted and even desired.

The SPS agreement has been put to the test by member states quite quickly, in three cases.

1. The US beef hormone case, discussed previously, which deals with the issue of protection of human health.
2. The Canadian challenge to Australia's import prohibition on fresh, chilled and frozen salmon, which deals with the issue of protection of animal health.
3. The US challenge to Japan's requirements that fumigation treatment of fruit imports be approved on a variety by variety basis, which deals with the issue of protection of plant health.

2.5 The Technical Barriers to Trade Agreement (TBT)

The TBT Agreement, by contrast, has not received as much attention as the SPS Agreement. Nevertheless this is an important agreement on procedural issues and we will examine this next to be able to better understand the requirements imposed by this Agreement.

The current version of the TBT is a modification of the original TBT that was negotiated during the 1973-79 Tokyo Round of multilateral trade negotiations. The broad objective of the TBT is to ensure that regulations, standards and testing do not create unnecessary obstacles to trade. It recognises a country's right to adopt certain standards considered right for the protection of human, animal plant life or health or the environment. As mentioned earlier, countries are encouraged to use international

standards where appropriate. However, nothing in the TBT forces a country to ensure that its standards conform to the suggested base standards. The positive obligation that the TBT imposes is the prohibition against the use of standards designed to benefit domestic producers from external competition.

At its core, the TBT is a reiteration of the national treatment principle contained in GATT Article III. This differs from the SPS Agreement that is linked to the more specific GATT Article XX (b) obligation which is directed at a specified health or safety risk. The TBT Agreement instead, is one which "enumerates the particulars of the national treatment obligations that members are under when they impose technical requirements or standards" (Thorn & Carlson, 2000, p.842).

2.5.1 The TBT and National Treatment

The underlying premise of the TBT Agreement is embedded in Article 2.1. Article 2.1 provides for a more circumstantially specific application of the national treatment obligation contained in GATT Article III which requires that:

> Parties shall ensure that in respect of technical regulations, products imported from the territory of any Party shall be accorded treatment no less favourable that that accorded to like products of national origin and to like products originating in any other country (Cameron, 1993, pp.11-12); (Department of Foreign Affairs and Trade: Commonwealth of Australia, 1995, p.93).

Accordingly, Article 2.1 is intended to encourage government behaviour that is fair, equitable and transparent whereby regulations that set product standards should be equally applied in a manner whereby imported and local products are afforded the same treatment (Rege, 1994, p.103).

The most important provision of the TBT Agreement is contained in Article 2.2 which provides that:

> Parties shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose,

> technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia, national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health or the environment. In assessing such risks, relevant elements of consideration are, inter alia, available scientific and technical information, related processing technology or intended uses of products (Cameron, 1993, p.12); (Department of Foreign Affairs and Trade: Commonwealth of Australia, 1995, p.93).

It is the breadth and generally of Article 2.2 that has led to the TBT becoming a 'second-best' safeguard against unjustified trade-related measures. The obligation contained in Article 2.2 is so general, the TBT is rarely used as a basis upon which to challenge trade discriminatory actions under the WTO dispute settlement provisions. In fact, there have been no dispute settlement findings on the TBT Agreement. Only once has a member used the TBT to challenge a trade partner's product standards, that being the US Beef Hormone Case. In the US Beef Hormone dispute, the US put forward an argument that EU regulations violated the TBT Article 2.2. Upon hearing by a GATT dispute panel, the Panel found the TBT Agreement was not applicable to the dispute (Thorn & Carlson, 2000, p.842).

In addition to Article 2.1 and 2.2, several other articles within the TBT are worth noting. Article 2.4 encourages Members to use international standards where they exist, but leaves it to the discretion of a sovereign government by using the following words:

> ...except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued ... (Department of Foreign Affairs and Trade: Commonwealth of Australia, 1995, p.93).

There are certain procedural rules that countries must follow when choosing not to adopt an international standard or formulating new standards where an international standard does not exist. These provisions provide for the notification of the WTO secretariat for the purpose of enabling comment by other Members (Rege, 1994, p.104).

In addition, Article 2.7 of the TBT recommends the adoption of mutual recognition, even when regulations differ, as long as they fulfill the objectives of their own regulations. Article 5 deals with the issues relevant to conformity assessment, such as: confidentiality of data, maximum processing time for administrative and regulatory tasks, right to inspect facilities, fees structures and the harmonisation of standards.

2.5.2 SPS and TBT Agreements: A Comparative Analysis

There is a certain degree of overlap between the SPS and the TBT Agreements. However, at the same time, there are some critical differences between the two. A brief analysis of similarities and differences is summarised as follows (Rege, 1994, pp.106-107):

1. The SPS Agreement like the TBT Agreement requires WTO member countries to base their measures on "international standards".
2. The SPS measures conforming to international guidelines are presumed consistent with those of the Agreement. However these provisions differ from those of the TBT Agreement:
    - 2.1 TBT Agreement requires that product standard regulations be applied consistent with the Most Favoured Nation (MFN) principle requiring equal treatment (Article 2.1). The SPS Agreement, by contrast, permits discriminatory application of measures, provided they "do not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail (articles 7 and 24 to 26)
    - 2.2 SPS Agreement is more flexible in allowing deviations from international standards, when compared with the TBT Agreement. Under the TBT Agreerment, deviations from an international standard to another standard (higher or lower) would need justification on scientific

or technical grounds (Article 2.4). Under the SPS Agreement, a country is allowed to introduce or maintain a measure which would result in a "higher level of SP protection that would be achieved by an international standard". This could be both in the case where scientific justification exists or where a country determines a higher level of protection is appropriate. Articles 17, 18 and 19 of the SPS Agreement lay down the matters to be taken into account by country in determining the appropriate level of protection as: scientific evidence and economic factors such as damage / loss of production or sales as a result of entry / establishment / spread of pests or disease; cost of eradication / control and relative cost effectiveness of alternative approaches and the objective of minimising negative trade effects.

2.3 SPS Agreement (Article 22) introduces a "precautionary principle" and permits member countries to adopt SPS measures on a "provisional basis" under circumstances where insufficient scientific evidence exists.

Accordingly, it is clear that the applicable tests underlying the TBT and SPS are quite different and are designed to serve different purposes. In particular, the TBT Agreement is framed more broadly and applies to products where SPS application is irrelevant, such as in the case of industrial products.

The SPS agreement centers around health risks, whereas the TBT agreement addresses the more complex issues relevant to fair treatment among the WTO meber states. Central to the TBT issue is the notion of bureaucratic processes which may in effect create hidden barriers to trade. Whilst the SPS test will be based largely on scientific evidence alone, the TBT will also consider issues such as bureaucratic behaviours and processes.

The TBT potentially has a wider coverage of issues, but these are much more difficult to prove, as evidenced by the lack of reliance on the TBT versus the SPS agreements in WTO dispute cases.

2.6 A Brief Overview of the Australian Context

In the Australian context, quarantine has been at the forefront of import screening and the Australian Quarantine and Inspection Services (AQIS) has traditionally been charged with the task of protecting the nation in relation to the import of biological substances, plant and animal and derived products. In the year 2000, some changes were made to AQIS and the task of import risk assessment now rests with another government agency: Biosecurity Australia. ("Biosecurity Australia Formed to Undertake Import Risk Analyses," 2000, p.3)

Australia has a "clean and green" image in world trade and produce coming from Australia is regarded as among the best in the world. Australia is relatively disease-free, thanks largely to historical developments and its remoteness in the past, which made any voyage from Europe or the North America effectively a "quarantine journey". Today's fast access between markets, aided especially by air transport makes disease containment much more difficult. Open markets mean higher quarantine risk and in Australia's case it means increased vigilance. Whilst each country has the right to set its own quarantine policy: "the nation's appropriate level of protection", it must minimise trade restrictions from that protection (Benchley, 2000, p.46).

Recently there has been some dispute between Australia and the Philippines over the refusal to allow banana imports from the Philippines, because of the threat of black sigatoka disease. The quarantine restriction imposed by AQIS are being challenged, not surprisingly by the Philippines' Agriculture Secretary Angara, who has

threatened to pull out of APEC and stop imports of Australian cattle unless Philippine bananas are allowed into Australia.

> This is AQIS' difficult balancing act - the link between Australia's conservative quarantine policy and the necessity to abide by WTO standards to ensure Australia can maintain aggressive agricultural exports. Lyall Howard, director of trade and quarantine at the National Farmers Federation, sees AQIS caught between complex scientific issues and a politically charged environment (Benchley, 2000, p.47).

There are certainly differing philosophical attitudes between countries over issues such as the bananas between Australia and the Philippines and this situation can be used to explain these.

From Australia's point of view there is the need to ensure that no new plant disease in introduced as a result of any importation of plants. The reasons are that Australia would lose some production if the disease was imported and spread locally. This would result in diminishing domestic production causing loss of export markets due to decreased supply caused by the disease and if this was to be severe enough, necessitating additional imports to satisfy local demand. This would leave Australia more vulnerable to overseas market supply conditions and it would lose any potential for export earnings.

From the Philippines' point of view, they may not care very much about the disease, it is after all of no threat to them, as they already have it. Their argument may be that the importation of fruit does not necessarily mean the importation of the disease. The problem is that once the disease is here it will more than likely never be possible to eradicate it and Australia will have one more disease on its list and if this is allowed to happen routinely, Australia will lose the natural competitive environment it now enjoys. Exporting cattle to the Philippines does not pose a threat to the Philippines, as the Australian cattle have remarkably fewer diseases than just about any cattle from other countries. The problem for the Philippines, is that they also need to export products in

order to pay for their imports and one of their comparative advantages is the availability of bananas, all be it with a disease not wanted in Australia.

Plant health issues are not always related to disease and in recent times, the question of Genetically Modified Organisms (GMO) food has gained increasing focus from consumer groups. These groups are questioning the lack of scientific data to support this food finding its way into the human food chain. The concern is raised over claims made by GMO manufacturers who have failed to provide any scientific back up data. Not surprisingly the Australian Conservation Foundation is opposed to GMO entering the food chain, citing research which shows in any case that premium prices in foods are not for GMO, but for organically grown produce. This issue is of importance because of the global trading nature of produce. Of the GMO canola harvested in South Australia, seeds have already been exported to North America (Phelps, 2000, p.23). Of concern is the issue that these seeds were from "experimental sites" and engineered to tolerate being sprayed with high doses of Roundup or Liberty herbicides.

Governments are faced with the difficult issue of evaluating a "new product" or technology and decide whether to let it enter its markets. This is after due process to ensure that the safeguard role as the country's highest authority has been played well and that no risk is posed to the importing nation.

Yet it seems that in trying to grapple with the new GMO foods, bureaucrats have been left wanting in terms of being able to provide guidelines and administrative processes, which satisfy special interest groups. Greenpeace with a membership of 2.5 million people and a high profile, commands the attention of a number of governments these days. There a number of "greenie" groups which have embarrassed governments in the US, Britain and Australia as a result of these groups exposing serious guideline flaws and even breaches of these guidelines (Correy, 2000, p.15).

As far as GMOs are concerned, consumer confidence is apparently the pivotal issue. The EU is seen as being a more conservative bureuacracy than the USA, but perhaps this is representative of its constituency. Certainly consumers have had some powerful effects against the manufacturers of GMOs .

> but the uncertainty of GM crops is affecting everyone. McDonalds in Germany and now Britain, would you believe it, has made the business decision they'll no longer use meat from animals fed with GM crops (Correy, 2000, p.15).

Although Europe seems to be the place where the anti GMO movements has raked up more success, reactions to consumer pressure have been reported elsewhere:

> After more than a year of protests, Europe was shutting Monsanto out of its markets. So for the most part was Brazil... Japanese companies had decided to stop using genetically altered products and Mexico's largest tortilla maker had ended its reliance on modified corn. Under pressure from Greenpeace, Novartis stopped using gen-modified soy and corn in its Gerber brand of baby food. Heinz said it would do the same. (Specter, 2000, p.16).

In this complex web of requirements and considerations for everyone involved: from the government as a regulator; to business as the trader and creator of economic welfare and activity; to the consumer, entitled to be safe in the purchase and consumption of food, it is easy to see how science can be pitched against science, to derive a desired result.

Perhaps this is best exemplified by the Chardon LL case. Aventis, a global biotech company with a 20 billion (US) dollar business, tried to get approval in the UK for a new GMO maize.

> Friends of the Earth managed to get a public hearing on the case. ... They got independent scientists to review an Aventis study on why GM maize should be grown in Britain. The scientists found the study to be scientifically flawed and they discovered some 'suspicious trends' in the death of chickens fed the maize. ... independent evidence from poultry experts...indicated that the research was ... quite an inadequate basis on which to make any decision. ... the science that Aventis is relying upon is woefully inadequate when it is exposed to careful consideration ... and the latest news on Chardon

> LL maize is not good for Aventis. The U.K. government has asked for an indefinite adjournment of the public hearing (Correy, 2000, p.15).

Apparently twice as many chickens in the trial died when eating the GM maize, this was the alarming fact which prompted Friends of the earth to act. One can only, but wonder, whether the UK bureaucracy would have picked up this flaw or not. Clearly in these situations, as with a new drug, for example, the onus is on the manufacturer to prove that the product is safe, almost a case of guilty until proven innocent. It has to be this way, otherwise the lack of regulations would increase risk to health and this is not a desirable situation.

Notwithstanding the above considerations, governments have an inescapable dual role. On the one hand a government has a role and a duty of care in respect to its country. On the other hand it has a responsibility to provide, at least, a framework where economic activity generates well being for its citizens. It is this second role that governments receive criticism for bureaucratic processes which are claimed to be discriminatory and against the interests of businesses.

One of the concerns about international trade and barriers has indeed been over the transparency, or lack thereof, in approving the use of substances in different markets.

2.7 Summary and Conclusions

In summary the WTO agreements provide member states with an individual right to ensure the safety of their citizens, while at the same time they try to discourage an anti-discriminatory environment through the transparent application of standards and regulations. Due to the notion of a country's sovereignty and the rights of a government to exercise whatever power it needs for safety reasons, the WTO agreements do not impose standards or the harmonisation of standards on member states. Harmonisation of standards would produce the type of level playing field that many seek, but agreement

on standards is a very difficult task to achieve especially when one nation (or a consortium) has a different opinion to other member states' views. What is considered risky in one country is considered less so in another.

Expediency in bureaucracy may well encourage the development of mutual recognition, which *per se* is not harmonisation of standards, but at least provides an avenue for recognising different standards for the sake of facilitating trade flows, as is the case within the EU.

As we have seen in this chapter, there are a number of complex issues involved in the notion of suitability of products on the basis of safety. Science alone does not provide an answer because science itself is divided by opinions. It is a difficult task to ensure that the scientific opinions of one prevail over another, unless of course there is some overwhelming evidence to cast doubt upon, or completely refute a set of scientific results which may be flawed.

When the vast number of potential TBT mechanisms are layered over the safety concern issues addressed by the GATT and SPS agreements and the pressures of market access are simultaneously considered, we are faced with some very difficult analysis.

In this chapter we examined the most salient points of the SPS in order to determine what its requirements and obligations are to be able to better understand what may be an appropriate measure and standard.

Having briefly examined the SPS and TBT Agreement as part of the overall WTO Agreements, we can now examine the procedures which are currently in practice in the EU in relation to the approval processes for veterinary biological vaccines. After we have examined these procedures, we can then assess the existence or otherwise of any contraventions to the SPS or TBT Agreements.

3. The European Union Regulatory Framework

3.1 Introduction

In Chapter 2, an analysis of the multilateral regulatory framework governing the creation and application of product standards was undertaken. Although it was shown that the multilateral framework provides guidelines for setting base product and safety standards, these rules are sufficiently flexible to allow each country to set their own domestic standards that often vary from the suggested multilateral standards. The analysis examined how variations from the base standards are to be judged in respect of whether they are justifiable from a health and safety standpoint or whether domestic regulations are designed to function as impediments to trade.

The purpose of Chapter 3 is to describe the regulatory framework implemented by the European Union and its separate states in respect of the certification and accreditation process of veterinary pharmaceutical products for both domestic and foreign products. The specific purpose of this exercise is to provide the basis for assessing whether the EU regulatory process imposes, although apparently non-discriminatory on the surface, a *de facto* barrier that discriminates against imported products. Put another way, do EU regulations, unfairly, limit access of imported veterinary pharmaceutical products?

Accordingly, in order to understand the complexity of the regulatory scheme, a discussion of the institutional/bureaucratic structure of the EU is first discussed in Part 3.1. This discussion is followed in Part 3.2 by a brief description of the three main product registration methods that foreign importer must use to gain access to EU country markets. In Part 3.3, a more detailed examination of the registration requirements is discussed.

3.2 The EU and its Institutional Structures

The notion of a united Europe dates back many centuries and is evident in the empires that were created and fell in an endless succession of armed conflicts and wars. A more modern notion of a united Europe is based upon a willingness and desire of the European nations to achieve a higher degree of cooperation in order to, collectively, create a better standard of living. The institutional foundation for this cooperative form of union began on the first of January 1958 with the signing of the Treaty of Rome (Harris, 1999, p.241);(Molle, 1994, p.56);(Bennett, 1997, p.3);(Welford, 1996, p.2);(El Kahal, 1998, pp.8-10).

The Treaty of Rome formed the European Economic Community (EEC), the forerunner of the current EU, having an initial membership of six nations: Belgium, France, Italy, Luxembourg, The Netherlands and West Germany. The EEC underwent a continuous evolution both institutionally and an expanding membership culminating in the signing of the Maastricht Treaty in 1993 which saw the creation of the European Union (Harris, 1999, p.56);(El Kahal, 1998, pp.25-27);(Mikic, 1998, p.480);(Molle, 1994, p.48);(Bennett, 1997, p.4).

3.2.1 The EU Decision-Making Bodies

The institutional structure of the EU is made of a multi-tiered series of decision-making bodies. At the top of the structure is the EU Council, or the Council of Ministers. This is the most powerful policy making body with the EU. Its responsibilities include justice, home affairs, inter-governmental co-operation and common foreign and security policy. Below this sits the European Council which is represented by heads of states and governments who are EU members. Next follows the European Commission. This is the civil service of the EU. The Commission is responsible for drafting EU legislation, which goes to the Council of Ministers. Finally,

there is the European Parliament. The European Parliament is made up of directly elected representatives from all member states.

The European Parliament has the ability to revise legislation, which has been proposed by the Commission before it is finally agreed by the Council of Ministers. As such, it plays an important accountability role with two otherwise unrepresentative bodies. The Parliament's powers include being able to influence and delay legislation on the environment, the single market and consumer affairs.

A further body that sits somewhat apart from the legislative arms of the EU bureaucracy is the European Court of Justice. The Court is comprised of judges nominated by each member state. One of the responsibilities of the Court is to ensure that EU legislation is consistent with the numerous treaties that form the legislative foundation of the union. An EU institution, a national government, or even a private citizen may bring an issue to the Court. The court may also be asked to give opinions on matters relevant to its members. Such opinions are not binding.

The body that is of most importance to this investigation is the European Commission. The Commission is divided into 23 separate Directorates General for administrative purposes. Proposed legislation usually comes from this administrative structure. It is also useful to briefly describe the types of EU legislation in order that a better understanding of the processes by which bureaucratic requirements are made affecting the operations of businesses.

3.2.2 EU Legislative Forms

The EU has several forms of legislative and regulatory mechanisms. These are presented in a sequence beginning with the most authoritative to least authoritative.

Directives: A Directive is binding on all member states. The fulfillment of a directive is left up to individual member governments which occurs through the enactment of national laws and decrees.

Regulations: The next level of legislative instrument is the EU Regulation. A Regulation is deemed to supercede all national laws and upon enactment its compliance is mandatory for all member states in its totality.

Decision: This is mandatory for the party to whom it is addressed. It may apply to an EU government, business or citizen.

Recommendations and Opinions: These are not binding.

The form of legal instrument that is most relevant to this study is the Directive. Less important are Regulations although a few will be considered as they have relevant effect on the subject mater being analysed. A further note is the relevance of the Treaty of Rome, which is the cornerstone of the EU, and is often referred to in the Directives relevant to this work.

Article 100a of the Treaty of Rome is of particular importance, in so far as the approximation of laws is concerned. Paragraph 1 of Article 100a states (in part):

> ... The council shall, ... adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in member states which have as their object the establishment and functioning of the internal market (European Union, 1995, p.204).

Further relevant legislative constraints imposed on member states appear in paragraphs 3, 4 and 5 of the Treaty of Rome. Paragraph 3 relates to the level of safeguard and states (in part):

> The Commission ... concerning health safety, environmental protection and consumer protection, will take as a base a high level of protection (European Union, 1995, p.205).

Paragraph 4 relates to the individual member state's rights to adopt different provisions, by stating (in part):

> If, after adoption of harmonisation measures by the Council... a member state deem sit necessary to apply national provisions on ground of major needs referred to in Article 36, or relating to the protection of the environment or the working environment, it shall notify the Commission of such provisions. The Commissions shall confirm the provisions involved after having verified that they are not a means of arbitrary discrimination or a disguised restriction on trade between Member States (European Union, 1995, p.205).

Paragraph 5 reinforces the right of a member state to take certain safeguards, subject to control procedures and it states (in part):

> The harmonisation measures referred to above shall... include a safeguard clause authorising the member states to take, for one or more of the non-economic reasons referred to in Article 36, provisional measures subject to a Community control procedure" (European Union, 1995, p.205).

Articles 30-34 which are referred to in Article 36, which is the subject of significant reference within Article 100, deal with the elimination of quantitative restrictions between member states. Article 36, instead deals with the important issue of a sovereign country's right to safeguard its territory and everything within it. It is effectively mirroring the provisions for Article XX (b) of GATT. Article 36 states (in part):

> ... shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; ... the protection of industrial and commercial property. Such prohibitions or restrictions shall not , however, constitute a means of arbitrary discrimination or a disguised restriction on trade between member states" (European Union, 1995, p.145).

These key foundation Articles of the Treaty of Rome present two complementary philosophical principles. The first principle is the notion that all laws within the EU are to be the same as much as possible; ie., the harmonization principle. However, some degree of flexibility is embedded in the inclusion of the word "approximation" which reflects the reality that a conglomeration of several nations with different requirements and systems will only gradually be able to achieve a harmonized set of laws, regulations and standards. The second principle, which is carefully guarded, is the notion of

sovereignty. A country's right to impose safeguard measures is kept sacrosanct, provided such measures are defensible. In this respect the requirements of the Treaty of Rome are no different, in essence, to today' requirements for WTO membership. The Treaty of Rome empowers the European Council via Article 100 to:

> ... issue directives for the approximation of laws, regulations or administrative provisions of the member states as directly affect the establishment or functioning of the common market (European Union, 1995, p.204).

It is this power which provides the basis for the European Council, through the use directives and regulations, to create the regulatory framework which governs the processes by which foreign veterinary immunologicals must be granted registration and certification in the EU prior to their sale. In this regard, an already vague foundation is further obfuscated by the three separate entry methods that can be pursued to gain access to EU markets. It is these three methods which are the focus of the discussion that follows in Section 3.2 below.

3.3 The Registration Methods

As mentioned above, within the scope of powers exercised by the EU and its member states, there are three separate methods, or registration pathways, an applicant firm may choose to register veterinary biological products for sale within the EU. These three methods are:

- National registration
- Centralised registration
- Decentralisared registration

In what follows below, each of the three registration methods is described. Following this, the specific procedural requirements, and the effects of these requirements, of each method is described.

3.3.1 National Registration (NR)

National registration is the traditional "old" method of registering veterinary biologicals. In brief, a foreign manufacturer is required to submit registration data to the relevant national authority of a single EU country for approval. If approval is granted, then the product in question is entitled to be sold within the territory of that sovereign government. Under the NR criteria, the applicant need only satisfy the relevant national authorities' requirements to obtain approval. There need be no consultation between the applicant, the registering country and other member states.

Before 1 January 1998, a firm could register a product in each individual country under the NR criteria pursuant to Directives 81/851/EEC and 81/852/EEC (The Council of the European Communities, 1981a);(The Council of the European Communities, 1981b). This method was regarded by many foreign exporters as the easiest way of breaking into individual EU member state markets. Each application is discrete and, in theory, a problem arising with an application in one member state should not influence the outcome of the same product registration application in another member state.

Autonomy in approving applications under the old system was the perceived advantage from the registrant's point of view. Some variations between member states requirements existed, although these were not significant. The major hurdle for Australian exporters is the requirement to have critical sections of the application/dossier written in the local language of registration application. Although a procedural problem, it is of concern in that the technical translation of highly sensitive and confidential data is sometimes difficult to achieve.

Following the 1 January 1998 amendments, the NR registration process has changed slightly. Now, a firm can only register a product in one country under the NR criteria and must use alternative methods for subsequent registrations pursuant to

Directive 93/40/EEC (The Council of the European Communities, 1993a). The impact of these changes is that the decentralised procedure has become mandatory for all second and subsequent applications (Lucken, 1998). Accordingly, there is an obligation for an applicant to disclose details of where registration applications have been lodged.

Once a product receives approval, a *marketing authorisation* (MA) is issued. The issue of an MA gives the named party authority to stock, distribute, market and sell the product in question.

3.3.2 Decentralised Registration (DR)

Should a potential applicant choose to pursue market access in more than one EU country, it must now follow the DR method. Under the DR method, an applicant firm may apply for registration of a product in two or more countries with the first country acting as the *reference member state.* Under Directive 81/85, as amended by Directive 93/40/EEC, provisions exist for what is known as "mutual recognition" by member states of a MA issued by another EU member state.

Prior to 1998, the registration process was such that a firm wishing to register under the DR process would notify the second and subsequent countries that it was submitting a DR application. Accordingly, the "initial recognition" procedure would be relied upon. The importance of this notification would give to a different administrative treatment, in scrutiny of the dossier, by the competent authority as opposed to a NR application. There is a positive side to a DR process, as this allows the elimination of much duplication on successive registration submissions as these rely on the first MA for much of the subsequent approvals. The new system (effective 1995) was then:

> designed to eliminate duplication of effort by national authorities and to impose where encouragement failed, a system of mutual recognition (Wesley, 1994, p.64).

At that stage, though, the firm still had the option of registering, through the DR process, or submit several NR applications. The firm therefore had a comparatively more flexible approach to the one now in force.

Since 1 January 1998, there is only one option a firm may exercise and that is that all second and subsequent applications have to undergo the DR process. So the firm's choice in relation to market entry strategies has been reduced. There are guidelines in place limiting the time for approvals by subsequent member states and decisions made must be capable of scrutiny and challenge, especially where they are not favourable. Remembering that Article 36 allows sovereignty, there may be cases where a DR may produce different results nevertheless. The DR system is designed to provide an environment where almost identical decisions are given by all EU member states.

> The situation described above will be more complicated where vaccines are concerned, however, since national authorities may reject the authorisation of a biological product if the disease against which it offers protection is largely absent from their territory, or if would just interfere in disease eradication campaigns (Wesley, 1994, p.64).

This is an important point as scientific reasons may be used to hinder or totally prevent the introduction of a veterinary vaccine to a particular country. If the refusal to entry was to be based on science alone, this could be acceptable. Unfortunately dubious and ambiguous scientific claims are at times used to form very effective scientific barriers, e.g. US Beef Hormone case (Thorn & Carlson, 2000, p.844).

> ... if the decentralised system is to run smoothly, it is vital that derogations are not cited artificially by member states in order to bloc authorisations of certain products for political reasons (Wesley, 1994, p.65).

The number of potential hurdles to have product acceptance may be many and these will be examined later in the thesis.

3.3.3 Centralised Registration (CR)

The CR method was introduced by Council Regulation 2309/93 in 1993 (The Council of the European Communities, 1993b). This procedure applies to high technology products defined in the Annex to the above regulation. It is obligatory for products listed in "Part A" of the Annex (certain biological products and novel growth promoters) and optional for others, "Part B" products (other innovatory products).

To be able to obtain CR, an application needs to be made to the European Agency for the Evaluation of Medicinal Products (EMEA). EMEA employs, under contract, the services of the EU's Committee for Veterinary Medicinal Products (CVMP). The CVMP will then act as "rapporteur" and will be involved in providing ultimately a scientific opinion on the status of the product's health and safety to the EMEA. The EMEA will in turn send this opinion to the European Commission for consideration. The Commission consults with the Standing Committee on Veterinary Medicinal Products (SCVMP). In the absence of any problems, the Commission issues a Draft Decision which, if adopted grants a MA. Where the Commission cannot adopt the Decision, the matter is referred to Council.

If the CVMP provides a negative opinion on the application, the matter is referred back to the applicant via the EMEA. The applicant may appeal and the matter is reviewed, once again by the CVMP. The CVMP's final opinion is then given back to the EMEA. The Draft decision is sent back to the SCVMP for opinion. If all is favourable, then the Decision is adopted by the Commission, otherwise the matter is referred to Council.

Once a CR MA is issued, it is valid in all EU member states. The steps under the CR may seems more bureaucratic than under the other market entry methods described above, however, the rewards are higher under the CR, as the successful applicant gains

total access to all EU markets. The problem with this type of approach is that it is limited to the products as shown in the Annex to regulation 2309/93, as amended.

3.4 The EU Registration Requirements

The three methods by which veterinary pharmaceuticals can be registered and certified for sale in the EU are briefly described above. The purpose of this Part is to describe, in greater detail, the specific aspects of the registration procedures and processes in order to provide the basis for an assessment whether these requirements just and equitable, or a disguise for some other motive.

3.4.1 Context

Before we proceed with the analysis described above, it should be noted that not all aspects of vaccine manufacture falls under the control of the EU umbrella. There has been, for quite some time, a process by which the production and sale of vaccines can occur under special circumstances. This process is known as "autogenous vaccine production". This process allows a manufacturer to produce an autogenous vaccine without a full licence application submission. Directive 81/851 provides an exemption to the usual registration requirement for such products (Veterinary Medicines Directorate, 1999).

> Autogenous vaccines are produced using micro-organisms isolated from infected animals from a specific herd at a veterinarian's request, and are only allowed to be used for vaccinating that particular herd or neighbouring herds ("AVBC Defends Autogenous Vaccines," 1997, p.11).

The reason for the exemption is to provide for the rapid availability of a vaccine in the event of an emerging disease problem in order to assist in the prevention of spread of disease within a particular area. Autogenous vaccines are not a replacement for the ordinary vaccines. Usually, they are much more expensive to produce because they are manufactured in small quantities which discourages economies of scale.

In the majority of cases, the manufacture of autogenous vaccines is controlled by a country's national regulations. Certain restrictions may include limitations on the number or type of manufacturer involved. In Italy, for example, autogenous vaccine manufacture can only be undertaken at specially licensed facilities. These are the *Istituto Zooprofilattico*, which are government laboratories. There are ten such institutes located around Italy, averaging a coverage of two regions each. These institutes are charged with autogenous vaccine production in accordance with the Italian government regulations. Interestingly, all matters to do with the food chain, in Italy, fall under the control of the Ministero di Sanita' (Ministry of Health). This includes all veterinary services. In other countries, veterinary matters usually fall under the responsibility of the Ministry of Agriculture. In Italy the Ministry of Agriculture is basically responsible for forestry, fishing and hunting.

Autogenous vaccine production therefore provides a flexible answer to a particular problem. Because of the unique composition and low demand for this type of production, it is not suited to sustainable profit making manufacturing activities. Indeed the very nature of a successful autogenous vaccine is disease control and therefore a paradox to commercial activities. If an autogenous vaccine is successfully implemented against a disease and therefore that disease is controlled, there no longer is a need for vaccination. From a government's point of view there are two basic considerations in this regard. First is that of animal health, ie., to vaccinate the animal for its well being. The second issue is that of human health; ie., where the animal is intended for human consumption. The injection of foreign protein into an animal host causes a reaction, which in immunological terms will result in the treatment, or prevention, of a disease. That is 'good health' is a public good.

One of the issues associated with vaccination of animals is the notion of material residues in the food chain. It is better if the animals are not vaccinated at all. This is the desirability of the autogenous manufacture. In being able to quickly use autogenous vaccines, the spread of disease is limited and, therefore, only the minimum quantity of livestock need be vaccinated. In the absence of autogenous vaccines, disease would spread further, awaiting the availability of a full licence vaccine and then more livestock would need to be vaccinated. Wherever possible, the EU has a policy of avoiding vaccination.

Having understood the advantages and limitations of autogenous vaccine production, its lack of potential competition as a substitute product against full license vaccines, and the fact that this type of arrangement is outside the scope of this research, we can now proceed to evaluate more closely the types of registration pathways available within the EU.

3.4.2 National Registration (NR)

As already discussed, the NR registration method is a continuation of the separate national registration schemes that were in existence prior to 1995. Given the post-January 1998 amendments under EU Directive 94/40/EEC, an applicant that registers a product under this pathway must carefully determine which country to approach. Although, since 1 January 1998, it is not permissible to have more than one NR process underway for a single product, it is possible to have several products undergoing NR in different EU countries. For example, an applicant firm may have three different products it wishes to sell in the EU. It can select to sell product A in country X, product B in country Y and product C in country Z, all under the NR pathway.

This example scenario is feasible only if the applicant firm has no interest in accessing a number of markets simultaneously, with the same product. In the absence of this situation one fails to see how profit maximisation may be achieved, given that sub-optimal demand will exist and economies of scale will not reach their full potential. This is substantiated quite obviously by the fact than one market will never be able to potentially achieve what two or more markets could.

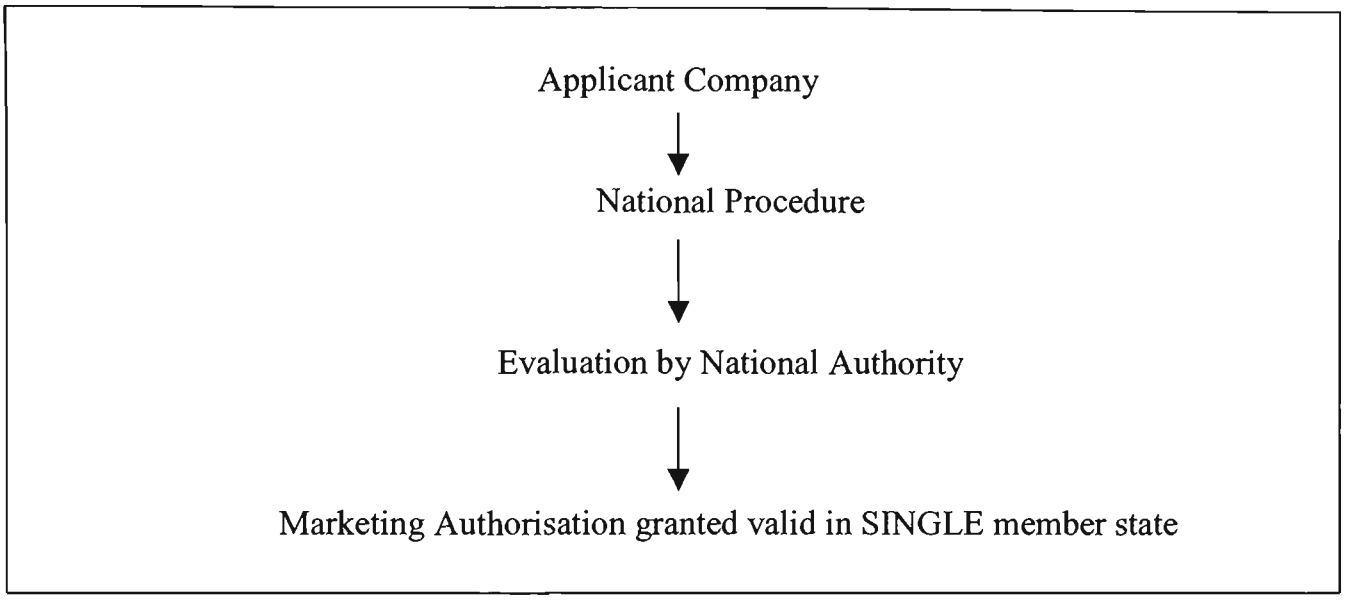
3.4.2.1 Strategic Considerations

Although an applicant firm will be able to register as many products as it likes under the NR process, this registration strategy runs the risk of excluding it from other potential markets. For example, if the firm registers its entire portfolio of products in country X under the NR process, it will embargo itself from access to any other EU member state, at least under the NR process. The firm wishing to enter individual EU markets utilising the NR process therefore needs to carefully consider the ramifications of pursuing such a strategy.

The NR pathway could become attractive in a situation where the firm has niche markets in each of the countries in which it wishes to register and where it has no interest, by the very nature of the products and their market fit, in simultaneous markets access. It is difficult to imagine a scenario such as this, given the propensity of vaccine immunological manufacturers to try and access every market possible to increase sales and profits. This desire is largely driven by the high cost research undertaken in the research and development of these types of products.

Figure 1 outlines the approval pathway for the NR procedure.

Figure 1: EU National Registration Procedure



3.4.2.2 Country Choice

The choice of which country to register in under the NR is critical due to a number of considerations in relation to product registration. These considerations include:

Language

Any submission in a country, not having English as its main language will necessitate the provision of a registration dossier in the host country's language. This presents some problems, as translation of technical material is notoriously difficult. Literal translation of technical terms often leads to a situation where the translated material simply does not make any sense. This consideration therefore is both one of time and money. It must be said that a local EU manufacturer wishing to place a product on the market would be faced with the same predicament, when going outside his home country and into another EU member state with a different language. Of course, the

established EU manufacturer has probably dealt with this sort of situation before and has, in all probability, a strategy in place to accommodate this eventuality.

From the Australian perspective it would appear, according to industry sources, that the most frequently used "beach head" approach to the EU markets has traditionally been via the U.K. in the first instance. The reasons for choosing the U.K. include language, the similarity of cultures and a comparatively similar legal system (and therefore consumer legislation). Much of these similarities are perhaps due to historical developments in the white settlement of Australia.

The administrative and bureaucratic framework for registration

Some countries are notorious for their slow approach and lack of data security and confidentiality. For example, the Italian system underwent a restructure in 1994 (Doyle, 1994, pp.10-11). This, in part, occurred because of the need for co-operation among the various Italian governmental agencies to curb black market activity that escalated following the opening of the European borders in 1 January 1993. Administrative procedures have been the subject of criticism in the U.K. as well. In 1995, between April and July, a House of Commons Agricultural Committee enquiry was carried out in the U.K.. As a result of this enquiry, the government was advised that:

> ... the Veterinary Medicines Directorate (VMD) is overly bureaucratic and that the staff are overworked. Pressure on staff could be reduced and licencing procedures expedited if the VMD significantly cut the paperwork it demands from applicants and contracted out some specific tasks ("UK VMD Told to be More Efficient, Flexible and Open," 1995, p.5).

Approval Time

Unlike other entry pathways, there is no general obligation for a country to make decisions within a stipulated time frame, unless such a requirement is self-imposed. In

other words, because the NR is controlled by the country whose market is being sought, and such a process is outside the relevant EU Directives, then that country has the unilateral right over the bureaucratic process it implements and follows. For example, if country X has no legislation, or regulation, which stipulates a maximum turn around from lodgment of an application to approval, then complete freedom is enjoyed by the authorities in how fast, or slow, approval, or denial, of market access is given. This has implications for the exporter, as market entry can be barred quite effectively by a slow moving bureaucracy. A good example is provided by the Italian authorities, in an attempt to more effectively and efficiently deal with the contentious issue of time frames under domestic registration processes:

> A decree...promises to replace Italy's notoriously slow veterinary product licensing procedure with a streamlined system which in theory should see approvals issued within 120 days of the date an application is filed ...The impending licensing changes as a unique opportunity to revive the Italian animal health industry, and in doing so to boost its somewhat tarnished reputation in the eyes of critics at home and abroad ("Italy Decrees 120-day Vet Product Licence," 1992, p.1)

In a subsequent report, it is alleged that:

> The highly problematic transfer of EC Directives 81/851 and 852 into Italian law is viewed as a major factor behind the 10% drop in veterinary medicines sales which occurred in the domestic market in 1992 ("Legislation Difficulties Hamper Growth in Italian Market," 1993, p.6).

This report provides some tangible evidence of the likely effects of regulations on the behaviour of a firm faced with either an uncertain or problematic operating bureaucratic environment.

In the U.K., there are target numbers of processing days for the authorities to expeditiously deal with an application. However this target is usually exceeded because in most cases, more information from the applicant is usually required. Indeed the

Veterinary Medicines Directorate, which is the body responsible for assessing applications states that:

> It is rare for an authorisation to be granted without the need for further information and for some changes to be made to, for example, the quality control procedures or labels" (Veterinary Medicines Directorate, 1997, p.5).

Of course, problems exist for domestic manufacturers, as well as for foreign firms, but it is generally accepted that firms with local presence are more able to influence local authorities, by either direct approaches to them, through the political arena, or simply by virtue of the fact that they are present and therefore able to respond quicker.

Fees and Charges

Each country where product registration is sought will cause a fee to be paid. This is a common worldwide practice. It is also common to observe that there are variations in the different amount of fees payable between countries. Where a choice of countries exist, such as the case of the EU, then the difference in the cost of the fees structure is another consideration on where to register under the NR. Under other registration pathways, due to their nature, this is less of a consideration.

Where the NR process is believed not be appropriate for the firm's entry strategy, or sustainable long term successful market presence it will be necessary to consider other registration pathways.

3.4.3 Decentralised Registration (Mutual Recognition) (MR)

Under the EU provisions of Directive 81/581, as amended, there is scope for what is known as "mutual recognition" by individual member states. The MR is the most bureaucratically complex process of all registration pathways options. On the other hand, certain aspects of this method may provide the most flexibility in respect of market access strategies.

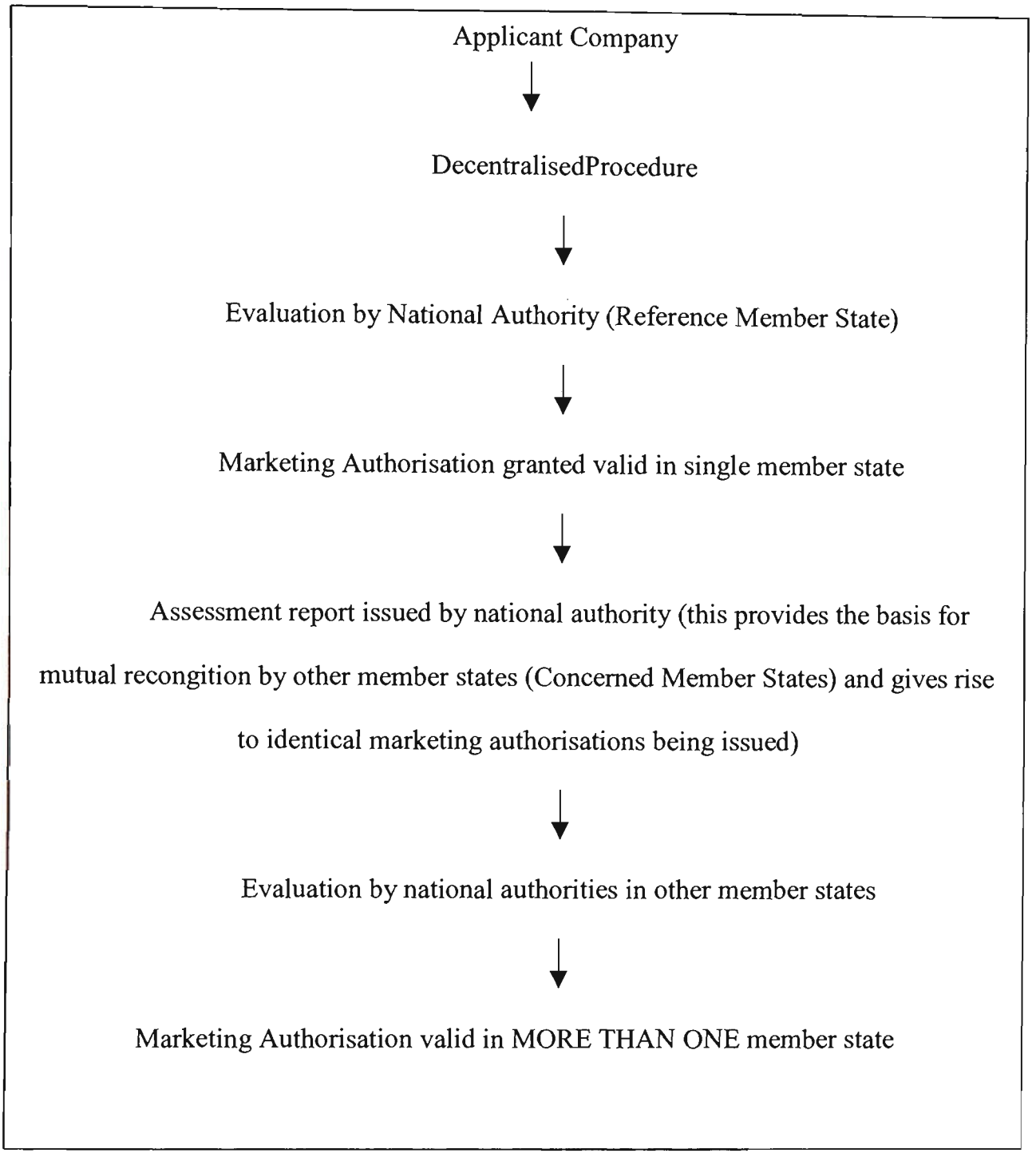
The MR process is the result of amendments to Directive 81/851 through Directives 93/39, 93/40 and 93/41 ("EC Calls for Registration System Data Review," 1998, p.2). In basic terms, the amendments replace the old NR process with one of mutual recognition and made this a mandatory requirement where a firm wishes to place its products in more than one EU member market concurrently. This took effect from 1 January 1998.

The approval process for medicinal products under the MR process is as follows (*The New European System for the Licensing of Medicinal Products,* 2000):

- An application lodged is with the primary target country chosen by the applicant to carry out the assessment work.
- Data is submitted that is examined and a decision to approve the application or otherwise is reached.
- Other countries must decide within 90 days of the original country's approval, whether they agree or reject the decision made in the original country (reference member state).

Figure 2 outlines the approval pathway for the MR procedure.

Figure 2: EU Decentralised Registration Procedure (Mutual Recognition of Authorisation given under National Procedure)



3.4.3.1 MR Recognition Issues

If an EU member state refuses to recognise a marketing authorisation issued by the reference member state, a referral for arbitration can be made to the EMEA (European Agency for the Evaluation of Medicinal Products). Under these

circumstances, ultimately the Commission will issue a binding decision based on the opinion of the CVMP (Veterinary Medicines Directorate, 1995, p.2). There is a facilitation group working on the problems of mutual recognition and this is the VMFRG (Veterinary Mutual Recognition Facilitation Group). The VMFRG was set up as a response and acknowledgment to the concerns expressed by industry and authorities that the MR procedures were not working as well as they should be (Bean, 1997, p.4).

Where a country refuses to recognise the marketing authorisation, the applicant firm cannot legally place its product on that market. Each member state has the sovereign right to accept or reject recognition of another member's decision and, of course, this may be subject to challenge. However, the sovereign rights of a nation have been challenged and upheld already under the EU legal processes. In 1996 the European Court of Justice (EJC) ruled on 21 March on CaC-297/94 Dominique Bruyere and Others v. Belgium (Davies, 2000, p.4). The plaintiffs were (in part) challenging Directives 81/851 and 90/676 and Belgian law as violating the free movement of goods under the EC Treaty.

> In rejecting the claim, the EJC effectively restated that products have to be licensed nationally, and re-asserted the right of countries to refuse imports of products not licensed nationally. Belgium has very restrictive legislation, commented FEDESA; any other verdict would have been a surprise ("ECJ Rules on Drug Import Case," 1996, p.3).

The role of the VMFRG is to find solutions to the problems, which were outlined during 1997, just prior to the 1 January 1998 changes. Some of the concerns were over the failure to meet the legal timetables for implementation of changes, others were over the level of confidence in the authorities of the member states.

> Dr Gabriella Conti, of the Italian Ministry of Health, agrees that product applicants and member states are encountering problems with the system. As of mid-March (1997) 15 applications had been finalised, of which six had been approved in all member states. One

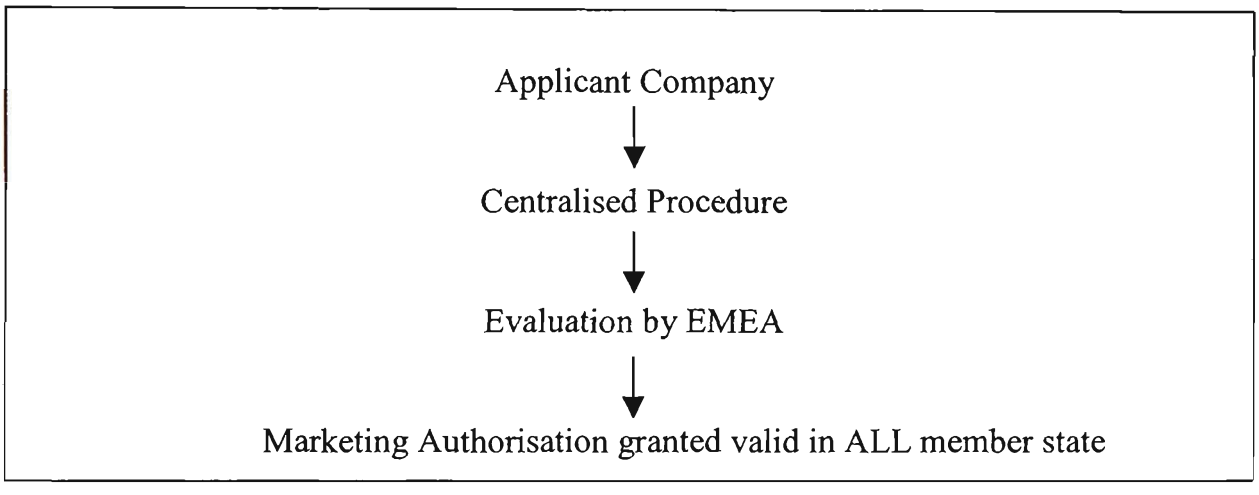
> product had been rejected by all member states, six by one member state, and the other two by more than one member state ("Concern Over Mutual Recognition," 1997, p.2).

The U.K.'s VMD was reported as stating that is was "in everyone's interest that it works" ("Concern Over Mutual Recognition," 1997, p.2).

3.4.4 Centralised Registration (CR)

The centralized registration method appears, on the surface, to be the easiest of all registration pathways options. However, it is not available under all circumstances. Figure 3 outlines the approval pathway for the CR procedure.

Figure 3: EU Centralised Registration Procedure



The application for a CR process is lodged by the applicant with the EMEA. The EMEA will undertake an assessment of the application in conjunction with assistance from the CVMP. In fact, one of the members of the CVMP will be appointed as a "rapporteur" under contract to the EMEA and this rapporteur will be responsible for the assessment co-ordination (Veterinary Medicines Directorate, 1995, p.2).

Once the application has been assessed, a scientific opinion is provided by the EMEA to the European Commission, which prepares a licensing draft decision (which must take place within 30 days). The Commission consults with the Standing

Committee on Veterinary Medicinal Products (SCVMP) and in the absence of any problems, the decision is adopted and a MA issued which is valid in all member states.

Where a negative opinion is adopted by the CVMP, the applicant is informed by the EMEA immediately. The applicant has 15 days in which to provide a written notice of intention to appeal. This has to be followed by detailed grounds for appeal within two months to the EMEA by the applicant. The CVMP has the same time frame in which to review its original opinion on the basis of the new response. The CVMP's final opinion is provided to the EMEA. The Commission's draft decision is sent back to the CVMP for opinion. If all is favourable the decision is adopted by the Commission. If not, the matter is referred to Council.

Restrictions exist on the type of product which may be subject to the CR procedure, as defined in the Annex to Regulation EEC No. 2309/93. There are two parts to the Annex which distinguish between Part A and Part B products. For all Part A products, the regulation is obligatory for these product, such as certain biotechnology products and novel growth promoters.

For Part B products, the regulation is optional, such as other innovatory products. To be able to obtain a MA for all countries under the CR procedure, the basic requirements under either part A or B must be satisfied. It is therefore important that we consider the definition of the Annex to Regulation 2309/93, as this provides a template for acceptable products.

3.4.4.1 Part A Products

Part A products are those who must undergo this procedure for registration in the EU. In other words if an applicant wishes to register product in the EU and it falls under the category captured by Part A description, the only acceptable method of

obtaining a MA is through the CR procedure. The products falling under Part A category are:

> Medicinal products developed by means of one of the following biotechnology processes:
> - recombinant DNA technology
> - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells,
> - hybridoma and monoclonal antibody methods.
>
> Veterinary medicinal products, including those not derived from biotechnology, intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals (The Council of the European Communities, 1993b, p.21).

It is important to note that the classification above applies generally to all medicinal products and more specifically to designated products. In other words the reference to veterinary medicinal products in the last paragraph of the part A refers specifically to veterinary applications and has no application to humans. However in the preceding paragraph, for example the reference to recombinant DNA technology captures both human and veterinary applications.

An applicant firm whose products fall under Part A classification can only avail itself of the CR procedure as the basis for lodgement of an application leading to a MA valid in all member states. The CR procedure is obligatory for all products which are genetically engineered or "high tech", including those "developed with" the use of monoclonal antibodies. We should note that this does not require manufacture with the use of monoclonal antibodies so if, for example, the vaccine strain is selected by exposure to a monoclonal then the product must be registered under the CR even if the production process is as low tech as it gets.

This seems to be a very restrictive practice, but one that appears to have been developed to ensure that new technological products are all treated the same way and, in theory at least, this should give rise, long term, to a situation of homogenous (CR)

approvals. We must remember, of course, that these regulations apply equally to both domestic as well as foreign manufacturers.

3.4.4.2 Part B Products

Part B of the same regulation makes it optional for a firm to avail itself of the CR procedure. That is a firm may choose this registration pathway if it so desires, but as there is no mandatory application, the firm has the option of choosing alternate methods of obtaining a MA under the other registration pathway options. Obviously the choice of either the NR or MR pathways will not give rise to a MA which is automatically valid in all member states at the onset. The products falling under Part B category are (in part):

> Medicinal products developed by other biological processes which, in the opinion of the Agency, constitute a significant innovation.
> Medicinal products administered by means of new delivery systems which, in the opinion of the Agency, constitute a significant innovation.
> Medicinal products presented for an entirely new indication which, in the opinion of the Agency, is of significant therapeutic interest.
> Medicinal products based on radio-isotopes which, in the opinion of the Agency, are of significant therapeutic interest. ...
> Medicinal products the manufacture of which employs processes which, in the opinion of the Agency, demonstrate a significant technical advance such as two-dimensional electrophoresis under micro-gravity. ...
> Veterinary medicinal products intended for use in food-producing animals containing a new active substance which, on the date of entry into force of this Regulation, was not authorised by any Member State for use in food producing animals (The Council of the European Communities, 1993b, p.21).

We should also note that Part B of the above regulation was subsequently amended and the last indent now reads:

> Veterinary medicinal products containing a new active substance which, on the date of entry into force of this Regulation, was not authorised by any Member State for use in animals (The Commission of the European Communities, 1998, p.1).

The effect of the changes to Regulation 2309/93 were to remove the limitation of the application of the regulation to food producing animals only.

An applicant firm wishing to pursue CR procedure may do so under Part B only if the product in question falls under the categorisation listed above. In reading such categorisation, it can be noted that a high degree of emphasis is placed on the Agency's opinion as to whether a product falls under the aegis of Part B. The Agency in question is, of course the EMEA.

With regard to Part B of the Annex, this applies to human and veterinary products, pharmaceuticals and immunologicals. However, it is not just a matter of the applicant's choice. If the applicant wants to use the CR procedure, they must first demonstrate that the product is eligible under part B. In other words it has to be novel in some way by compliance with any of the listed criteria in the annex. This has to be agreed by either the CPMP or CVMP (as appropriate) before a centralised application can be made.

In practice what happens is that a two page summary dossier is lodged with the EMEA explaining what the product is, how it is made, intended use and it should be considered under the CR procedure. The relevant committee then considers the arguments and makes a decision.

3.4.4.3 Satisfying the Innovation Requirement

The issue of what constitutes innovation, especially, as far as the opinion of the agency is concerned, has been a matter of some debate. It seems that two schools of thought exist on this matter within the EMEA ("EMEA Addresses Drug Innovation Question," 1996). One school is that the EMEA board should provide a definition for "innovative" while the other view is that the CVMP/CPMP (the human pharmaceutical scientific committee of the EMEA) is best placed to judge innovation on a case-by case

basis. Fortunately the first school of thought prevailed and the then head of the EMEA's veterinary unit (Dr Peter Jones) supported consistency in decision making and pushed for a definition to be promulgated for both veterinary and human preparations. In Dr Jones' words "a lack of consistency could prove dangerous" ("EMEA Addresses Drug Innovation Question," 1996, p.3).

We can at least glimpse that there is a willingness to be seen to be impartial and transparent from the EU bureaucracy's point of view. This is an important point as more firms are likely to turn towards the Agency to lodge CR applications and this is expected to grow exponentially as new research and development is commercialised over time.

Notwithstanding any new definition of the word "innovation" for the purposes of the CR procedure, the basic underlying principle remains unchanged. An innovation, being something which is new, must form an integral part of the claim before it will qualify for a CR application. A firm wishing to place an existing product on the market in the EU under the CR procedure will not be able to do so unless it can claim that at least one aspect of the product to be innovative. This is not limited to the actual inherent product and its composition alone, but may extend to the delivery method employed to administer the drug. For example, the practicality/occupational heath and safety aspect of a new drug delivery system presenting a higher degree of protection to the user, because of a better injection mechanism or tool, may be acceptable under Part B of the CR procedure. The drug may not be a new preparation, if the delivery system is novel it may be acceptable.

If a new drug, not previously approved anywhere in the EU becomes available then, under the new regulation (as amended by 649/98), this would be acceptable. Because of the application of regulation 2309/93, the observation can be made that it

appears to be a barrier to entry for a new manufacturer as it impedes new entrants from presenting existing products in the market. Existing products, by the fact that they were available in the EU markets before regulation 2309/93 became effective, are not prevented from being sold in the future, but merely allowed to exist and continue to be sold. The new firm however cannot enter the EU market using the CR procedure. In other words we can observe a protection of existing and well-established market structures.

3.5 An Assessment of the Ramifications of Multiple Pathways

Classical economic theory also supports the view that consumer benefit is derived, *inter alia*, as a result of increased competition. Why, then, would a bureaucracy instigate what is essentially protection of its own markets? The answer has to be in the effects of competition to its domestic industry. The EU has major competitors in the broader pharmaceutical area from the US and Japan and to a lesser extent Canada. It is in the EU's best interest to protect its own domestic industry against intrusion from foreign firms and to provide an environment which ensures a captive base market giving rise to long term sustainability, industry investment and employment of local citizens.

Where the firm is prevented from accessing the CR procedure because of the limitation imposed by Regulation 2309/93 as amended, then the only alternatives are either the NR or MR pathways. If the firm has an interest in concurrent market penetration across several member states, then the NR procedure is simply not appropriate. Under these circumstances the only available option for the firm is to pursue the MR procedure. By comparison to the CR procedure, the use of the MR procedure may be described as a 'piece meal' approach to market. Surely the mutual recognition guidelines will come into effect, but essentially we have a longer route to market with potentially a higher degree of problems.

Whereas the CR procedure will deliver a verdict of approved or not which will simultaneously apply to the whole of the EU, the MR procedure (as described earlier) will necessitate an individual application to each of the countries concerned. The process under the MR is longer than that of the CR. The level of fees payable, which need to be pre-paid is also less certain with the MR procedure, as compared with the CR procedure. Under the MR, each member state sets its own fees structure, whereas under the CR there is one set fee for total access to all EU member states markets.

The restrictive application of the CR procedure may have the effect of discouraging firms from entering the market or cause delays in market penetration by a foreigner in traditional market sectors. Whilst the maximum process times for CR is 210 days, the maximum time frames under the MR procedure are longer by (potentially) at least 90 days (*The New European System for the Licensing of Medicinal Products,* 2000, p.1). The days quoted above are commonly known as "clock days" in the industry and these relate to the actual working days spent on assessing the application. If the application assessment has to stop for whatever reason, e.g. lack of data necessitating further information to be provided, then the clock stops. The application is held in abeyance until a complete response has been received by the applicant upon which the assessment work starts again and the clock is started once more (Davies, 2000, p.3). The clock day idea applies to both the CR and MR procedures, whereas under the NR procedures each member state has its own guidelines for assessment criteria under national laws.

The CR procedure is suitable where a firm wishes to:

i. obtain simultaneous MA in all member states,

ii. achieve products registration (issue of a MA) in the shortest possible time frame across all EU member countries,

iii. register a product which has characteristics falling under Annex Part A of Regulation 2309/93 (obligatory procedure),

iv. register a product which has characteristics falling under Annex part B of regulation 2309/93 (optional pathway),

v. deal with only one application and one agency to obtain the MA,

vi. enter all markets simultaneously, or have a right to do so,

vii. have certainty about the value of prepayment of fees

The CR procedure is not suitable where a firm does not have:

i. a product which falls outside the definitions of Annex Part A or B of regulation 2309/93,

ii. a need to access simultaneously all EU member states markets,

iii. a requirement /resource or willingness to prepay high assessment fees

As one may imagine, given the relatively recent implementation of these regulations, applications under the CR procedure are not abundant. In 1998, eight applications were received and there was a forecast for 11 to be received in 1999 ("11 Centralised in 1999, Says EMEA," 1998, p.3). Of course the number of applications submitted is subject to both the variables outlined above as well as the availability of new drugs ready to market from manufacturers. By necessity new drug availability rests on its own large number of variable peculiar to those processes. Table 3.1 summarises the available options for EU product registration.

Table 3.1: Choosing the most appropriate registration pathway in the EU

Type of registration	National Registration	Mutual Recognition	Centralised Registration
Fees payable	Depends on the member state	Depends on the member state	Fixed by the EMEA
Maximum time frame (clock days)	Depends on the member state	300 days	210 days
Market access type	Single market	All markets subject to mutual recognition guidelines	All markets
Product eligibility	All products	All products	Restricted access Regulation 2309/93 applies: Mandatory (Annex Part A) Optional (Annex Part B)
Application assessment	National Authority	National Authority	EMEA

Having examined in detail the available registration pathways, in the next chapter we will analyse the process of obtaining a MA authority. We will use the U.K. as a sample member state, representative of the system which is used in the EU.

3.6 Summary

The EU's roots can be traced back to the Treaty of Rome (1958), which was in essence the forerunner to the current EU.

The amalgamation of a multitude of nations into a single 'entity' has seen the development of quite a complex bureaucratic structure, which is confronted with diverse cultures, languages and philosophies. This has in turn led to a legislative process which makes some allowances for the above factors and has resulted in the promulgation of EU laws which are subject to approximation when translated into domestic laws of individual member states. Notwithstanding the approximation of laws and the commonality of EU membership, the countries concerned in this union still have the sovereign right to decide on what enters their individual jurisdictions. Exporters and importers are therefore not immune from being subjected to the applicable bureaucratic processes.

In so far as placing a product into the market place a veterinary biological immunological, successive directives and regulations have changed the status quo during the 1990's. Interested parties need to obtain a MA in the countries in which they wish to operate. There are three pathways to obtaining a MA depending on the product and the strategy the individual firm wishes to pursue. Each of these, as discussed in this chapter, presents advantages and disadvantages. The approach of the NR procedure means limited market potential and has no maximum approval time frame. The MR procedure is the most complex, but probably the one most widely used, because it produces more market opportunities, due to the limitations imposed by the CR. The CR is the 'simplest' in its bureaucratic approach, but the most difficult to obtain and its availability is limited to specific circumstances. Both the MR and CR have maximum approval time frames in place.

A prospective MA applicant nevertheless has to walk through intricate web of regulations and procedures to be able to place a product on the market in the EU under the MR procedure, which is the most widely used. In the following chapter we will examine such a process based on the U.K. as an example member state.

In considering each of the three registration options available to any potential new market entrant into the EU veterinary biological vaccine markets, it would appear that some concerns exit between the bureaucratic requirements and the TBT principles, as outlined below.

i. The NR procedure is restricted to a single product / single country and may not be philosophically aligned with the TBT as it would seem discriminatory. Why limit this registration pathway to a single country / single product? Is it to protect existing market players? If so then it would seem to contravene the spirit of the TBT.

ii. The MR procedure enables registration of any quantity of product in any or all member states and appears not to provide impediments to market penetration, but approval to enter a market is based on a country-by country basis. This approach may not necessarily yield consistent results, as each country's sovereign rights are still able to be exercised. This pathway's transgression of the TBT would be more difficult to prove.

iii. The CR procedure. This appears to be restrictive as it can only apply to specific types of products or 'innovative' products.

It would seems therefore that no single EU wide entry point is available for all circumstances. Again, it would be difficult to prove a breach of the TBT, especially as confidentiality between potential entrants and authorities exist. Because all of the

requirements are followed unilaterally, regardless of the origin of any applicant, the EU would doubtlessly argue consistency, therefore no transgression.

In relation to the SPS, the lone scientist notion alone would be enough to counteract any debate.

To explore the TBT issues further a more in depth analysis of some of the implicit barriers follow in chapter 4.

4. Barriers Implicit in the Application Process

4.1 Introduction

In Chapter 3, a description of the EU registration pathways and their respective registration processes is given. In addition, an analysis of the differences between the registration pathways is provided. The analysis shows how the present EU registration scheme, in effect, discriminates against new non-EU market entrants owing to the absence of an expedient method by which 'non-innovative' products can be registered for sale within the EU. The disadvantage stems from the fact that non-EU market entrants are not eligible to obtain a critical 'grandfathered' status that EU producers are given.

The purpose of this Chapter is to examine, in more detail, some of the more specific technical requirements of the EU registration process in order to assess whether detailed features of the regulatory scheme impose further impediments that function as market access barriers. In Part 4.1, an analysis of the registration application form is undertaken. This is followed by an analysis of labeling, product testing, plant inspection and data confidentiality requirements in subsequent parts of this Chapter. Observations relating to the equity of this provisions is made in the summary to this Chapter.

4.2 The Registration Form (the Dossier)

The content of the actual application document lodged by an applicant in order to achieve the issue of a marketing authorization (MA), regardless of the registration pathway chosen, is made in the form of a dossier lodged with the appropriate authority (which is determined by the registration pathway chosen). The dossier must be complete and provide all information required to satisfy the relevant authority to enable the issue

of a MA. Product safety, quality and efficacy are paramount consideration in the assessment process.

The dossier accompanying the application must satisfy the requirements of either the national authority and/or community law depending on the registration pathway chosen. In some countries the authorities try to take a proactive approach towards new applicants. In the UK, for example, the VMD (Veterinary Medicines Directorate) will meet with any prospective applicant prior to the lodging of an application to discuss the requirements and the usual areas of concern. The fact that these meetings are desirable further supports the view that registration and the issue of a MA is a somewhat torturous process. Indeed the VMD is quite candid about this issue:

> it is rare for an authorisation to be granted outright. It is more common for the assessment to conclude that an authorisation could be granted if satisfactory further information were provided, or if certain changes were made, e.g. top the quality control procedures, or in the SPC and/or label (Veterinary Medicines Directorate, 1996b, p.11).

Accordingly, from the outset, an applicant is put on notice and an anti-expectation is created, that being the knowledge that it is rare that an applicant will be granted an MA outright. The detailed scientific data of a particular biological product are so varied and the biology too complex to be considered in this thesis. However, we can consider some of the ancillary requirements for the product, such as packaging and labeling, control testing as well as administrative matters such as costs and fees.

4.2.1 Labelling

> Under the Regulations the labels and package inserts for a product become part of the marketing authorisation. They therefore need to be approved by the competent authorities and any subsequent changes may be made only as a variation to the authorisation (Veterinary Medicines Directorate, 2000, p.2).

This statement, issued in accordance with Directives 81/851 and 90/677, provides an indication of the pedantic nature of labeling requirements. However, some

of the labeling requirements may be regarded as reasonable, in so far as they do present a barrier, but this is more of a "natural" barrier, rather than a fabricated one. Language may be regarded to fall in this category. In the EU there are over ten different languages in use over fifteen member states. It is reasonable for customers to be able expect to purchase products with labeling in their own language. This does become both a costly and time-consuming exercise, initially, to have all the labeling set up accordingly. It is just another cost and raises the barrier to entry into a market. This requirement may be more a fact of life and it is a hurdle which is also experienced by domestic EU manufacturers, as they are not immune to this requirement, so in this sense they are no better off by being domestic producers.

The labeling requirements have a logistic implication in terms of stock segregation in production as each differently labeled product will have its own unique code. This results in the creation of another stock line item. This has implications for warehouse and storage and limits and the cross-supply of material across different member states to satisfy sudden and unprecedented surges in demand. Multi-language labeling may be an ingenious solution, but this has limited applications, as the packages tend to be comparatively small and there is just simply not enough surface area on which to legibly inscribe all of the required information. To overcome this problem, a single language labeling system seems to be the only practical solution. Given the diversity of cultures and languages within the EU, it is not possible to imagine how, in the foreseeable future such an arrangement may be achieved.

To the extent that labeling may perhaps be regarded as a barrier to trade is where there are requirements for specific types of packaging, such as the ban on polystyrene packaging in Germany or the Dutch requirements for packaging to be 65% recyclable ("Watch Out for Non-tariff Barriers in 2000 - Federation of Thai Industries," 1999, p.1).

These requirements arise from a sovereign member state's concern for its environment and it would be difficult to bring about a change in thinking or indeed bring action against these requirements under the various WTO agreements. It would seem that under the protection of the environment such measures would be allowed as legitimate exceptions under the SPS, TBT and Article XX of the GATT 1994. Although these measures may have the effect of keeping competition out of a domestic market, proving a non-legitimate motivation for such requirement would be difficult.

To put the labeling issue in a broader context, labeling issues across different industries in various countries continue to provide a source of frustration for traders. Eggs in the EU now have to be labeled according to their production method to facilitate consumer choice. Descriptive phrases such as "free range, semi-intensive, deep litter and cage production" in some countries must appear on packaging. These measures are brought in under the auspices of consumer choice facilitation ("EU Calls for Clear Labelling on Eggs," 2000, p.2). Where labeling falls outside the scope of international obligations is where there are different requirements between domestic and foreign producers, such as in the case of the Korean beef imports:

> Korean regulations that require more stringent labelling on foreign beef, as opposed to domestic beef, along with limitations on distribution outlets and the channelling of higher subsidy outlays in 1997 and 1998 to domestic beef producers were also considered inconsistent with its international obligations (UPI, 2000b, p.1).

In this sense, because the EU does not discriminate between domestic and foreign suppliers, and all market entrants are subject to the same rules, it would be more difficult to prove a case of a non-tariff barrier to trade in respect of this issue. Other issues arise, which make it difficult for the firm to operate in what is often referred to as a "borderless" Europe. Unfortunately borderless does not equate to homogenous treatment and product release practices serve as a good example of such anomalies.

4.2.2 Product Release Control Testing

The issue of release control pertains to the testing and monitoring of new product releases. The specific obligations placed on MA holders are set out at Articles 42c and 42d of Directive 81/851 (Veterinary Medicines Directorate, 1996a, pp.2-3). It is the responsibility of a MA holder to ensure that a product placed on the EU market complies with all necessary release control procedures. The procedures outlined in Directive 81/851, in practice, are not uniform and vary between member states.

Release control processes are governed by the relevant national authorities throughout Europe. The feature that is common to all is the policy that all new products registered must undergo control testing before release onto the market. The technique that is commonly used is known as the 'batch by batch' control release mechanism. The conduct of control testing processes have financial, logistical and strategic implications for the applicant. Most obviously, since it is the MA holder that is obligated to pay for these tests, the result is an additional direct cost of market entry, as well as indirect costs incurred stemming from delays in product release. The logistical knock-on effects can be increasing inventory holdings, as pipeline stock would increase. In addition, because of the nature of immunologicals, all products have short expiry dates (or use-by dates) where delays in testing and release approval may reduce competitiveness against substitute competing products in the market, if those enjoy a longer expiry date.

It may be possible for the authorities to favour local manufacturers by testing domestic product first and foreign product later. For example, where there is a queue of products to be tested, anecdotal evidence indicates that foreign products are frequently relegated to the end of the queue. Under the policies in operation, no product may be released to market without the official approval. Holding back or delaying the official approval is a very effective way of lessening competition and frustrating market entry

and penetration, with the result that protection is afforded to the local industry. Of course, such an allegation would be difficult to prove, but these practices are not new.

Another concern that may arise under this situation is variability in test results. It is a commonly known fact that no two biological tests will yield exactly the same results at different times. There are too many variables involved in the test input to be certain that a 'cloned' result will be achieved all the times. This may also prove to be an additional source of frustration in trying to enter the market.

4.2.3 Product Application Fees and Plant Inspections

Depending on the registration pathway chosen the applicant is faced with different options in relation to the payment of fees.

Table 4.1 summarises the fees payable according to the type of registration.

Table 4. 1: Summary of Product Application Fees Payable for EU Registration

NR Procedure	Fees are set by each individual country according to their regulations and these vary greatly depending on the type of application and the country's individual fee setting mechanism. The U.K. is at the high end of the scale, with Portugal at the lower end of the scale.
MR Procedure	Fees are set by each country. There are cheaper fees for CMS procedures than the levels set for an initial application (RMS). This is essentially due to the fact that the second and subsequent country will be relying on the RMS assessment for mutual recognition. Again the fees vary depending of the type of application.
CR Procedure	The applicant pays one sum for the total of the EU markets. There is a scale of fees depending on the type of application, but this is much more easily determined than under the other two registration pathways options listed at a) and b) above.

The applicant may need to pay the fees upon lodgement of the application and these may be in excess of AUD 40,000, depending on the type of application. If the

assessment of the application involves an overseas visit by the assessing competent authority, the applicant will need to pay a fee for this service, as well as the accommodation and sustenance costs of the inspector whilst on duty. As one can appreciate, the costs would increase considerably for long haul journeys, e.g. between the EU and Australia.

It must also be remembered that these costs are incurred prior to the product being released to market. The necessity of a plant inspection by the competent authority will see the clock stopped until the inspection has been carried out. Inspectors are seldom available at short notice and it does take time to arrange for the inspection, as both the applicant and the inspector will need to agree on the agenda and data for the inspection.

4.2.4 Mutual Recognition Treaties and GMP Certification

Since 1 January 1998, a "Mutual Recognition Agreement on Conformity Assessment (MRA)" has been in place between Australia and the EU. Basically this agreement provides recognition of certification between the EMEA and the NRA (National Registration Authority in Australia). This agreement was to be reviewed at the end of 2000 and there is no currently available information pertaining to this review in the public domain. This agreement does not currently deal with recognition of each other's Good Manufacturing Practices (GMP).

There are several differences in GMP between the respective parties to the MRA and it is beyond the scope of this thesis to analyse these. Nevertheless, even though there is a MRA and certification is mutually recognized in spite of differences in the GMP, it is still the prerogative of an importing country to require plant inspection from foreign applicants (Johnson, 2000). In practice, the NRA is generally satisfied with paper certificates from prospective importers and, in practice, does not pursue plant

inspections. On the other hand, the same does not apply to EMEA resulting in a situation giving rise to the potential to impede market entry.

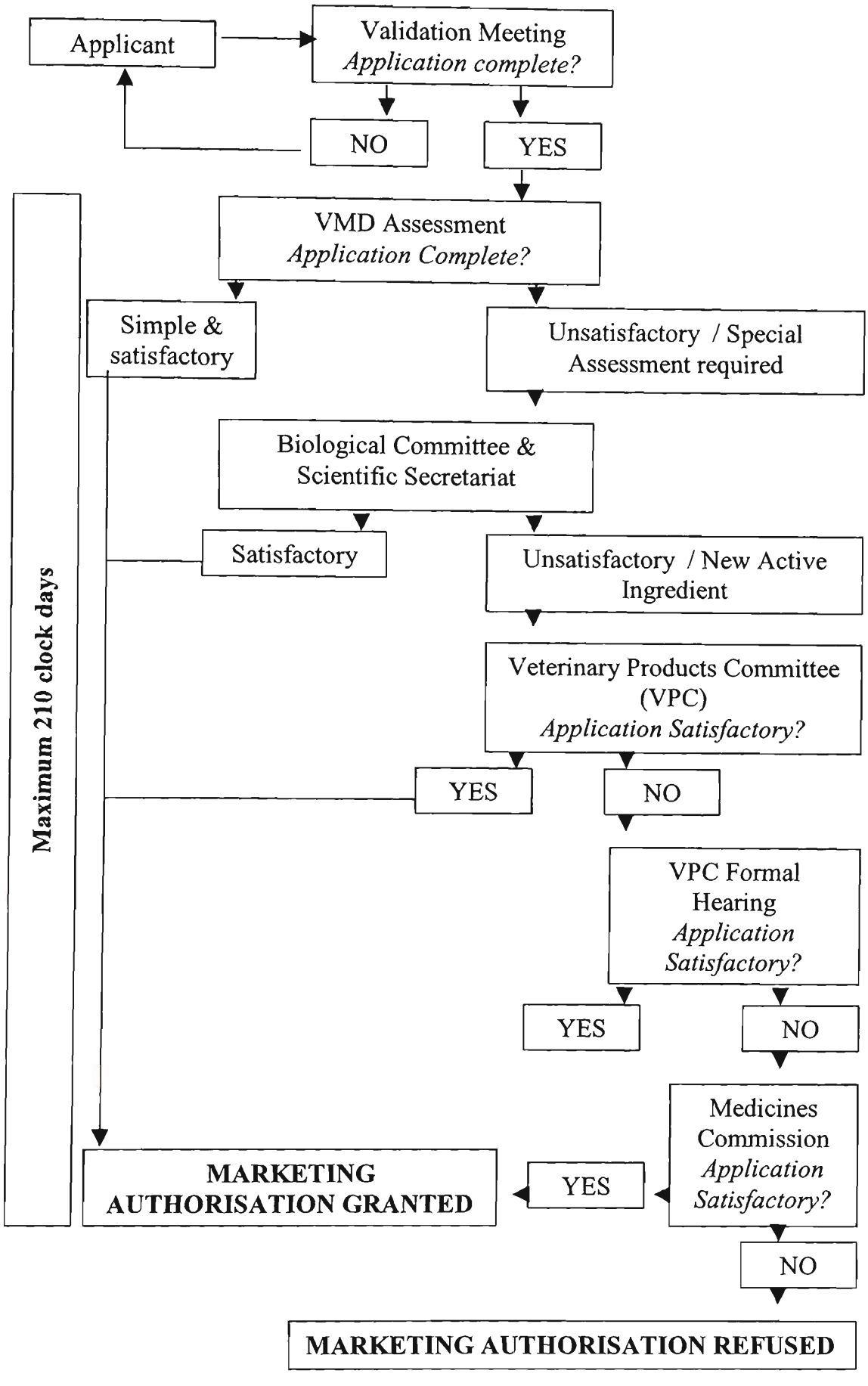
It is not uncommon for the clock to be stopped for several months during the application assessment process because an inspector is not immediately available and the agenda needs to be agreed upon. This is a very effective means of preventing market entry. Of course, the importing country would claim they are doing all they can in terms of providing inspectors and that, after all, inspections are required to ensure that the government of the importing country is providing a safety net to its citizens and their environment.

4.3 Application Assessment Hurdles

Once an application has been lodged, there may be a maximum time-frame within which a decision must be made. The time frame is dependant upon the type of registration pathway chosen. The usual step is for the applicant to lodge the necessary application documents with the relevant competent authority and then wait for some form of communication.

Figure 4 outlines the typical procedure which is followed in the UK for the issue of a Marketing Authorisation.

Figure 4 : UK Marketing Authorisation Procedure



4.3.1 Dossier Validation

The authority first must check that the documentation provided is complete as required. This is called the validation step. The clock starts at the end of the validation step. The clock then keeps going until the assessing authority finds a flaw in the documentation provided (which will henceforth be referred to as the *dossier*). If the dossier, according to the authority, is lacking in detail the assessment cannot continue. The clock is stopped and the applicant is asked to provide answers to specific questions. The clock will only be started again after receipt of these answers. If the answers are satisfactory the assessment proceeds with the clock running. If the answers are not adequate, the clock remains stopped pending the provision of satisfactory answers. This stop/start process can occur several times during the course of an application's assessment, in the meantime no product may be placed on the market.

4.3.2 Trial Data Assessment

The situation becomes even more bureaucratic in cases where the examining authority decides to reject trail data based on overseas field trials and insists that trails be done in the importing country on domestic livestock. If this insistence arises because of insufficient or poor data provided by the applicant, the assessing country is within its rights to be provided with acceptable data.

In cases, however, where "scientific" objections are made, which result in a refusal to recognise trial data from another country, even where the disease causing organism is the same, the net effect is a delay of, usually, between eighteen to twenty four months in trail design, execution, data capture and presentation. The above time frame is a conservative estimate on the basis of little, if any, deviations from unforeseen circumstances that may arise in the course of a trial, e.g. animals dying, or falling ill during the trial period. The time delays alone will cause concern, but added to this is the

expense of conducting an acceptable (by way of protocol) trial, that might run into the hundreds of thousands of dollars. For a firm, this has potentially devastating repercussions, both in the short and the long term, as it will result in decreased business earnings.

If these requirements are imposed on "marginal revenue" products, a cost/benefit analysis is likely to tip the balance against proceeding to obtain certification and result in the abandonment of product introduction. For example, in 1995, an Australian application to an EU member state authority in 1995 came perilously close to such a situation. The authority in question refused to accept trial data generated domestically and initially insisted on replicating the trials in sheep in the U.K. The rationale was, apparently, that the U.K. sheep were different to Australian sheep! Fortunately such fallacy did not prevail, but other requirements have continued to remain a stumbling block in the introduction of this product.

Dubious and ambiguous scientific objections or questions can be quite effectively used as forms of trade barriers. The onus of proof rests on the applicant to overcome all objections from the relevant competent authorities. Dealing with such dubious requests requires, at times, require extensive efforts (not to mention increased costs) to convince the bureaucrats to change their mind and shift their position on issues. We should add to this dimension the lobbying power of the local EU manufacturers, which are much more capable of intervention than outsiders, if for no other reason than their presence and local economic performance.

4.3.3 Data Confidentiality

Data confidentiality is a concern to all applicants. One of the fundamental considerations a firm has is the release of data to external parties, especially if data is commercially sensitive or reveals trade secrets. To this end, an applicant's concerns lie

in the confidential treatment of such data and its non-disclosure to third parties, especially if this will lead, directly or indirectly to increase competitors' intelligence. Industrial espionage in its various forms is also a matter of life.

The EU seems to have taken this seriously, at least in the EMEA's code of conduct. At times, though, it appears that legislation paves the way for competitors to have access to a manufacturer's confidential dossier. For example (Lucken, 2000), when the German Government transposed Directive 81/851 into national law, it added several additional requirements that are not included in the EU Directive. The first addition is that an EP (European Pharmacoepia) monograph exists, then not only does that product have to meet that standard, but it has to be tested by the methods described (on a batch by batch basis), even though the EP states this is not necessary.

An Australian manufacturer currently provides, under a supply agreement, a biological veterinary vaccine in bulk to a rival in Germany, who subsequently blends this component with others that it manufactures to make a combined vaccine. The German manufacturer is not able to produce the foreign vaccine due to technical difficulties. The Australian manufacturer does not wish to provide details of the methods of production to the rival and so deals directly with the authorities. The product is registered with the authorities, but there needs to be an AQP appointed in the territory of sale, that is Germany. The foreign supplier does not have anyone who can fill that role and so the German manufacturer is appointed as the AQP, therefore they become the MA holder. This way the MA holder can access the information supplied in the dossier.

Where this information is currently protected by patents applicable in that country, it would be illegal for the German manufacturer to use the information, but if the product was patented, the methods would be on the public record, so no advantage

arises here. However, where it becomes advantageous for the German manufacturer to have access to the foreign supplier's dossier is where the product is manufactured with trade secrets. This way the German manufacturer gains knowledge about the foreign production steps and can use this knowledge to its advantage. This may ultimately lead to the German firm changing from a buyer to a competitor and even worse, the new knowledge acquired could be made available to others. There is no apparent protection against this loophole under German legislation, the only way to overcome this problem would be for the contracting parties to enter into separate confidentiality agreement.

4.4 Obtaining Marketing Authorisations in the UK: A Case Study

In Chapter 3 as well as the previous sections of this Chapter, some of the methodological and procedural difficulties associated with obtaining a marketing authorisation were identified. It is useful at this point to examine in more detail the actual processes of a particular EU country. Given the historical linkages between Australia and the past practice to use the UK as the marketing entry point, an analysis of the UK regime is undertaken.

The principal body responsible for overseeing the dispensation of marketing authorisations in the UK is the Veterinary Medicines Directorate (VMD). The VMD is an executive agency of the Ministry of Agriculture, Fisheries and Food. It is required to operate consistent with national law, which by implication, must be consistent with EU legislation (also referred to as Community law). The mechanism by which conformity with EU law arises is as a result of Community directives and regulations implemented within UK law in the form of the *Marketing Authorisations for Veterinary Medicinal Products Regulations*, 1994. Under this legislative structure, the VMD is permitted to issue MA's for both the NR and MR processes. Accordingly, a veterinary medicinal

product may not be imported or held in possession in the UK unless it is the subject of an authorisation valid in the U.K. (Veterinary Medicines Directorate, 1999, pp.5-6).

Prior to a MA being issued, the VMD will, in the case of a MR procedure, issue a preliminary A*ssessment Report*. The assessment report is a report that assesses the status of the application's contents in relation to the sufficiency and adequacy of information. By virtue of the issue of the *Assessment Report*, the VMD then causes the UK to become the reference member state (RMS). Other member states having an interest in this product, by way of an application lodged with their authorities will become concerned member states (CMS).

A CMS will rely on the RMS assessment report as the initial basis for acceptance or refusal of the application. From receipt of the initial RMS assessment report, the CMS has a maximum 90 clock days in which to approve or refuse a MA to the applicant. The CMS has every right to seek clarification about the RMS assessment and to seek further data from the applicant as part of the approval process. On the surface this appears to be a very transparent system; however, one can see how the matter may become frustrated by bureaucratic processes, especially where requests for clarification or additional data may be undertaken under the disguise of science. Indeed this can be a point of debate even where the CR procedure is followed, as a recent example highlights.

> ... consistently high standards were applied, - higher than would have been expected from national procedures. He was disappointed however when the ethics of using the product began to be questioned and said it felt like the "fourth hurdle" was being applied ("EU Regn Profiled at Info Day," 1998, p.2).

This same industry expert was also critical of dissenting views expressed by two member states at the CVMP level. The stand taken by some of the CVMP members

was defended though by one of their own CVMP colleagues, Cyrill O'Sullivan who stressed the Committee operates on democratic principles:

> The members have a right to their own scientific opinions. We aim for uninamity, but if not seek to achieve consensus ("EU Regn Profiled at Info Day," 1998, p.2).

In this particular example, the CR procedure took a total of 510 calendar days. This is nearly 17 months of assessment. From this period, if a five month period is deducted because the applicant itself stopped the clock, the fact is that it took approximately 12 months or roughly 360 days for the approval to be granted. The question now needs to be asked in relation to Regulation 2309/93, which stipulates a maximum of 210 clock days, where did the other 160 days go?

In seeking to explain the 160 over-run, there are two possible explanations. First, the assessment period took longer than expected and, therefore, constituted a breach of the regulations. This seems unlikely or the applicant itself would have, in all probability, complained. Alternatively, the extra time was utilised in providing information requested as part of the assessment process. This is the more likely scenario, especially in light of comments made earlier that it felt like the 'fourth hurdle'.

The above example cannot but cast doubt on the timeframes utilised to grant MA under the EU registration procedures. Form this instance we can glean very easily that it would not be difficult at all for a process to be instigated which could be designed to frustrate the entry of a product to a market, simply by doing no more than asking questions. A similar scenario is equally as possible under any of the registration pathways. Again, it must be stated that this is difficult indeed to prove and awkward to challenge as each member state has sovereign rights and the ability to have its own scientific opinions.

4.5 Conclusion

A non-EU exporter of veterinary biological vaccines faces considerable challenges in achieving market access to what are generally regarded as lucrative EU markets. In our analysis, several aspects of the relevant bureaucratic and administrative processes applied in the EU are identified as being trade discouraging. Some are legitimate, others are more suspect. In addition, where regulatory requirements do appear to be legitimate, a less-than-fair application of the rules arising from domestic favoritism can result in a non-transparent abuse of process.

The difficult task non-EU exporters face is the "hindsight" protection of markets in the EU. A lot of the currently biological immulogicals were sold in EU markets before the introduction of the current rules and as such were provided with the so-called "grandfathering" status. Added to this is the way the regulations apply for new applications. The old products are protected from a total attack across the whole of the EU markets with one single application, because by definition they do not fall within the ambit of Regulation 2309/93 as amended Annex Part B. This means that they are not new products. The only way to attack these is by choosing the MR procedure, which is lengthier and does not guarantee the same outcome.

It is now no longer possible to register a product in one EU country under the NR procedure, if subsequently there is a wish to have that product sold in another EU-member state. This is another restriction. If a new process product, e.g. recombinant DNA becomes available, then it can only be registered at the global EU level under the CR procedure.

Although there have been advances towards mutual recognition between Australia and the EU, these have not resolved owing to differences in GMP. Therefore, manufacturing plant inspections may still need to be undertaken. There are differences

between EU member states in the way products are released to market and there are still internal barriers to the free flow of trade, which have to be resolved through the EJC. Finally, there are questions of confidentiality breaches that need to be considered, such as the one available under the German laws.

In summary, it is clear from the long lists of bureaucratic requirements discussed in this chapter that there is tremendous latitude for any regulatory authority to abuse its position as an objective referee. Instead should circumstances be that the regulator is put under pressure by either its government or local industry, the regulatory authority can easily react and behave in accordance with protectionist policy pressures. Because of the wide scope for regulatory discretion that may be exercised in respect of any of the regulatory requirements discussed in this chapter, it is easy to see how regulatory processs may be abused in a non-transparent manner to the benefit of the local industry.

5. An Economic and Trade Flow Analysis of the Impact of EU Regulations

5.1 Introduction

The objectives of this Chapter are several. The first objective is to conduct an economic analysis of the expected effects of Council Regulation 2309/93 (The Council of the European Communities, 1993b) upon the market structure and behaviour of EU biological immunological producers relative to foreign competitors. A second objective is the use the economic insights derived from the previous analysis as a contextual basis for a trade flow analysis examining the effects of Council Regulation 2309/93 upon trade flows in biological immunologicals between Australia and the EU. The third, and final, broad objective of this Chapter is to link the observations derived from the previous two analyses to an interpretation of how Council Regulation 2309/93 may have had a profound effect upon a global restructuring of the biological immunological industry thereby radically altering trade flow patterns in biological immunologicals between the EU and Australia.

5.2 An Economic Analysis of the Structure of the EU Industry: Overview

The world market for manufacturers of biological immunologicals is quantitatively small and oligopolistic in structure. Almost all the significant firms in the industry segment can be classified as large multinational enterprises that originate from the USA and the EU. The cost of operating in such a market segment is extremely high because product research and development costs are high. In addition, the road to market is frequently very long. In some cases, the commercialization process is up to 10 years or more depending on the type of product and the scientific evidence needed to satisfy relevant authorities in meeting health and safety requirements.

The high cost of product research, development and commercialization is further compounded by high operating costs and long production lead times. In combination, these factors create a general barrier to entry for potential industry entrants. In conjunction, there are considerable risks involved in operating in such a market segment, due to the uncertainty of the subject matter researched. Biological production is difficult and risky. Reproducibility of successive manufacturing episodes requires a high degree of skill and a massive investment in resources. Consequently, these factors tend to discourage market entrants, an effect which is reflected in the industry's oligopolistic structure.

One of the characteristics of oligopolistic industry structures is the effect upon the competitive behaviour of the industry participants. It is not uncommon for firms within oligopolistic industries to engage in an array of forms of collusion resulting in anti-competitive conduct such as cartelisation, market splitting and price fixing. The purpose of the next section is to examine the relationship between EU industry structure and the competitive behaviour of EU firms.

5.2.1 The Regulation 2309/93 Annex and its Competitive Effects

As mentioned earlier, one of the principal factors contributing to the concern that the EU regulatory scheme for the certification of veterinary immunologicals acts as a technical barrier to trade is closely linked to the mechanical operation of the Regulation 2309/93 Annex. There is evidence that the promulgation of the regulation has the effect of slowing down the entry of external competition into the EU markets, whilst simultaneously protecting EU domestic manufacturers. The means by which Regulation 2309/93 may cause this effect is because of its introduction of mandatory measures for the approval of certain products under the centralised registration

procedure (which is the only route available for a firm to obtain simultaneous blanket approval across all EU member states).

The restrictions imposed under the Annex to Regulation 2309/93 Part B mean that only certain new products, which are in some way innovatory, will be given approval under this process. In all other cases, the intended applicant has to choose a less convenient path of decentralised registration, which is fraught with potential delays and a less certain route to market. The imposition of these restrictions means, in effect, that a new entrant without an innovatory product cannot enter the market under the centralsied procedure, but the existing products on the market, of course, are allowed to continue to exist. Hence, local manufacturers are given an inherent advantage insofar as the barrier to entry acts as a deterrent to import competition from foreign exporters that cannot make a viable business case for pursuing certification of marginal revenue products.

An example is useful in further illustrating the discriminatory effects of the EU regulatory scheme. We begin with a specific product produced within the EU designed to treat a particular condition. A foreign firm wishes to enter the EU market, with a substantially similar product, with no innovatory properties. The foreign firm believes there is potential in the EU markets for its product to do well. As part of the entry to the market, the foreign firm would prefer a registration approach that would give it simultaneous access to the entire EU market rather than on a country by country basis. Under regulation 2309/93 this is not possible. The product lacks innovatory properties and cannot therefore obtain certification using the centralised procedure. The foreign firm is required to use the decentralised procedure and apply to each individual market for access. The 15 individual national registration applications required can be expected to result in different interpretations between member states in relation to matters related

to the application. Consequently, a multitude of delays can be expected to occur. (For example, among the requirements of registration under the decentralised procedure are that parts of the dossier have to be provided in the language of the country where registration is sought. There is no such requirement for the centralised procedure as the registration dossiers are lodged in English. The workload and expense involved in having to prepare 15 different registration packages will cause grave concern to any foreign firm).

In general, the success of a product, in an oligopolistic market with high entry costs/barriers, will be affected by the speed of entry to such market. When the new entrant is effectively prevented from gaining quick access to market, the time lag can be exploited by the existing market players to devise strategies to minimise the impact of impending competition of the new product.

If, under the decentralized certification method, the foreign firm is forced to apply in each market individually, it will not be difficult for the existing domestic (EU) firms, who are often operating in various member states, to work out the strategic approach of the competitor and implement steps to protect their markets. It must be remembered that the domestic (EU) firms are already operating in those markets and generating revenue, whereas the foreign firm is trying to gain entry to generate some future revenue.

The existing domestic firms in the EU market are, for the most part, producing and distributing established products which are frequently in the mature stages of their product life cycle and probably at the "cash cow" stage. The domestic firms marketing products at this stage of their life cycle will be strategically motivated to ensure the product life cycle is extended to its maximum, particularly because it provides for the generation of revenue which is, in part, used to cross-subsidise new and future product

development costs. In order to maintain a maximized revenue flow, there is likely to be an effect on the pricing of such products by the EU firms.

5.2.2 Likely Pricing Effects of Discouraging Competition

Because of the impediments to gaining market access imposed by the restrictive application of Regulation 2309/93, it is highly likely that EU market prices will be affected. In the classical economic theory framework, competition is good, because, *inter alia*, it will bring a reduction in price while simultaneously increasing consumer choice. Within an oligopolistic market structure, if there is price competition (ie., open market access), the consumer will derive benefit from lower prices and greater choice of goods.

However, firms interested in extracting positive economic profit prefer to operate within a market structure that allows them to behave more like monopolists. In this regard, under the regime in the EU, Regulation 2309/93 provides a structural impediment to foreign competition where market access is bureaucratically restricted. These measures favour domestic producers who have an established foothold in the market. The expected effect of these measures is that prices will remain high for the consumer flowing on from competition being sub-optimal. Consumers will also have less choice because fewer drugs are approved than otherwise would be the case. Veterinary immunological prices remain much higher in the EU than Australia, according to industry sources. This may well be influenced by other factors, such as the relative higher prices of the animals and the different livestock management practices, but the less than optimal level of competition remains, nevertheless, an important factor. The effects of reduced competition are illustrated in Figure 5.

Figure 5 : A Monopolistic Competitive Firm in Market Before Trade Opens

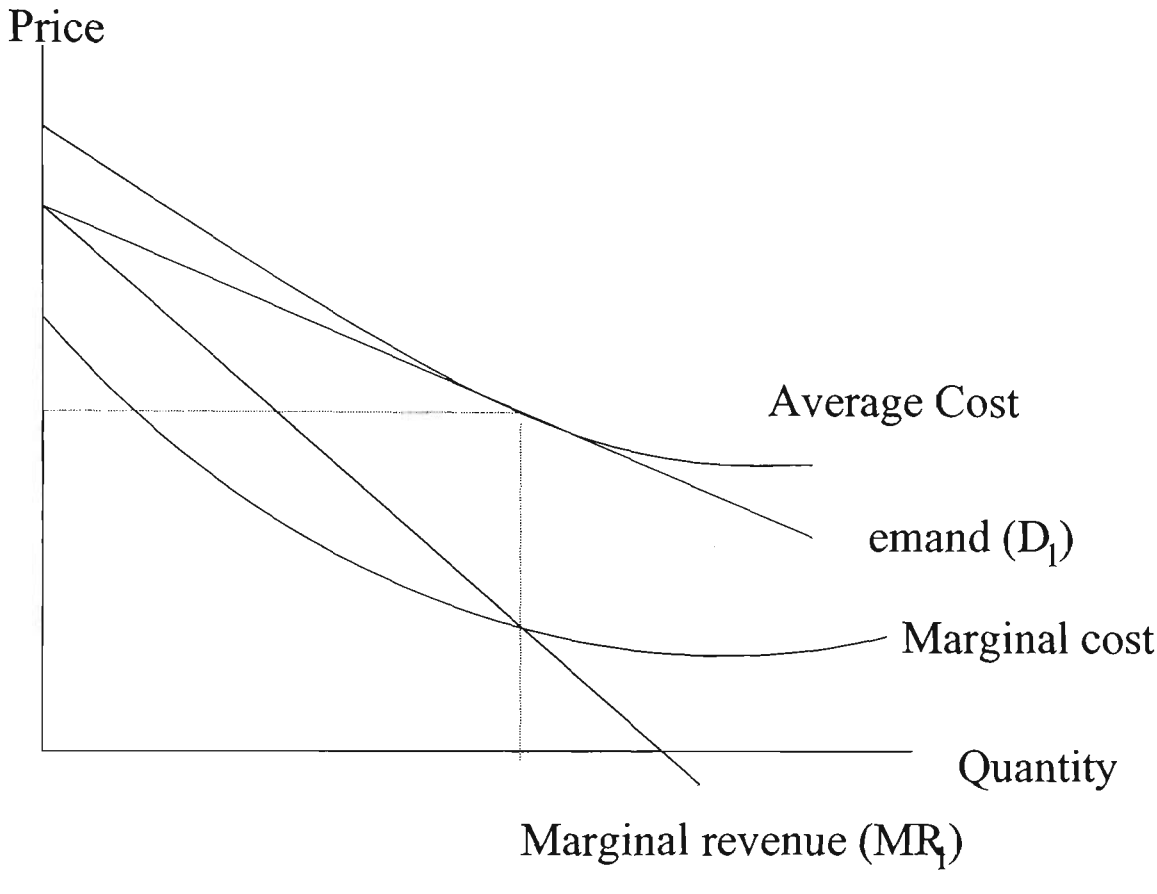
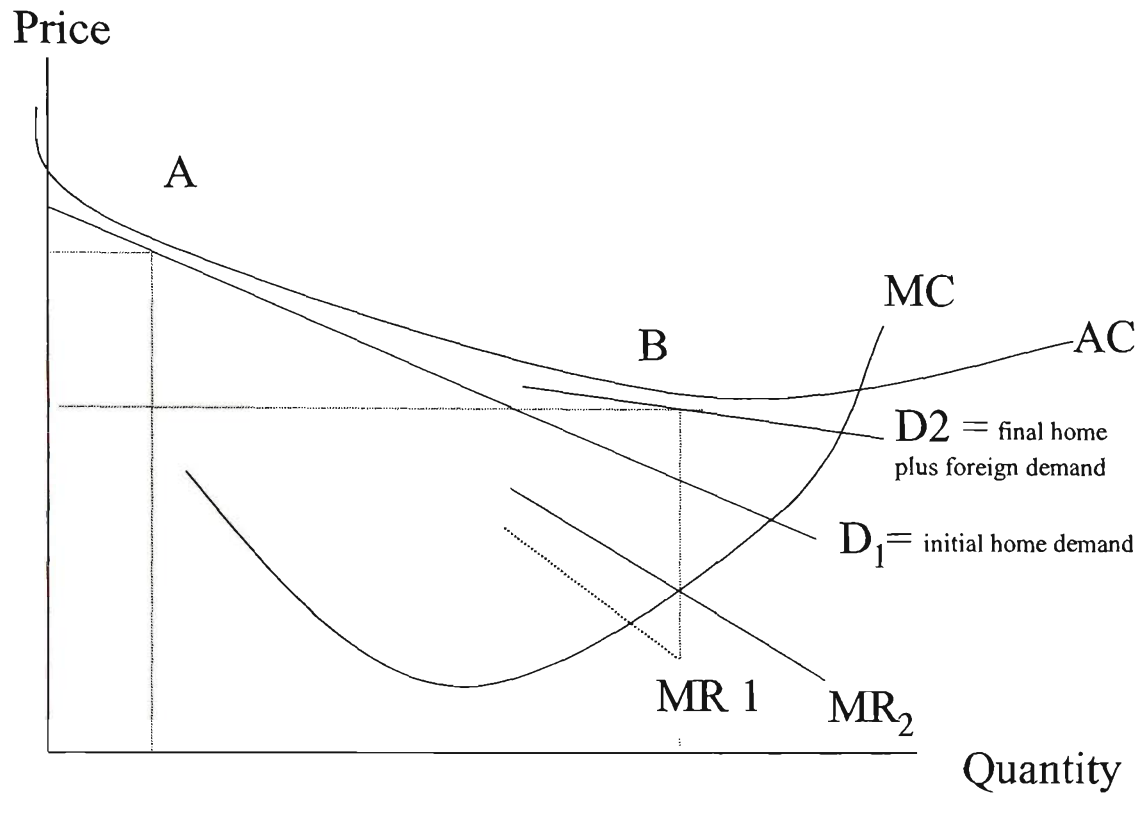


Figure 5 illustrates the behaviour of domestic firms before free trade. The domestic firms base their profit maximising decision along the marginal revenue curve. From this, it is apparent that an expansion in production and sales leads to a reduction in price that leads to a reduction in total revenue. Therefore the domestic firms expand production to a point where marginal revenue just covers the marginal cost of making and selling vaccines. That is represented in the diagram at point C. To sell that amount of vaccine, the domestic firms (acting in tacit or explicit concert) will charge what the market will bear, which is dictated by the demand curve at point A. The likely effects of the opening of the markets to free trade are shown in Figure 6.

Figure 6: A Monopolistic Competitive Firm in a Market After Trade Opens



If market access restrictions are reduced or removed, two things will happen:

- local producers can export to foreign markets where demand for their products exist.
- local producers will face increased competition from foreign imports.

In the short run, there will be some market adjustments, with firms entering and leaving the market. In the long run, a tendency towards a more stable equilibrium will result. When this transition is complete, domestic firms will once again find price just equal to the average cost level, but in a somewhat changed situation. Point A in Figure 6 represents the equilibrium point that existed in the pre-free trade period, similar to that shown in Figure 5 (note that the scales on the axes have been changed). Point B represents equilibrium after the adjustments caused by the increased competition

resulting from free trade. Curve D2 represents the final demand curve facing domestic producers. We presume that world demand, due to competition and substitute or substitutable products, will cause demand to be more elastic than the initial home-only demand. The net result is that domestic producers output will be greater, but at lower prices.

The downward shift in prices, as a result of free trade are shown in Figure 6 as the movement from point A to point B, which indicate a higher quantity of demand, but at lower prices as a result of competition. The veterinary immunological market is oligopolistic in nature as there are relatively few players and market power is concentrated in the hands of very few. This market is also highly regulated by authorities. These factors lead the market players to behave as if monopolistic competition existed. The reality may be a hybrid between oligopoly and monopoly. To simplify the analysis we are developing a theoretical framework based on monopolistic competition to demonstrate the before and after effects of free trade. We find that in the absence of competition, prices remain high, while demand is static. Demand will be effected to some degree by prices, but there will be segments of the market where product must be used due to government regulations, e.g. for disease control or eradication campaigns. In the presence of competition, from external EU manufacturers and under complete free trade, the market behaviour will change and we are likely to see a picture more akin to Figure 6.

However, it is unlikely that total free trade will exist because of at least the following factors:

1. Regulation 2039/93, which is not available to new entrants with non-innovative products. In essence this rules deliver monopoly power to existing market players, unless they break this by using the decentralised procedure. This will enable the

eventual entry to market, but it will be achieved much slower and there are no guarantees access will be achieved for all member states.

2. Sovereign nations have the right to determine which products are allowed on to their markets. There are valid reasons for a highly regulated process to exist and to bar immunologicals on the basis of safety, one of the paramount options available under the WTO/GATT. Where foreign products are made using different substances to domestic products, acceptance and therefore market access may become more difficult. Science has often been used as a thin veil to disguise protectionist barriers.
3. Domestic producers provide economic activity, so authorities are likely to artificially administer barriers to impede or slow foreign product access to local markets. Questions of local labour employment fall under this umbrella. Sustainability of local industry may enable an expansion offshore, so the domestic industry may end up being an income producer.
4. High technology industries attract capital at high rates, making them attractive to governments as a source of economic activity and employment.

Demand under an open market is likely to increase as a result of a reduction in consumer prices. This would see livestock owners purchasing more product, as the cost benefit ratio would become more favourable towards immunologicals. The only way to introduce competition into the market and gain results close to Figure 6, would be to completely open up the market to free trade. This has not yet been instigated.

In conclusion what we are likely to find, in reality, is some gains by a partial opening of the market to foreign manufacturers, but not a complete opening of the market. We can argue that even a partial opening of the market produces some consumer benefits, therefore we might be better off. However, this is a qualified opening of the markets and one of the important aspects is the way in which the market

is opened. As a case in point we can cite Council Regulation 2309/93, where it allows centralised registration procedure only for innvovative products. The foreign manufacturer is not "locked out" of the market completely, but rather is allowed access on a "piece meal" approach and is discouraged from entry. If the EU is a free market, what then are the reasons for having such a (restrictive) system in place?

5.2.3 Rationalising the Existence of the Rules

The EU, much the same as other nations, has a preference to be well off economically. In this industry sector, some of the EU's philosophies may well stem from the need to ensure that manufacturing remains viable. This is a high technology industry attracting much investment and capable of exporting its product abroad to earn high value-added foreign reserves. This industry sector is an economic activity generator, with downstream effects in other industries, such as engineering, electronic, transport, animal husbandry management as well as other industrial manufacturing (e.g. packaging and labelling). All of these activities add value to the processes involved and create employment. Employment generation is a major policy consideration motivating the policy-making initiatives and decision-making processes of all governments.

It is likely that all of these factors, as well as others, such as self-serving lobbying from domestic firms, have influenced the method by which the administration of the bureaucracy is conducted. There appears to be some evidence to suggest that the EU is pursuing a "multifunctionalism" policy, which provides a social balance between the urban and the agricultural sectors. There seems to be a desire on the part of the EU to ensure the agricultural sector and its support industries remain viable. In this context, it is likely the EU will view domestic producers in a more favourable light than external producers and act accordingly.

5.3 An Analysis of Trade Flows Between Australia and the EU

The objective of this section is to assess whether the structural changes affecting the EU market as a result of the implementation of Council Regulation 2309/93, have had a discernable impact upon import and export trade flows between Australia and the EU. This objective is carried out using a basic trade flow analysis to identify whether a distortionary effect of the Regulation can be detected. In conducting this analysis, an explanation of the data collection and its limitations must occur before examining and extracting conclusions from it.

Veterinary Biological Vaccines are classified for trade statistical purposes using the Harmonised Commodity Classification System (HS). The HS is administered by the World Customs Organisation (Australian Bureau of Statistics, 1999, p.E-01). The eight digit classification used for this data is HS code 3002.30.00. Its description is Vaccines for veterinary medicines and is found in Chapter 30 of the HS code under heading 3002:

> Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera and other blood fractions, and modified immunological products, whether or not obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products. (Australian Bureau of Statistics, 1999, p.3003); (Australian Customs Service, 1996, p.303).

The classification of the product therefore covers much more than just veterinary biological vaccines, but nevertheless the data incorporates the products in question. The data is collected from Customs entries generated by traders when clearing consignments through the Australian Customs Service. This data is collected by the Australian Customs Service (ACS) and shared with the Australian Bureau of Statistics who, then, authorise the data to be available to the public.

The data is not completely audited as the ACS relies, under current legislation, on self declaration of cargo details. Some concern about the validity of this data has

been expressed by the ACS since 1998, especially in relation to the export declarations under the EXIT system[2]. The data to be analysed here was obtained through the Centre for Economic and Strategic Studies (CSES) at Victoria University[3]. The data covers the period from 1 January 1996 to 30 September 2000. Table 5.1 and Figure 7 provide a summary of the data by individual EU member state for both Australian exports and imports. Table 5.2 examines exports by state of origin within Australia. Finally Figure 8 examines aggregate import and export flows between Australia and the EU.

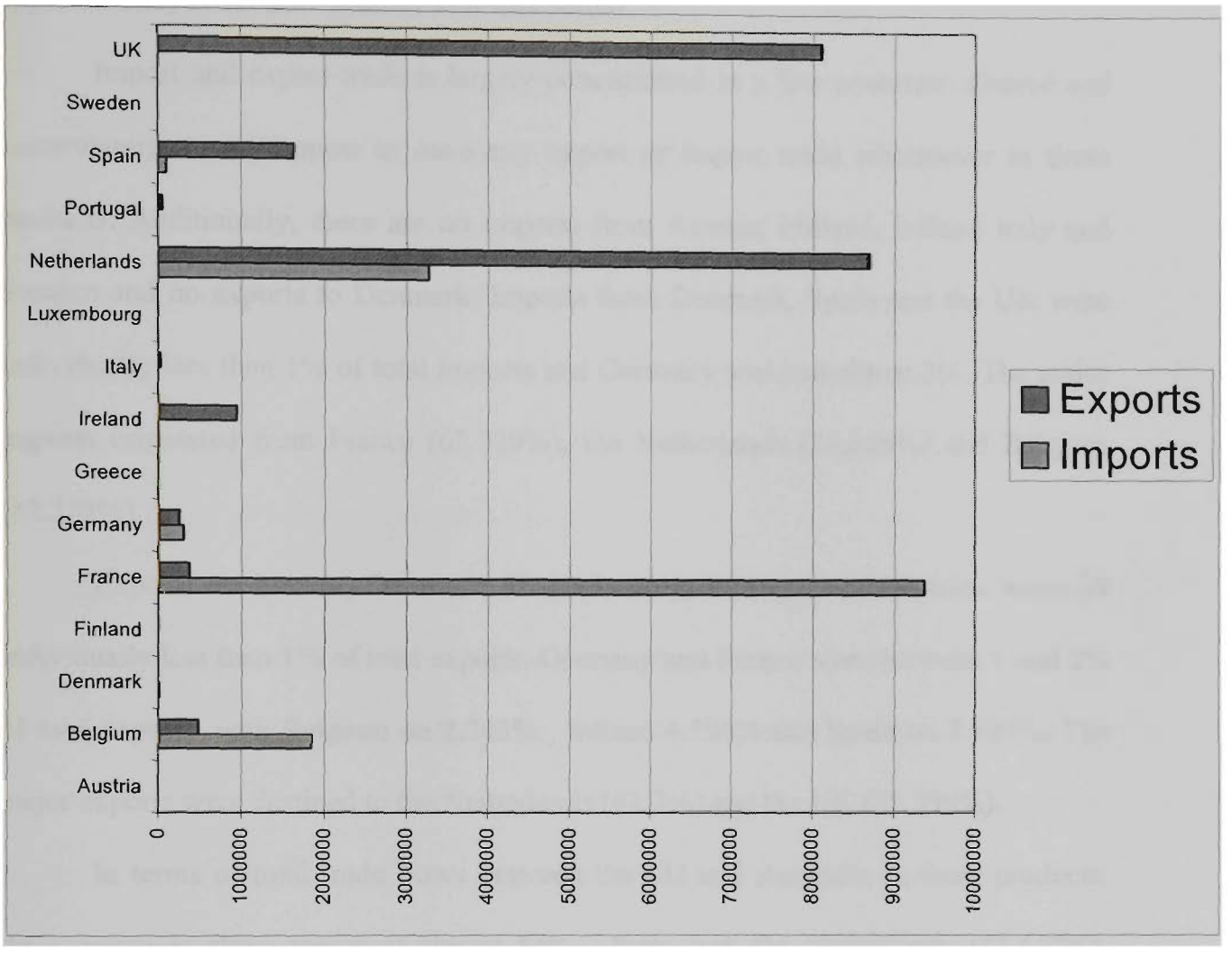
Table 5. 1 : Australian Imports and Exports Summary (1996-2000) in AUD

	Import	Export
Austria	0	2564
Belgium	1849695	483256
Denmark	17478	0
Finland	0	8230
France	9381669	376781
Germany	307742	257154
Greece	0	0
Ireland	0	947697
Italy	0	35531
Luxembourg	0	0
Netherlands	3270873	8704841
Portugal	0	59502
Spain	109213	1635156
Sweden	0	2274
UK	7192	8114718
Totals	14943862	20627704

[2] The EXIT system is an electronic lodgement of export cargo declarations and relies on the exporter (or agent) self declaration. EXIT is an acronym for Export Integration.

[3] Mr. Bruce Estler, CSES provided the data. This data is extracted from the ABS/ACS through a proprietary computer program called TRADEDATA.

Figure 7 : Summary of Imports and Exports Trade Flows (1996-2000) between Australia and the EU (AUD)



5.3.1 Trade Flows by Country

From Table 5.1, we can derive the following observations. The total value of trade between Australia and the EU is reported at approximately AUD$ 35.6 million. Exports represent approximately 58% of two-way trade in this sector with imports, therefore, accounting for the balance of approximately 42%. In aggregate terms, Australia appears to export, in aggregate, more than it imports. However, an examination of the trend indicates that major changes have been occurring affecting the behaviour of industry participants- particularly since the implementation of Council Regulation 2309/93. At a more superficial level, the figures for the period analysed suggest that Australian exports were approximately AUD $20.6 million versus imports

of AUD $14.9 million dollars. Australia experienced a positive balance of trade of approximately AUD $5.7 million over this period.

Import and export trade is largely concentrated in a few countries. Greece and Luxembourg do not appear to have any export or import trade whatsoever in these products. Additionally, there are no imports from Austria, Finland, Ireland Italy and Sweden and no exports to Denmark. Imports from Denmark, Spain and the UK were individually less than 1% of total imports and Germany was just above 2%. The major imports originated from France (62.779%), the Netherlands (21.888%) and Belgium (12.378%).

Exports to Austria, Denmark, Finland, Italy, Portugal and Sweden were all individually less than 1% of total exports. Germany and France were between 1 and 2% of total exports, with Belgium on 2.343% , Ireland 4.594% and Spain on 7.927%. The major exports were destined to the Netherlands (42.2%) and the UK (39.339%).

In terms of total trade flows between the EU and Australia in these products, three countries alone represent almost 84% - these are: the Netherlands (33.667%), France (27.433%) and the UK (22.883). Of this group only the Netherlands could claim the more balanced position with respect to reciprocal trade. Although Australia exports twice as much as it imports to the Netherlands, the situation with France is entirely different. Australia is a net importer in this situation (imports of AUD 9.6 M and exports of only AUD 0.3 M). The opposite comments may be made in respect to the UK, where Australia enjoys a positive trade balance position (imports of AUD 0.007 M and exports of AUD 8.1 M).

An important observation from this data is that it highlights a 'tale of two markets' within a bigger conceptual market. In particular, although the EU is viewed as a unified market in global terms, the reality is that considerable internal market

differences continue to exist, particularly in comparing those of the UK and France. As the figures suggest, Australia has a negative trade position with France, in it that imports almost 25 times as much as it exports. France has a reputation for being difficult with bureaucracy and administration and at times the application of "strange" rules, e.g. the Poiteirs case. Industry sources in the past have voiced complaints about the difficulty of doing business in France and cultural differences and attitudes have been among the reasons. This has had the effect (perhaps desired at the French end at a least) of shifting business away from this market and targeting alternative markets which may be considered as being more easily penetrated.

The UK presents itself as a good penetrable market, comparatively speaking. Australia enjoys a positive trade balance with exports at 1128 times higher than imports. Although this figure may seem high, the available data provides us with a paltry import of AUD $7,192 and exports of AUD $8.1 million. Among the issues related to market access is the notion that the UK is a more "comfortable" market for Australians. In support of this there are claims made as a result of history and all this brings with it. Traditionally the UK has always been seen as the "motherland" and ties have always been strong between the two countries. Among the factors of influence are historical family roots, sharing of a language, traditions and customs. This makes the UK mentality and philosophy easier to understand and this translates into an easier business environment. The commonality of language makes it perhaps easier to contest bureaucratic decision-making and challenge administrative procedures.

In trying to explain the relative absence of imports from the UK, one of the major contributors would be the BSE problem[4]. This has seen bans imposed by a number of countries on the importation of beef and beef derived products. Where

pharmaceuticals are manufactured with beef derivatives, these would not be an allowable import. Another factor that may be useful to know is that there is little veterinary pharmaceutical manufacturing conducted in the UK, as most of this is done on continental Europe. Essentially the UK relies on imports of veterinary pharmaceuticals to satisfy domestic demand. Indeed there was not one UK company in the world's top 20 manufacturers in 1992 (Harnden, 1993), although the UK market at the end of 1994 in veterinary biologicals accounted for USD 93 M, or 4.6% of the world's total market (Anne, 1996). This compared with Australia having two significant manufacturers in a market worth USD $11 million, accounting for 0.5% of the world's share.

5.3.2 Trade Flows (Export) by State

Table 5.2 provides shows total exports by state of origin. This data is also from TRADEDATA. The state of origin of the goods is a mandatory information field and is provided by the exporter to the ACS as part of the export clearance process. From the data provided, we can substantiate the geographical concentration of this industry in Australia and we can also derive some observations, which may be useful in explaining or substantiating the market structure.

[4] BSE is the Bovine Spongiform Encepalopathy, or "mad cow disease" which has all of the world concerned, as it may be responsible for a degenerating brain disease variant in humans CJD (Cruezfelt Jacob Disease).

Table 5. 2 : Australian Imports and exports Summary (1196-2000) in AUD

Destination	State					% of
	VIC	NSW	QLD	REX	Totals	Total Exports
Austria	1205	1359	0	0	2564	
% of tot E	0.01%	0.01%	0	0		0.01%
% Origin E	47%	53%	0	0		
Bel-Lux	9479	473777	0	0	483256	
% of tot E	0.05%	2.29%	0	0		2.34%
% Origin E	2%	98%	0	0		
Denmark	0	0	0	0	0	
% of tot E	0	0	0	0	0	0.00%
% Origin E	0	0	0	0		
Finland	8230	0	0	0	8230	
% of tot E	0.04%	0	0	0		0.04%
% Origin E	100%	0	0	0		
France	746	377285	0	0	378031	
% of tot E	0.00%	1.8%	0	0		1.83%
% Origin E	0%	100%	0	0		
Germany	257154	0	0	0	257154	
% of tot E	1.25%	0	0	0		1.25%
% Origin E	100%	0	0	0		
Greece	0	0	0	0	0	
% of tot E	0	0	0	0	0	0.00%
% Origin E	0	0	0	0		
Ireland	46360	901337	0	0	947697	
% of tot E	0.22%	4.37%	0	0		4.59%
% Origin E	5%	95%	0	0		
Italy	35531	0	0	0	35531	
% of tot E	0.17%	0	0	0		0.17%
% Origin E	100%	0	0	0		
Netherlands	84569	8472588	0	147684	8704841	
% of tot E	0.41%	41.06%	0	0.72%		42.19%
% Origin E	1%	97%	0	1.70%		
Norway	3485	0	0	0	3485	
% of tot E	0.02%	0	0	0		0.02%
% Origin E	100%	0	0	0		
Portugal	0	59502	0	0	59502	
% of tot E	0	0.24%	0	0		0.24%
% Origin E	0	100%	0	0		
Spain	575971	1059185	0	0	1635156	
% of tot E	2.79%	5.13%	0	0		7.93%
% Origin E	35%	65%	0	0		
Sweden	2274	0	0	0	2274	
% of tot E	0.01%	0	0	0		0.01%
% Origin E	100%	0	0	0		
UK	200482	7911721	2495	0	8114698	
% of tot E	0.97%	38.35%	0.01%	0		39.33%
% Origin E	2%	97%	0.03%	0		
						100.0%
Total AUD	1225492	19256761	2495	147684	20632432	
Total % Exports	5.94%	93.33%	0.01%	0.72%		100.00%

REX = Re-exports

% of tot E = Percentage of Total Exports

% of Origin E = Percentage Origin Export

% of Origin Export = the % of state of origin export proportion to named EU country

% of Total Export = country's relative importance in overall exports

Almost all of our exports to the EU originate from Victoria and New South Wales (NSW). The only other state reporting any activity is Queensland with a sale to the UK of AUD $2,495. No other state or territory has reported any export sales. There was one instance of a re-export to the Netherlands and this was for AUD $147,684 and is being considered an extraneous item for the purposes of this analysis. It represents product imported for another ultimate destination, or more likely indicates product imported and subsequently returned to the exporter. Given that this instance relates to trade with the Netherlands, where Australia enjoys reciprocal international trade activities, it seems a plausible situation.

Of the two states, the most predominant exporter is NSW. In aggregate terms this state accounts for just over 93% of all exports to the EU, with Victoria recording just under 6%. Our two major export destinations, as mentioned before are the Netherlands (about 42% of total exports) and the UK (about 39% of total exports). For these two countries, we can observe that the majority of supply comes from NSW, where 97% of exports originate. This pattern indicates that perhaps a more export focused strategy on EU exports and perhaps a greater success rate in penetrating that market. However, given what we know about the market structure domestically, we may cast doubt on the veneer the figures indicate.

The Australian veterinary biological industry has an oligopolistic structure, with two main firms dominating the market: CSL Ltd (formerly the Commonwealth Serum Laboratories) in Melbourne and Fort Dodge Australia (FD) (formerly Cyanamid Webster, formerly Arthur Webster) in Sydney. CSL is still Australian owned, whereas FD is US owned and belongs to American Home Products (AHP) who have interests in this industry by virtue of their subsidiary Fort Dodge Animal Health (formerly Fort Dodge Laboratories) (FDL). FDL have manufacturing facilities in the Netherlands,

Ireland and Spain and it may be easy to see how a specific export strategy (by head office in the US) may impact on the FD's Australian operations.

In the classical multinational structure, FD would be manufacturing and exporting as part of a global master plan. The fact that FDL have other subsidiaries in the EU would certainly help to provide demand for products where a comparative advantage exists for FDL. FDL will wish to see all of its operations operating at profit, to maximise its returns. Where FD can provide some comparative advantage, be it by way of price, or product purity or plant capacity availability, it will undoubtedly be in FDL's interest to keep the plant operating at most efficient level. The synergies between FD and FDL would allow for product to be exported at different stages in the process, e.g. as finished product, as intermediate product for further manufacturing purposes or as raw components for processing abroad.

CSL on the other hand does not as yet have a manufacturing presence in the EU, although it recently acquired a business in the US, as part of its international expansion. CSL's export efforts are likely to be achieved against a tougher background, as it cannot rely on a head office - subsidiary role to generate demand from within its own structure. Apart from the two dominant exporters already mentioned, there is another smaller enterprise operating in Bendigo (Victoria): Ausvac. This is a fledgling concern and according to industry sources concentrates almost exclusively on satisfying local market demands. Apparently Ausvac has been successful in foreign relationship with some multinationals with a view to becoming an additional alternate source of manufacturing capacity should this be required. Ausvac has also apparently touted itself as a contract manufacturer.

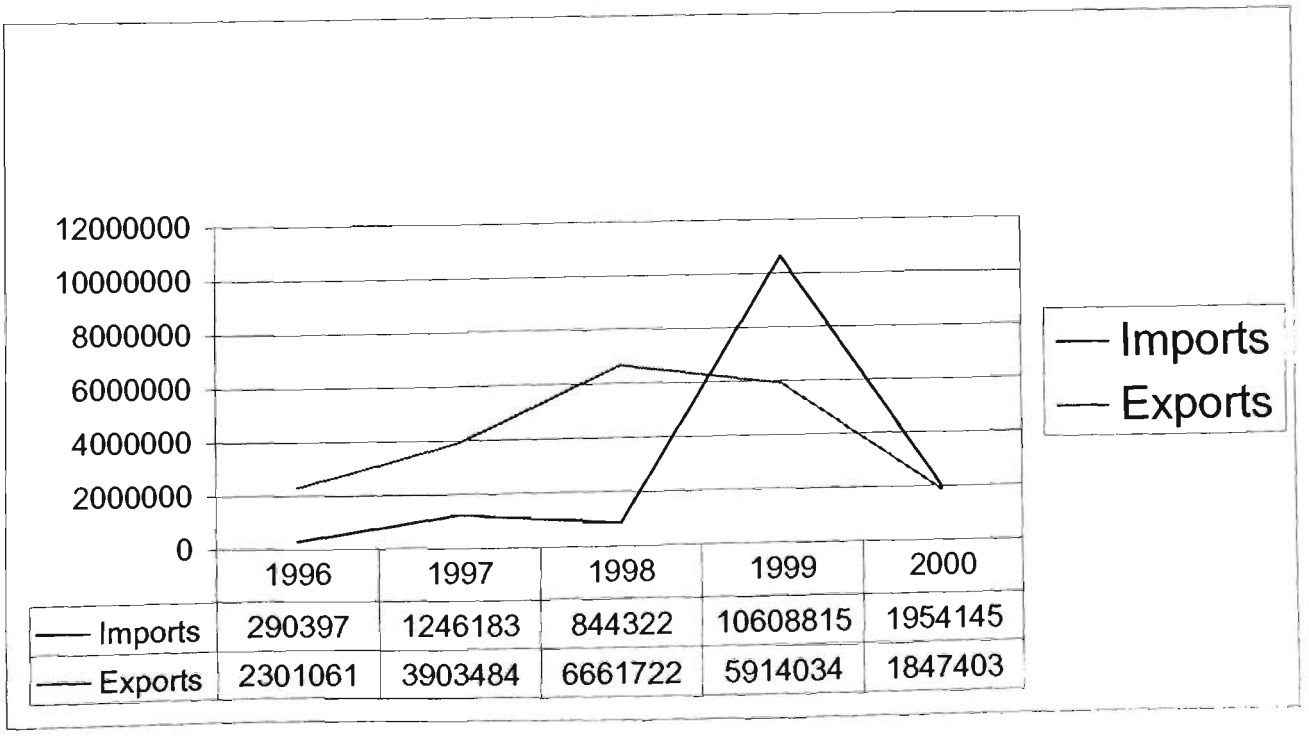
Some multinationals are operating in Australia under contract manufacture agreements and industry sources have revealed that products from Smith Kline

Beecham (SKB) are only branded and labelled as such, but are actually manufactured by local concerns. SKB apparently has derived some its products from CSL and FD in the past. Their Australian market share is claimed to be small. It may well be that the relatively small Australian market size, the existence of two large scale manufacturers, the distance from affluent markets, the Australian quarantine requirements and the sheer magnitude of investment required to set a biological manufacturing plant to "world" standards provide too high a barrier to entry. Given these circumstances, the local manufacturers are, theoretically, well poised to exploit markets abroad, provided these are able to be accessed and penetrated and not kept artificially closed through non tariff barriers.

5.3.3 Aggregate Trade Flow Analysis

As mentioned above, theoretically, local manufacturers are in a good position to be able to exploit markets abroad. However, an analysis of aggregate trade flows, provided in Figure 8, shows a very different story. Instead, Figure 8 shows a massive change and alteration in export flows is underway.

Figure 8 : Australia Aggregate Import / Export Flows (AUD)



	1996	1997	1998	1999	2000
Imports	290397	1246183	844322	10608815	1954145
Exports	2301061	3903484	6661722	5914034	1847403

In particular, evidence of the changes can be observed through the data presented in this chapter and in particular by reference to Figure 8. The following comments assist in explaining and understanding the trends shown.

As discussed earlier, until the early 1990's the Australian veterinary biological manufacturing industry was dominated by two companies, one in Victoria and the other in NSW. However, during the mid-1990's significant changes took place in this industry, through changes in ownership in both companies. The Victorian company was the subject of a stock market float as the Australian Government sought to divest its interests in this industry. The old Commonwealth Serum Laboratories (a quasi-autonomous government enterprise) ceased to exist in 1991 when this organisation was incorporated as CSL Limited. CSL Limited continued to operate under Government ownership until a stock exchange float in Australia in May 1994, which resulted in the privatisation of this company. The Australian Federal Government from that point relinquished effective control and the firm became a private enterprise.

The NSW company, Arthur Webster Pty Ltd, was purchased by a foreign buyer, American Cyanamid and renamed Cyanamid Webster Pty Ltd. Subsequent to this, American Cyanamid was purchased by American Home Products (AHP) a few months later. AHP has active interests in veterinary biological manufacturing and owns (through its umbrella structure) manufacturing facilities in the USA and the EU operating as Fort Dodge Animal Health (FDL). FD's presence in Australia now exists under the name of Fort Dodge Australia. The strategic control that AHP through FD exerts over the NSW manufacturing site and its outputs, especially in relation to the foreign owner's global strategy, is considerable. FDL has manufacturing sites in the Netherlands, Ireland and Spain.

As discussed previously, the majority of exports from Australia during the period 1996-2000, as reflected in Table 5.2, indicate that NSW, therefore FD, was by far the major exporter. FD accounted for nearly 94% of all export trade. The most significant exports were, in order of magnitude, to the Netherlands ($ 8472588), the UK ($ 7911721), Spain, ($ 1059185) and Ireland ($ 901337). The UK had been a market which was developed and held by Arthur Webster and therefore the ultimate acquisition of this business by AHP gave it ownership of exports to that country. This is significant in the Australian export context as it represents the second export revenue country within the EU. The other three countries, namely the Netherlands, Spain and Ireland all feature FDL manufacturing sites. This must be more than mere coincidence. The presence and the influence of the multinational enterprise can be clearly seen in this situation. The opportunities for the multinational to influence trade flows when it holds considerable market power and controls sources of into a global network are high.

The effect of foreign ownership appears to have contributed to a trade diversionary effect from the supply of finished product to offshore markets to the supply of bulk products to specific markets. We can refer to this as "intra-product" trade diversion. The effect of the shift to exporting bulk from finished product has a significant effect on the value of exports. Finished products are more expensive than semi-finished bulk products and therefore command a higher price in the market. This price-effect is reflected in the lower value of exports. As bulk products are sold at an intermediate manufacturing stage, that is they are still "in-process" products, the price commanded in the market is much lower.

There are a number of factors to consider in the decision to sell semi-processed versus finished products. Finished products have been a lot more value added when

compared to the bulk item. For example, we can consider the typical finished product that comprised of:

- The products itself, which has undergone dispensing in its final container. This has been undertaken under sterile condition and it is both time-consuming and costly.
- The product needs to be labelled and packaged, again with more cost added to it. The prospect of packaging product for sale offshore, where the labeling requirements may differ significantly brings with it its own logistical concerns. Labeled stock cannot be easily diverted between different markets where their requirements differ.
- Storage and transport of finished product becomes more expensive, as obviously the finished product occupies more physical space, when compared to the bulk product.
- Finished product will need to be tested more than the bulk product. The bulk product is tested before dispensing commences, to validate the quality. After dispensing, the finished product undergoes several more tests, again to validate it suitability.

Bulk products offer their own advantages to the manufacturer.

- It is cheaper to store and transport bulk products comparative to finished products.
- The lead-time for availability of bulk material has to necessarily be earlier than finished products, because bulk products are only intermediately processed.
- Bulk products provide flexibility where they are going to be combined with other products exotic to the bulk product country of export. For example, the

Australian supplier can make available bulk product for combination into a multi component vaccine. The other components are not manufactured locally, because there is no need for such a vaccine, or because the authorities will not allow the import of an exotic virus or bacterium. In this sense the multinational overcomes legitimate quarantine barriers.

- Bulk products can be diverted to any alternate manufacturing site consistent with the global strategy adopted by head office. This strategy has a number of considerations, including the capability of each of the manufacturing sites the global firm owns and controls, the market demand for each type of product in each market the global firm operates in and the price (relative to the attractiveness or otherwise of any profit realisation) it can command.

- Local manufacturing plant specialisation can also contribute to a production efficiency maximisation. The global firm will try to locate and utilise the local firm where it can demonstrate that it is exceptionally good at manufacturing a product and it can do so much more effectively and efficiently than any other alternative available to the global firm. Where the global firm is able to build a network of synergistic manufacturers it will obviously be able to operate at highest efficiency and therefore profit maximisation.

From the above considerations, it can therefore be observed that there are a number of factors which make the proposition to source bulk, rather than finished products in the context of a global operation which has a number of alternate manufacturing sites to choose from, much more attractive. One of the major considerations will remain the comparative advantage that each manufacturing location has over others within the global network operated by the multinational. The best result for the firm operating with a global network would be ownership of each site with a

comparative advantage which does not compete with the other sites. Therefore this would be a specialisation of activities based on an individual site's comparative advantage.

5.4 Conclusion

The trade flow figures provided in this Chapter indicate that a substantial change in trade patterns in veterinary pharmaceuticals between Australia and the EU has occurred in recent years. Two major factors influencing this change can be identified.

- Acquisition of Australian manufacturers by large multinational firms;
- The introduction of the EU regulations hindering market access of finished products from Australia.

In light of the difficulties Australian exporters have encountered in registering new products for sale in EU markets, and considering the interrelationship and combined effects of both transfer pricing and the decision on which products to supply out of Australia to foreign markets, which are largely influenced by the global firm, we can formulate a hypothesis.

The hypothesis is that foreign ownership of the Australian firm has resulted in, both, a change in export composition as well as a consequential change in the prices of the exported products. In other words, the change in export composition, being a shift from exporting finished to now selling bulk products has influenced a lower selling price. A second factor explaining a reduction in price may be linked to control of the local firm by the global firm pricing the local product in a manner consistent with the global firm's strategy or transfer pricing. These factors help to explain the shifts in trade over this particular time. The absence of any other significant factors during the time series analysed further supports the suppostions made here.

6. Conclusion

6.1 Overview

In this era of globalisation, international trade is being conducted in an increasingly open global economy. However, in spite of globalisation, remnants of protectionist trade policies continue to exist. These protectionist trade policies are maintained to provide trade barriers as an artificial competitive advantage to producers of certain classes of goods. Among the most ubiquitous forms of trade barriers is the non-tariff barrier (NTB). Of the various forms of NTB, technical barriers to trade (TBT) are among the most difficult forms of trade barrier to identify and quantify.

Technical barriers are unique in that their protectionist characteristics are closely intertwined with legitimate qualitative standards. As a result, technical barriers are more difficult to identify, analyse, as well as demonstrate, their trade distortionary characteristics. As a result, Governments that wish to implement protectionist trade policies will seek to 'hide' protectionism within complex regulatory schemes. Whilst the Uruguay Round of negotiations produced major reductions in tariff barriers, the results of negotiations directed towards addressing the complex issue of NTB's were mixed. Perhaps a reason governments were so willing to reduce tariffs was because they knew these could be replaced by NTBs (Lindert, 1996, p.136).

6.2 The Research Question

The objective of this thesis is to analyse the impact that a regulatory scheme that has characteristics of, and appears to function as a TBT, has on the flow of veterinary biological vaccines from Australia to the European Union. The identification of the TBT is not a straight-forward process. On one hand, the principle exists whereby it is every country's sovereign privilege to place legitimate control upon goods crossing its national boundaries. This privilege has always been held as sacrosanct in trade

negotiations and related agreements, including the various WTO Agreements. Under the circumstances examined in this thesis, what is being questioned is whether this privilege is being applied in the spirit of the agreements, ie. for a legitimate purpose; or whether it is being used as a thinly disguised veil of protectionism strategically aimed at sheltering domestic EU manufacturers from foreign competition. In brief, the legitimate application of a TBT to prevent harm and injury to a country's citizens, animal and plant life and the environment is justifiable. The application of TBT as a protectionist measure alone is to be condemned.

Under a combination of WTO Agreements, a framework exists that articulates the principles within which the scope of health and safety standards enacted by national governments will be deemed to be legitimate and justifiable. These agreements are intended to provide a single set of rules for all WTO members. In this regard, this thesis examines whether the EU regulatory regime put in place to control the certification/approval of veterinary vaccines for sale within the EU has been justifiably applied, or whether there are additional or different applications, which are retarding market access and penetration.

In particular, the central question addressed within this thesis is whether EU regulatory scheme falls within, or outside, the scope of the principles contained in the WTO TBT and SPS Agreements. If outside, a secondary question is whether the EU scheme has had an identifiable impact on trade flows or the effect of retarding market access discriminating against foreign competitors. In order to be able to substantiate an assertion of trade discrimination, a greater understanding of the relevant WTO Agreements is required.

Article XX of GATT 1994 sets the foundation for the creation and maintenance of national safety standards. Part (b) of Article XX provides the basic mechanism that,

on one hand, permits a government to set its own standards to safeguard its citizens, yet, on the other hand requires that the safeguards be justifiable. However, because justifiability is not precisely defined anywhere as a clear-cut set of rules and regulations, it is subject to interpretation. The freedom allowed to a country to set its own standards has allowed co-operation between member states to develop a system of mutual recognition of differing standards. Mutual recognition, however, is not harmonisation.

Mutual recognition is a form of bureaucratic expediency. Rather than develop harmonised standards, the mutual recognition principle enables governments with different regulatory regimes to recognise each other's standards for the sake of facilitating trade flows. However mutual recognition does not provide open market access. In the case of Australia and the EU with respect to mutual recognition, the GMP differences still render the Australian manufacturer subject to EU authorities plant inspection and approval before a MA will be granted. Mutual recognition allows acceptance of an Australian issued manufacturing licence, but does not allow the automatic sale of product into the EU.

6.3 The International Framework

In Chapter 2, an analysis of the SPS was conducted to determine whether the SPS Agreement provides a clear framework to detect market retardation through the application of a covert NTB. The purpose of Chapter 2 was to describe and analyse the level of international standardisation provided by the relevant WTO agreements and what these levels entailed by way of obligations and rights of individual member nations. These rights and obligations form the international framework underpinning the operations of the WTO agreements among its member nations. The most important issues arising from the SPS and TBT agreements are summarised below.

6.3.1 Scientific based principles, according to the SPS - but whose science?

Articles 3.3, 3.4 and 5.7 of the SPS Agreement require that sanitary or phytosanitary measures are applied in a manner that reflects international standards, such as the Codex Alimentarius, for food products. The SPS also leaves it open for a country to impose measures that are different or higher than the international standards. There is a requirement for scientifically based evidence for the imposition of such measures. The problem that arises is determining whose scientific evidence is to be relied upon? For example, the Beef Hormone dispute has had a profoundly negative effect upon EU/US trade relations over the past twenty years and is not yet completely resolved. In this case, a difference in scientific opinion is at the core of the dispute. As the SPS Agreement does not provide any determination of what constitutes the "right " science, the matter has had to be decided by a WTO dispute settlement process.

Article 5.7 of the SPS extends the sovereign right of health and safety protection permitting it to impose restrictive measures under 'emergency' circumstances and in the absence of conclusive scientific evidence. It is enough for the importing country to be 'suspicious' to justify provisional introduction of sanitary or phytosanitary measures, while scientific evidence is sought within a reasonable time.

In terms of the 'volume' of science required, all a government needs to provide is a lone scientist who is qualified to provide a dissenting view opposing the main body of scientific evidence in order for this to be justification for the imposition of restrictions, as the soundness of the science is not in question (Ambrose, 2000, p.864). The important issue to remember though, in the application of the SPS, is that the importing country must be able to withstand a challenge to the imposition of restrictions, by other exporting members. Of course there must be a challenge for the

measures to be questioned. The SPS principles and their applications have been tested over the years and where justifiable action was taken, the measures stood in place. Examples of these are the French ban on Canadian asbestos and the Australian ban on the antibiotic Avoparcin.

6.3.2 TBT versus domestic standards, transparency and fairness

Whilst the SPS Agreement has received a lot of attention and scrutiny, the TBT Agreement has not. This does not make the TBT any less important, it is just that it has not been relied on as much as the SPS. The broad objective of the TBT is to ensure that regulations, standards and testing do not create unnecessary obstacles to trade. As such, the TBT is important to the research question investigated in this thesis.

The TBT encourages the use of international standards, but does not obligate countries to do so. However, the TBT does prohibit the use of standards designed to benefit domestic consumers from external competition. Article 2.1 of the TBT encourages government behaviour that is fair, equitable and transparent. It requires that regulatory schemes be applied equally to domestic and imported products. Article 2.2 further goes on to say that technical regulations shall not be prepared adopted or applied with a view to, or have the effect of, creating unnecessary obstacles to international trade. The breadth and generality of this article is its weakness. It is seen as a "second best" safeguard against unjustified trade related measures. As a consequence, the TBT has only been used once to challenge measures under the WTO and that was in the US Beef Hormone case.

In brief, the TBT therefore provides a general framework that has not been extensively relied upon for challenging trade related measures. Nevertheless coupled with the SPS, this agreement does provide a base from which the EU regulations can be examined.

6.4 The EU regulations and their applications

Chapters 3 and 4 analysed the historical and current regulations applicable to veterinary biological vaccines and how these regulations are bureaucratically administered within the EU. The Treaty of Rome is the constitutional cornerstone of the EU. The treaty deals, *inter alia*, with safeguards, individual member states rights and the conformity of national laws as well as issues surrounding the gradual harmonisation of intra-EU country laws. The purpose of Chapters 3 and 4 is to examine whether the EU regulations result in a violation of the principles contained within the WTO Agreements insofar as market access to the EU for Australian veterinary biological vaccines is concerned.

Before market access will be granted under EU regulations, veterinary vaccine products must be granted a marketing authorisation which is dependant upon an approval and registration process. In general terms, this is a normal requirement of all countries worldwide. However, it is the detail of the EU requirements that present unusual difficulties for foreign registrants. There are three pathways to registration and therefore market access:

- National Registration. Only available for single EU member state registration since 1998, pursuant to Council Directives 81/81/EEC and 81/852/EEC. This effectively stops the opportunity of targeting each successive individual market with the same product. It is therefore only available limitedly. The closing off of this option has contributed to a retardation of EU-wide market penetration for foreign products.
- Decentralised Registration. Available since 1998 for registration of products in more than one EU member state against individual application, pursuant to Council Directives 81/85/EEC and 93/40/EEC. This system provides for mutual recognition with the first member state application resulting in that country being, the reference

member state for future application processing. Nowadays this is the most commonly used method because of the limitations imposed by decentralised method described above and the centralised method to be examined next.

- Centralised Registration. This is only available for innovative products or certain biological products and novel growth promoters, pursuant to Council Directive 2309/93. This system is limited to the products covered by this regulation and additionally certain products can only be registered using this pathway. This option is therefore quite restrictive and attracts a very high application fee.

Within the framework, a plethora of Committees oversee the process of product registration- each having differing time frames and procedural requirements. For example, the time frames set for the decentralised and centralised procedure are 300 and 210 working days respectively. However, in the case of the national procedure, which is internally controlled by the individual member state, no time set frames exist. Reference to working days is to be understood in context, that is working days where the registration information is being assessed. Therefore the time taken to seek and receive additional information or clarification of data are excluded from the maximum time frames. It would not be difficult to hypothesise that an inefficient or malicious bureaucratic process may provide a very effective market retardation tool, preventing market penetration, or at the very least delay it.

6.5 Trade flow effects of the EU regulations

The objective of Chapter 5 was to analyse the two-way trade flows between Australia and the EU for veterinary vaccines in order to determine whether there is any discernible evidence of a trade discriminatory effect that may be attributed to the EU regulations. During the 1990's there was a tremendous shake up in the veterinary vaccines manufacturing sector. This sector was tradionally controlled by two entities,

accounting for virtually 100% of the domestic market. One concern was the old Commonwealth Serum Laboratories turned into a private concern named CSL Limited, in 1994 and not very active at all in the EU. The other concern, Arthur Webster Pty Ltd, with developed markets in the EU (primarily in the UK) and effectively the only competitor to CSL was acquired by American Cyanamid. The new company was named Cyanamid Webster (CW). Within six weeks, American Cyanamid was acquired by American Home Products (AHP). AHP own Fort Dodge Laboratories (FDL), a multinational enterprise with existing manufacturing facilities in the US and the EU. The new company is now under the name of Fort Dodge Australia (FDA). The acquisition of FDA gave instant access to both the Australian and the EU markets to FDL.

FDA was attractive because this plant was approved by the EU and therefore product could be sold without impediments. At the stage of the acquisition, the product sold was finished product. This is the finally-dispensed, labelled and packed product, ready for sale, and therefore commanding the highest possible price in the market. There are a number of factors however that need to be considered in the decision to sell finished product. The transport costs are comparatively higher than those of bulk product. Additionally the time taken for the finished product to reach the market is considerably longer than bulk product. The reasons for the differences are that

- bulk product is shipped in denser type packaging - usually 220 litres (44 gallon) drums, whereas finished product is packed into boxes and there is some loss of density simply due to the different nature of the product, and
- bulk products are released from the manufacturer at an earlier stage of their processing. By their very nature bulk product need further manufacturing and this is done later in the process.

FDL's real attraction to the Australian manufacturing site lay not merely in acquiring an extra plant, but rather in being able to gain control of a manufacturing plant that it could re-organise in accordance with the overall global strategy of the firm. FDL already had plants in the EU and could therefore choose the type and quantity of output from FDA. FDA has basically become a bulk product supplier to FDL owned EU manufacturing concerns in Spain, Ireland and the Netherlands. As a result of the strategic re-organisation choice made by industry, Australia has lost a major opportunity in the export of finished product in this area.

6.6 Final Conclusions

As identified in Chapter 5, the trade flow analysis indicates that a substantial change in trade patterns in veterinary pharmaceuticals between Australia and the EU has occurred in recent years. Two major factors influencing this change were identified.

- Acquisition of Australian manufacturers by large multinational firms;
- The introduction of the EU regulations hindering market access of finished products from Australia.

In light of the difficulties Australian exporters have registering new products for sale in EU markets, and considering the interrelationship and combined effects of both transfer pricing and the decision on which products to supply out of Australia to foreign markets, which are largely influenced by the global firm, we can formulate a hypothesis.

The hypothesis is that foreign ownership of the Australian firm has resulted in, both, a change in export composition as well as a consequential change in the prices of the exported products. In other words, the change in export composition, being a shift from exporting finished to now selling bulk products has influenced a lower selling price. A second factor explaining a reduction in price may be linked to control of the local firm by the global firm pricing the local product in a manner consistent with the

global firm's strategy or transfer pricing. These factors help to explain the shifts in trade over this particular time. The absence of any other significant factors during the time series analysed further supports the suppostions made here.

Given that the global production and pricing strategies of the multinational firms that now dominate and control the global industry for veterinary pharmaceuticals are such that the combined effects are:

- Efficient global distribution of production for the multinationals;
- Transfer pricing related benefits;
- Circumvention of restrictive market access regulations for finished products.

It is clear that the multinational firms have the flexibility and means by which to fashion strategies that function to their financial benefit as well as circumvent any potentially restrictive EU trade barriers.

Given that there are no longer any small Australian firms that are overtly disadvantaged by the EU regulations, it is unlikely that the Australian Government would have sufficient motivation to expend resources and diplomatic capital initiating a dispute against the EU regulations pursuant to the dispute settlement Articles XXXI and XXXII of the WTO Agreements.

7. Bibliography

11 Centralised in 1999, Says EMEA. (1998). *Animal Pharm,*(403), 3.

Agreement on the Application of Sanitary and Phytosanitary Measures (2000). Animal and Plant Health Inspection Service, United States Department of Agriculture. Available: http://www.aphis.usda.gov/ppd/sps/agreement.htm [2000, 21 May].

Ambrose, K. A. (2000). Science and the WTO. *Law and Policy in International Business, 31*(3), 861-868.

Australia Bans Avoparcin in Poultry. (1996). *Animal Pharm,*(360), 1.

Australian Bureau of Statistics. (1999). *Australian Harmonized Export Commodity Classification, Catalogue Number 1233.0.* Canberra: Australian Bureau of Statistics.

Australian Customs Service. (1996). *Combined Australian Customs Tariff Nomenclature and Statistical Classification.* Canberra: Commonwealth of Australia.

AVBC Defends Autogenous Vaccines. (1997). *Animal Pharm,*(381), 11.

Baron, M. (1983). Protectionism: Nobody's Perfect. *Europe, 236,* 10-12.

Bean, C., (Ed.). (1997). *MAVIS* (22 ed.). Addlestone: Veterinary Medicines Directorate.

Benchley, F. (2000, 18 July). Banana Split. *The Bulletin, 118,* 46-47.

Bennett, R. (1997). *European Business.* London: Pitman Publishing.

Biederman, D. (1998). Trade barriers: Everywhere. *Journal of Commerce Inc., 255*(10), 33-34.

Biosecurity Australia Formed to Undertake Import Risk Analyses (2000, October). *AQIS Bulletin, 13,* 3.

Cameron, J. (1993). *The Uruguay Round's Technical Barriers to Trade Agreement.* Gland, Switzerland: World Wide Fund for Nature.

Concern Over Mutual Recognition. (1997). *Animal Pharm,*(369), 2.

Cooke, J. (2000, 18 November). The life and crimes of CJD in Australia. *The Age Magazine Good Weekend,* 61.

Correy, S. (2000). GM Crops 2000: The Unmaking of a Genetically Modified PR Campaign, *Background Briefings.* Melbourne: ABC Radio National. [transcript]

Davies, P., (Ed.). (2000). *MAVIS* (33 ed.). Addtlestone: Veterinary Medicines Directorate.

Department of Foreign Affairs and Trade: Commonwealth of Australia. (1995). *Australian Treaty Series 1995 No 8 Marrakesh Agreement Establishing the World Trade Organisation (WTO Agreement)*. Australian Government Publishing Service, Commonwealth of Australia. Available: www.austilii.edu.au/au/other/dfat/treaties/1995/8.html [2000, 26 May].

Doyle, C. (1994). Italy's Vet Services Benefit from a United Approach. *Animal Pharm,*(300), 10-11.

EC Calls for Registration System Data Review. (1998). *Animal Pharm,*(404), 2.

ECJ Rules on Drug Import Case. (1996). *Animal Pharm,*(346), 3.

El Kahal, S. (1998). *Business in Europe.* London: McGraw-Hill Publishing Company.

EMEA Addresses Drug Innovation Question. (1996). *Animal Pharm,*(345), 3.

EU Calls for Clear Labelling on Eggs. (2000). *Trade Compass Daily Brief, 52*(5), 2.

EU Proposes a Ban on BST for Dairy Cows (1999, October/November). *European Union News, 17,* 5.

EU Regn Profiled at Info Day. (1998). *Animal Pharm,*(393), 2-3.

European Union. (1995). *Selected Instruments Taken From the Treaties* (Vol. I). Brussels: Office for Official Publications of the European Communities.

Evans, P. (1994). *Unpacking the GATT.*: International Organisation of Consumer Unions.

Feaver, D., & Mahmood, M. (1997). *International Business and Australia.* Marrickville: Harcourt Brace & Company, Australia.

Foy, G. (1992). Towards Extension of the GATT Standards Code to Production Processes. *Journal of World Trade, 26*(6), 121-131.

Hamilton, P. (1997). Debate Begins on Standards for International Trade. *American Society of Mechanical Engineers, 119*(6), 38-39.

Harris, N. (1999). *European Business* (2 ed.). London: Macmillan Press Ltd.

Italy Decrees 120-day Vet Product Licence. (1992). *Animal Pharm,*(253), 1.

Johnson, R. B. (2000). Biologicals Immunogicals. In R. Bergami (Ed.). Melbourne.

Kerr, W. A. (2000). Is It Time to Re-think the WTO? A Return to the Basics. *The Eastey Centre Journal of International Trade Law and Policy, 1*(2), 99-107.

Kisling, J. W. (1997). Missouri DEC Hosts Seminar on International Standards and Access to Foreign Markets. *Business America, 118*(3), 23-24.

Koopel, N. (2000). WTO Rules French Ban on Absestos is Legal. *Trade Compass Daily Brief, 52*(12), 1-2.

Legislation Difficulties Hamper Growth in Italian Market. (1993). *Animal Pharm,*(271), 6.

Lindert, P. H. a. P., Thomas A. (1996). International Economics (10 ed., pp. 133-152): Irwin Publishing.

Lucken, R. (1998). Vet Biological Registration. In R. Bergami (Ed.). Melbourne, Victoria, Australia.

Lucken, R. (2000). German laws. In R. Bergami (Ed.). Melbourne, Victoria, Australia.

McMullan, B. (1995). *Winning Markets: Austalia's Future in the Global Economy.* Canberra: Department of Foreign Affairs and Trade.

Meat Hormones (2000, 30 June). *EUR-OP News, 10,* 1.

Mikic, M. (1998). *International Trade.* London: McMillan Press Ltd.

Molle, W. (1994). *The Economics of European Intergration: Theory, Practice, Policy* (2 ed.). Aldershot: Dartmouth Publishing Company Limited.

The New European System for the Licensing of Medicinal Products (2000). Veterinary Mutual Recognition Facilitation Group. Available: http://wwww.hevra.org/newsystem.htm [2000, 12 November 2000].

Patterson, E. (1990). International efforts to minimise the adverse trade effects of national sanitary and phytosanitary regulations. *Journal of World Trade, 24*(3), 91-102.

Pearson, A. (2000, 18 November). An Unthinkable Death. *The Age Magazine Good Weekend,* 58-64.

Phelps, B. (2000, June). Gene Tech for Dinner - No Thanks! *Habitat Australia, 28,* 22-23.

Rege, V. (1994). GATT Law and Environment-Related Issues Affecting the Trade of Developing Countries. *Journal of World Trade, 28*(3), 95-169.

Specter, M. (2000, 10 June). The Food that Bit Back. *The Age Magazine Good Weekend,* 16-24.

Stevens, C. (1993). Harmonisation, Trade and the Environment. *International Economic Affairs, 5*(1), 42-49.

Swan, N., Dr. (2000). Origin of AIDS, *The Health Report.* Melbourne: ABC Radio National. [transcipt]

The Commission of the European Communities. (1998). Commission Regulation (EC) No 649/98 of 23 March 1998 Amending the Annex to Council Regulation (EEC) No 2309/93 (Text with EEA relevance). *Official Journal of the European Communities, L 88*, 7.

The Council of the European Communities. (1981a). Council Directive of 28 September 1981 on the Approximation of Laws of the Member States Relating to Veterinary Medicinal Products (81/851/EEC). *Official Journal of the European Communities, L 317*, 1-15.

The Council of the European Communities. (1981b). Council Directive of 28 September 1981on the approximation of laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (81/852/EEC). *Official Journal of the European Communities, L 317*, 16-28.

The Council of the European Communities. (1993a). Council Directive 93/40/EEC of 14 June 1993 amending Directives 81/81/852/EEC on the approximation of laws of the Member States relating to veterinary medicinal products. *Official Journal of the European Communities, L 214*, 32-40.

The Council of the European Communities. (1993b). Council Regulation (EEC) no 2309/93 of 22 July 1993 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Agency for the Evaluation of Medicinal Products. *Official Journal of the European Communities, L 214*, 1-21.

Thorn, C., & Carlson, M. (2000). The Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade. *Law and Policy in International Business, 31*(1), 841-854.

UK VMD Told to be More Efficient, Flexible and Open. (1995). *Animal Pharm,*(336), 5.

Understanding the Codex Alimentarius (1999). Food and Agriculture Organisation of the United Nations/ World Health Organisation. Available: http://www.fao.org/docrep/w9114e/W9114e01.htm#TopOfPage [2000, 14 December].

UPI. (2000a). Britain Worries That Mad Cow Disease May Have Spread to Sheep. *Trade Compass International Trade News,*, 2-3.

UPI. (2000b). WTO Rules on Beef Import Issue. *Trade Compass Daily Brief, 51*(1), 1-2.

Veterinary Medicines Directorate. (1995). *VMD Guidance Note - AMELIA 7.* Available: http://www.open.gov.uk/vmd/Old%20VMD%20web%20pages/amelia7.htm [2000, 21 May 2000].

Veterinary Medicines Directorate. (1996a). *VMD Guidance Note - AMELIA 12 (January 1996)*. Available: http://www.open.gov.uk/vmd/Old%20VMD%20web%20pages/amelia12.htm [2000, 21 May 2000].

Veterinary Medicines Directorate. (1996b). *VMD Guidance Note - AMELIA 5 (July 1996)*. Available: http://www.open.gov.uk/vmd/Old%20VMD%20web%20pages/amel596.htm [200, 21 May 2000].

Veterinary Medicines Directorate. (1997). *The Work of the VMD*. Surrey: Veterinary Medicines Directorate, Ministry of Agriculture, Fisheries and Food.

Veterinary Medicines Directorate. (1999). *VMD Guidance Note - AMELIA 2 (Revised July 1999)*. Available: http://www.open.gov.uk/vmd/Old%20VMD%20web%20pages/amelia2.htm [2000, 21 May 2000].

Veterinary Medicines Directorate. (2000). *VMD Guidance Note - AMELIA 4 (Revised January 2000)*. Available: http://www.open.gov.uk/vmd/Old%20VMD%20web%20pages/amelia4.htm [2000, 21 May 2000].

Watch Out for Non-tariff Barriers in 2000 - Federation of Thai Industries(1999, 27 December). *Business Day,* pp. 1.

Welford, R. a. P., Kate. (1996). *European Business* (3 ed.). London: Pitman Publishing.

Wesley, T. (1994). *Veterinary Vaccines in the EU Markets and Regulations*. Richmond: PJB Publications.

WHO Fears Global Crisis from Infectious Disease. (1996). *Animal Pharm,*(350), 13.

Wilson, J. S. (1996). The New Trade Agenda: Technology, Standards and Technical Barriers. *SAIS Review, 16*, 67-91.

The WTO Agreements (2000). World Trade Organisation. Available: http://wwww.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr03_e.htm [2000, 11 November].

The WTO and GATT - Are They the Same? (2000). World Trade Organisation. Available: http://wwww.wto.org/english/thewto_e/whatis_e/tif_e/fact6_e.htm [2000, 11 November].