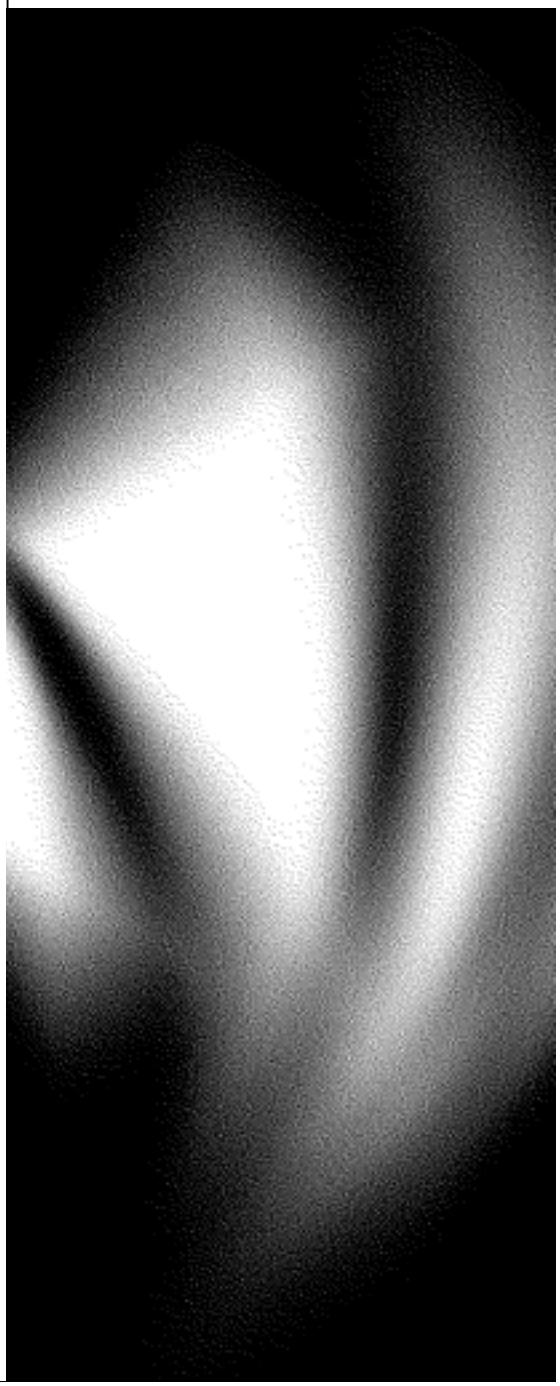
PRODUCTIVITY COMMISSION

International Pharmaceutical Price Differences

Research Report



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The Productivity Commission

The Productivity Commission, an independent Commonwealth agency, is the Government's principal review and advisory body on microeconomic policy and regulation. It conducts public inquiries and research into a broad range of economic and social issues affecting the welfare of Australians.

The Commission's independence is underpinned by an Act of Parliament. Its processes and outputs are open to public scrutiny and are driven by concern for the wellbeing of the community as a whole.

Information on the Productivity Commission, its publications and its current work program can be found on the World Wide Web at www.pc.gov.au or by contacting Media and Publications on (03) 9653 2244.

Foreword

The Commission has prepared this research report in response to a request from the Assistant Treasurer. The study originated from meetings of the Pharmaceutical Industry Working Group, which is a consultative forum comprising government and pharmaceutical industry representatives. In its discussions, the Group identified a need for improved estimates of pharmaceutical price differences between Australia and other countries, given concerns about previous price comparisons.

The report compares the prices that manufacturers receive for 150 pharmaceuticals under Australia's Pharmaceutical Benefits Scheme with those obtained in seven other countries. It finds that, on a bilateral basis, prices for these products in Australia are much lower than those in the United States, Canada, the United Kingdom and Sweden but closer to those in France, Spain and New Zealand.

The report has drawn on information obtained from consultations with government officials, industry representatives and academics both in Australia and overseas. The Commission wishes to thank the many people who have contributed to the study.

Gary Banks
Chairman
July 2001

Contents

Abbreviations and explanations

Abbreviations

AFR	annual financial return
ASMR	*Amelioration du Service Medical Rendu* (France)
ATC	Anatomical Therapeutic Chemical
BC	British Columbia
BCG	Boston Consulting Group
BCP	British Columbia Pharmacare
BP	brand premium
CBO	Congressional Budget Office
CPI	Consumer Price Index
DBP	Drug Benefit Price
DBS	Drug Benefit Scheme
DDD	defined daily dosage
DGFPS	Directorate General of Pharmacy and Health Products (Spain)
DHAC	Department of Health and Aged Care
DHBs	District Health Boards
DoH	Department of Health (UK)
DQTC	Drug Quality and Therapeutics Committee (Canada)
EMEA	European Medicines Evaluation Agency
ER	exchange rate
EU	European Union
FDA	Food and Drug Administration (US)
FSS	Federal Supply Schedule
GAO	General Accounting Office (US)

GDP	gross domestic product
GP	General Practitioner
GSK	GlaxoSmithKline Australia Limited
HC	Health Canada
HMOs	Health Maintenance Organisations
IAC	Industries Assistance Commission
IC	Industry Commission
LCA	low cost alternative
LIF	Swedish Association of the Pharmaceutical Industry
NFC	new form codes
NHS	National Health Service (UK)
NICE	National Institute for Clinical Excellence (UK)
NMF	no match form
NMM	no match molecule
NMS	no match strength
NZ	New Zealand
ODB	Ontario Drug Benefit
OECD	Organisation for Economic Cooperation and Development
OTC	over-the-counter
PBAC	Pharmaceutical Benefits Advisory Committee
PBM	pharmaceutical benefit management
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
PC	Productivity Commission
Pharmac	Pharmaceutical Management Agency Limited (NZ)
PIIP	Pharmaceutical Industry Investment Program
PIWG	Pharmaceutical Industry Working Group
PMPRB	Patented Medicines Prices Review Board
POS	Point-of-Service
PPOs	Preferred Provider Organisations

PPP	purchasing power parity
PPRS	Pharmaceutical Price Regulation Scheme
QALY	Quality Adjusted Life Years
R&D	research and development
RDP	Reference Drug Program
RFV	Riksförsäkringsverket (National Social Insurance Board, Sweden)
ROC	return on capital
RPBS	Repatriation Pharmaceutical Benefits Scheme
Rx&D	Canada's Research-Based Pharmaceutical Companies
SSRIs	Selective Serotonin Re-uptake Inhibitors
TGA	Therapeutic Goods Administration
TGP	Therapeutic Group Premium
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
US	United States
WAMTC	weighted average monthly treatment cost
WTO	World Trade Organization

Glossary

Active ingredient	The primary chemical substance contained in pharmaceuticals. Some pharmaceuticals contain more than one active ingredient (combination molecules).
Anatomical Therapeutic Chemical (ATC) codes	ATC codes provide a method of grouping pharmaceuticals according to their anatomical site of action, and therapeutic and chemical characteristics.
Bioequivalence	Two or more brands of a molecule (in the same dosage type and strength) are released into, and absorbed by the body at the same rate.
Brand premium	Premium charged by a manufacturer above the reimbursed price of the bioequivalent brands of the PBS items, and is paid by the patient.
Brand substitution	Substitution of a generic bioequivalent version by the pharmacist where the patient agrees, when not disallowed by the prescriber.
Combination molecules	Pharmaceuticals that contain more than one active ingredient. An example is the pharmaceutical containing *amoxycillin* and *clavulanic acid*.
Concessional benefit	Under the PBS, holders of a Commonwealth concession card are entitled to a lower copayment on purchases of PBS-listed pharmaceuticals (currently $3.50 per script).
Copayment	A patient contribution towards the cost of subsidised pharmaceuticals. In Australia the copayment is a maximum of $21.90 for general patients, and a maximum of $3.50 for concession card holders.
Cost-effectiveness analysis	Compares therapies which have the same outcomes, but the outcomes can be achieved to different degrees (for example, the number of lives saved). It aims to identify the most efficient therapy that minimises cost per unit of outcome.

Deductible	The yearly out-of-pocket payment by a member of a health plan (for example, HMOs in the United States), which is required before the health plan will make a payment.
Economic evaluation	Economic evaluation aims to examine the clinical and economic impact of pharmaceuticals, requiring an assessment of the costs and health benefits to patients.
Federal Supply Schedule (FSS)	In the US, Federal departments and agencies can purchase pharmaceuticals at prices listed in the FSS.
Form	Pharmaceuticals come in different dosage types (for example, tablet, capsule or injection), strengths and pack sizes. Each combination of these is considered a form of a particular pharmaceutical product.
Generic pharmaceutical	Pharmaceuticals subject to competition from bioequivalent versions. In this report it applies to both originator brands and copies of the originator pharmaceutical.
Indications	Denotes the situations (such as symptoms) in which a pharmaceutical may be used.
International price benchmarking	The practice of comparing pharmaceutical prices across countries, usually for the purpose of determining reimbursement prices.
List price	The manufacturers' posted price. This price does not include any discounts or other incentives offered by manufacturers.
Manufacturer price	Also referred to as the ex-factory price. This is the price that pharmaceutical companies receive for their products.
Marketing approval	Before a new pharmaceutical is sold in the market, the supplier first must obtain marketing approval from the relevant authority. The quality, safety, and efficacy of the product is assessed before awarding marketing approval.
Me-too pharmaceuticals	Pharmaceuticals for which alternatives are available.
Molecule	All forms of a particular pharmaceutical.
New innovative pharmaceuticals	Pharmaceuticals for which there are no reasonable alternatives, and also those with efficacy, quality of life and/or safety improvements, including better modes of delivery of active ingredients.

Pharmaceutical	Chemical entities that are designed to treat or prevent a variety of illnesses and conditions. May be available in many different forms.
Price-volume agreement	The agreed price of a pharmaceutical is based on a forecast volume of sales. If the actual sales volume exceeds the forecast, the price of the pharmaceutical is usually reviewed downwards.
Reference pricing	The practice of setting a ceiling on the amount that will be reimbursed to patients or pharmacists, for defined groups of molecules. For example, it might involve setting a maximum reimbursement price for a group of molecules based on the price of the cheapest product in the group.
Reimbursement price	This is the maximum amount that the insurer will pay towards the cost of a subsidised pharmaceutical. This amount is usually paid to the pharmacist rather than the patient. The manufacturer may be free to price above the reimbursement price, with the patient required to pay the difference.
Retail price	The price charged by retail pharmacists to the general public. It includes any pharmacy mark-up, dispensing fees, and may include a brand or therapeutic premium.
Therapeutic group	Group of molecules, for treating the same condition.
Therapeutic premium	Premium charged by a manufacturer above the reimbursed price of a molecule in one of the four therapeutic groups under the therapeutic group premium policy of the PBS, and is paid by the patient.
Therapeutically interchangeable	When two molecules both deliver the same therapeutic (health) benefits to patients.
Wholesale price	The price charged by wholesalers to the retailers (usually pharmacies). It includes any wholesale mark-up.

Terms of reference

International Pharmaceutical Price Differences

PRODUCTIVITY COMMISSION ACT 1998

The Productivity Commission is requested to undertake a research study examining the differences between the prices of pharmaceutical benefit items in Australia (those listed on the Pharmaceutical Benefits Scheme (PBS)) and the prices of the same items in comparable overseas countries, and to identify as far as possible the reasons for any differences.

In undertaking this study, the Commission's analysis should have regard to the following:

2. The basket of drugs to be examined should include new, innovative drugs (those for which there is no reasonable alternative and also those with efficacy, quality of life and/or safety improvements, including better modes of delivery of active ingredients), new chemical entities for which alternatives are available (so called 'me-too' items) and drugs subject to generic competition. At least ten of the major drugs in each group should be examined.
3. The group of countries to be considered in the price comparison should include a sample of those which offer similar subsidy arrangements for drugs as Australia and those which adopt different arrangements.
4. Price comparisons should be made at the ex-factory levels so as to avoid any confusion that may arise due to the application of wholesalers' mark-ups/margins and fees/allowances, and mark-ups added by pharmacists or other retailers.
5. Some form of weighted average prices should be estimated, using for example, Australian sales volumes as weights.
6. The Commission should also take account of:
   (a) both the price of generic brands and the original brand for drugs subject to generic competition;
   (b) the range of medical conditions for which a drug is subsidised;
   (c) discounts, bonuses and other incentives offered by industry;
   (d) risk sharing arrangements (price/quality arrangements); and
   (e) the regulatory arrangements and the underlying cost structures in the countries for which prices are compared.
7. The Commission is required to provide regular progress reports. The Final Report is to be published within nine months of commencing the study.

ROD KEMP
1 September 2000

Key messages

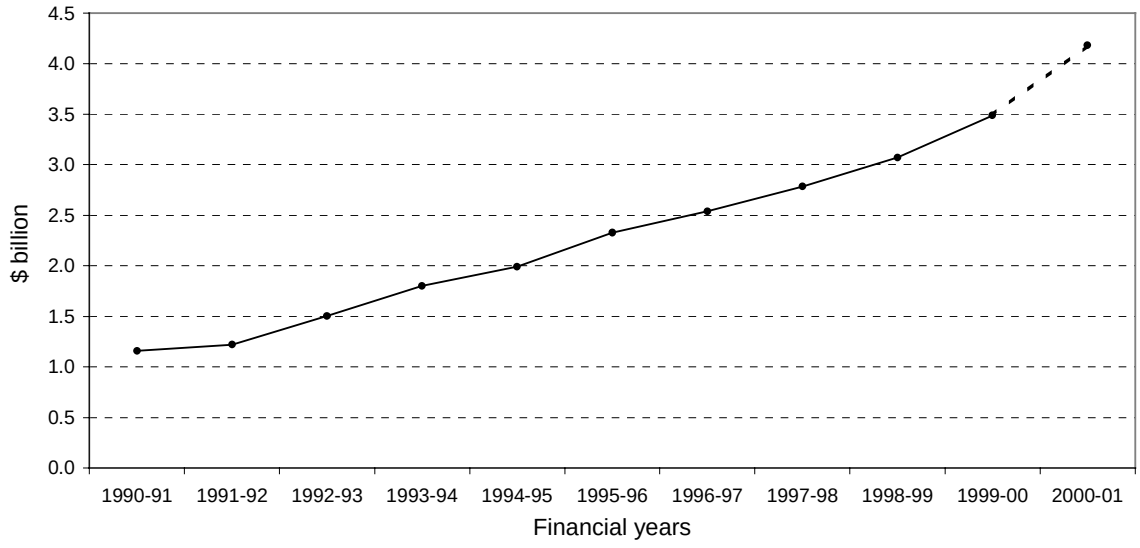
- The pricing of pharmaceuticals listed on the Pharmaceutical Benefits Scheme (PBS) is an important issue for Australia. Between 1992-93 and 1999-2000, government spending on pharmaceuticals rose from under 12 per cent of public expenditure on health to over 15 per cent. In 2000-01, the cost to the Commonwealth Government of the PBS increased by around 20 per cent, to over $4 billion.
- This study examines differences between manufacturer prices in Australia and seven other countries for 150 PBS-listed pharmaceuticals, as at 30 June 2000. These items account for over 80 per cent of total expenditure on PBS-listed pharmaceuticals.
- The bilateral comparisons show that manufacturer prices in Australia for the top 150 pharmaceuticals are much lower than in the United States, Canada, the United Kingdom and Sweden. Prices in Australia are closer to those in France, and about the same as those in Spain and New Zealand.
- The price differences vary across different categories of pharmaceuticals. Prices for new innovative pharmaceuticals are much closer to those in the other countries. The largest price differences are observed for 'me-too' pharmaceuticals and they are also significant for generic pharmaceuticals.
- It is difficult to identify robust specific explanations for the observed bilateral price differences.
  - Rather, the price differences are probably due to a combination of factors, including differences in health systems, subsidy and cost-containment mechanisms, market conditions and production costs.
  - There is, nevertheless, some evidence to support the view that Australia's cost-containment arrangements, particularly reference pricing, may have contributed to keeping prices relatively low.

Overview

Pharmaceutical products and their pricing are an important issue for Australia. Between 1992-93 and 1999-2000, total spending by Australian governments on pharmaceuticals rose from under 12 per cent of total public expenditure on health to over 15 per cent.

In Australia, around 75 per cent of all pharmaceuticals prescribed outside of hospitals are eligible for subsidisation under the Pharmaceutical Benefits Scheme (PBS). In 2000-01, the Commonwealth Government is estimated to have spent around $4.2 billion subsidising PBS-listed pharmaceuticals, an increase of around $700 million over the previous 12 months, and more than three and a half times the cost ten years earlier (figure 1).

Figure 1 **Cost to the Commonwealth Government of the PBS, 1990-91 to 2000-01[a]**



a The cost of the PBS to the Commonwealth Government is estimated to have grown by around 20 per cent in 2000-01.

Data source: DHAC (2001).

Once a prescription pharmaceutical is approved for marketing in Australia, companies usually seek to have the item listed on the PBS. Because of the attraction

of the scheme to consumers, it is usually necessary for the company to do so for viable marketing to occur.

Once listing has been recommended by the Pharmaceutical Benefits Advisory Committee, the price of the pharmaceutical is negotiated with the company. The Pharmaceutical Benefits Pricing Authority is responsible for advising the Government on the price at which pharmaceuticals should be listed on the PBS. Its objective is to secure a reliable supply of pharmaceuticals at the most reasonable cost to Australian taxpayers and consumers, consistent with maintaining a sustainable pharmaceutical industry in Australia.

Australia's pharmaceutical industry is small in global terms — with around one per cent of global pharmaceutical output in 1999. Europe, the United States (US) and Japan account for the majority of world pharmaceutical production.

The local pharmaceutical industry comprises around 120 companies with an annual turnover of around $6 billion. The industry is dominated by subsidiaries of some of the largest multinational enterprises but there are a small number of significant locally-based companies. Most pharmaceuticals are manufactured locally, primarily from imported active ingredients. Australia is a net importer of medical and pharmaceutical products — in 1999-2000, exports were valued at $1.7 billion whereas imports were worth $3.5 billion.

Purpose of the study

The purpose of this study is to compare the prices that manufacturers receive for pharmaceutical products in Australia under the PBS with those obtained in countries with similar and dissimilar subsidy arrangements, and to identify, as far as possible, the reasons for any differences.

It has been argued that the Government has used its power to determine which pharmaceuticals will be eligible for subsidisation under the PBS, to negotiate manufacturer prices for PBS-listed items that are significantly below prices in other countries (IC 1996). While this may benefit taxpayers and consumers, it has led to concerns about the potential for low prices to undermine investment in the Australian pharmaceutical industry.

However, the study does not assess the effects of the PBS on the pharmaceutical industry. Examining this broader issue would require an understanding of the many factors that can affect the potential net returns to investment by pharmaceutical companies in Australia, such as the patent system, the quality and availability of skilled workers, the nature of links with educational and research institutions, the

tax system, pharmaceutical evaluation processes, industry policy arrangements, as well as pharmaceutical subsidy and cost-containment mechanisms.

This study draws on information provided to the Commission by a market research company, IMS Health, publicly available data sources, and information provided by several Australian government departments, the pharmaceutical industry and several overseas agencies. It reports the results of a comparison of prices for a sample of pharmaceuticals listed on the PBS.

Methodology and data

Several aspects of the methodology affect how the results can be interpreted, including the:

- sample of pharmaceuticals;
- ratios used to compare prices;
- choice of countries;
- categories of pharmaceuticals covered; and
- use of 'list' prices.

Sample of pharmaceuticals

Following the terms of reference, the study focuses on the prices of items listed on the PBS. The sample comprises the top 150 chemical entities (hereafter referred to as molecules) listed on the PBS during the financial year 1999-2000, ranked by total expenditure. These molecules account for over 80 per cent of total expenditure on PBS-listed pharmaceuticals.

Therefore, the results of this study apply to the top-selling PBS-listed pharmaceuticals and cannot be generalised to all pharmaceuticals that are available in Australia.

The 150 top-selling PBS molecules are marketed in Australia in 584 forms (that is, different dosage types, strengths and pack sizes). As far as possible, the Commission identified matching forms in each country so as to enable price comparisons on a like-for-like basis. However, only 18 of these 584 forms are available in all comparison countries, thus precluding multilateral comparisons. Instead, the Commission has estimated pair-wise comparisons between Australia and selected other countries, based on prices of forms common to both countries.

Therefore, the results can only be used for bilateral comparisons between Australia and individual countries. Multilateral comparisons are not possible.

To increase the number of matches, there were some occasions where the Commission assumed a linear relationship between pack size and price (if the pack size of the matching form was sufficiently close to the Australian pack size). If there were several different pack sizes in the comparison country that were significantly different from those available in Australia, higher and lower estimates of price comparisons were reported. Higher and lower estimates also were reported if it was found that several manufacturers produced the matching forms, but with each charging a different price.

Price ratios

The terms of reference require the Commission to calculate some form of weighted average price. This is required to ensure that the results are not distorted by the inclusion of forms that have a large price differential but a small market share.

Australian sales volumes were used to weight manufacturer prices. This choice reflects the purpose of the study, which is to compare the prices for a sample of PBS-listed items in Australia with those obtained in comparison countries.

The price comparisons are reported using a ratio of prices between Australia and each comparison country. These ratios were calculated by dividing an overseas revenue estimate by an estimate of Australian revenue for those forms that were available in both Australia and the comparison country. The overseas revenue estimate is derived by multiplying overseas prices for each matched form by the corresponding Australian sales volumes. This yields an estimate of the revenue that could have been obtained by pharmaceutical companies if they had sold their Australian volumes at the overseas prices. Similarly, the Australian revenue estimate is derived by multiplying Australian prices, for the same forms, by the Australian sales volumes. The price ratio, therefore, provides an indication of how the revenues of companies operating in Australia would change if they had achieved overseas prices (rather than Australian prices) on their Australian sales.

The sales volumes also act as weights on the prices. For example, a high priced item may make a small contribution to the revenue estimates for Australia and comparison countries if it has a low volume of sales in Australia. The price ratio also can be interpreted as showing whether Australian prices for the matched pharmaceuticals are higher or lower than those overseas.

Choice of countries

The terms of reference require the Commission to compare Australian prices with those in countries with similar and dissimilar subsidy arrangements. The seven comparison countries included in this study are: the US, Canada, the United Kingdom (UK), France, Spain, Sweden and New Zealand (NZ).

Whereas all Australians are eligible for subsidies under the PBS, the coverage of government subsidies is narrower in the US and Canada. The UK is dissimilar to Australia in that pharmaceutical companies are relatively free to set prices (subject to an overall profit constraint). The UK also automatically reimburses all new products that have been approved for marketing, unless the Government decides to remove eligibility for subsidisation (by registering the product on a 'negative list').

Sweden, France, Spain and NZ are similar to Australia as they offer universal eligibility for pharmaceutical subsidies. However, they differ in the ways in which their governments seek to influence the prices of subsidised pharmaceuticals.

Pharmaceutical categories

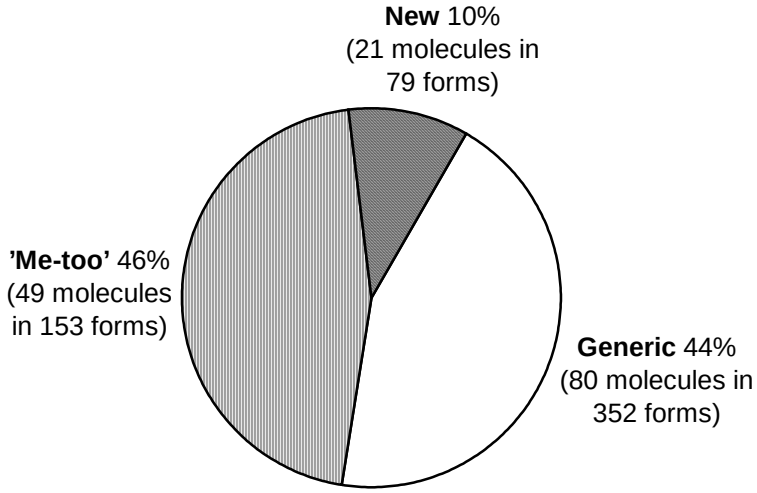
Unlike the majority of previous studies of international pharmaceutical price differences, the Commission is required to estimate separate price differences for *new innovative*, *'me-too'* and *generic* categories of pharmaceuticals. These categories are defined below. The top 150 molecules on the PBS were allocated into these categories by the Department of Health and Aged Care (DHAC) (figure 2).

List prices

This study, like most previous cross-country comparisons of pharmaceutical prices, has, in the first instance, used 'list' prices as the basis of comparison. The list price is the manufacturer's posted price, exclusive of any discounts or other incentives.

Data on manufacturer prices in Australia as at 30 June 2000 were obtained from DHAC. Manufacturer prices in Sweden were obtained from the Swedish National Social Insurance Board. Price data for the US, Canada, the UK, France, Spain and NZ were obtained from IMS Health. Manufacturer prices from IMS Health do not take into account manufacturer incentives (discounts) that are offered in some countries to large private and public sector buyers (such as Health Maintenance Organisations in the US).

Figure 2 **Breakdown of total expenditure on the top 150 PBS pharmaceuticals, as at 30 June 2000**



Data source: PC estimates.

The Commission sought information on the actual prices received by suppliers. Anecdotal information suggests that discounting is not widespread in Australia, Canada and Sweden but may be more common in the UK, especially for generics. Information on discounts in NZ, France and Spain was unavailable.

Discounts to large buyers in the US were estimated using the Federal Supply Schedule (FSS), which lists prices for pharmaceuticals purchased by the US Department of Veterans Affairs and other Federal agencies. While the FSS prices are not necessarily the lowest prices available in the US market, information on these lower prices is usually confidential.

Manufacturer prices in local currencies in the comparison countries were converted into Australian dollars using the average exchange rate over the month of June 2000. Sensitivity analyses showed that using nominal exchange rates covering different periods does not alter the results in a significant way.

Key results

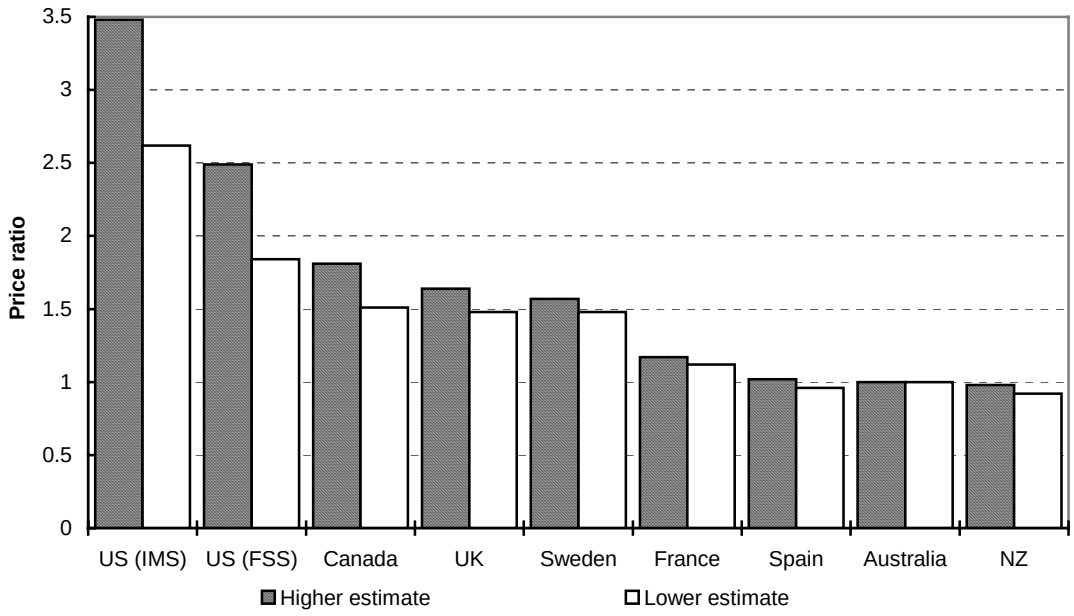
The Commission has undertaken price comparisons for all available forms of Australia's 150 top-selling pharmaceuticals (all categories), and for three individual

categories of new innovative, 'me-too' and generic pharmaceuticals. These results show whether manufacturer prices in Australia for the top-selling (matched) pharmaceuticals are higher or lower than the relevant foreign price as at 30 June 2000. A value greater than one indicates that manufacturer prices for the matched forms in the comparison country are greater than the prices of those items in Australia.

Price differences — all categories of pharmaceuticals

Figure 3 provides results for all categories of pharmaceuticals based on list prices and other sources and, where available, prices taking into account manufacturer discounts. As noted above, the results cannot be used to compare price levels across the comparison countries.

Figure 3 **Results for all categories[a]**



a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn.

Data source: PC estimates.

The results show that manufacturer prices for Australia's top-selling items are:

- at least 162 per cent higher in the US (based on the lower estimate of list prices);
- at least 84 per cent higher in the US when discounts are taken into account (using the FSS prices);

- at least 48 to 51 per cent higher in the UK, Canada and Sweden; and
- much closer to the prices received in France, Spain and NZ.

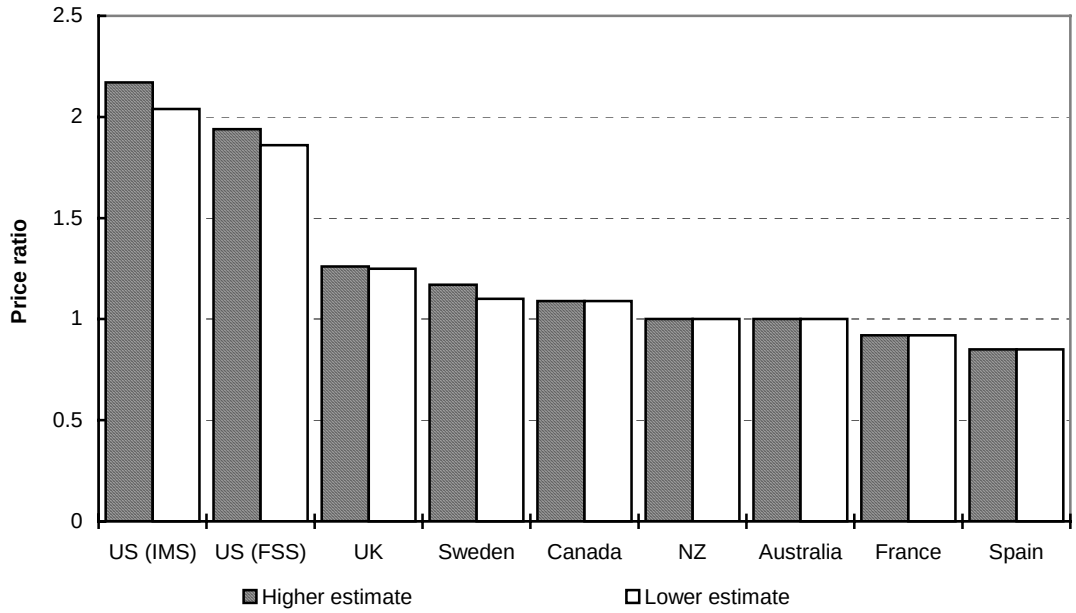
The estimate of US prices using the FSS prices provides a more reasonable indication of price differences between Australia and the US. However, accounting for discounts does not alter the finding that prices are significantly higher in the US.

New innovative pharmaceuticals

New innovative pharmaceuticals are chemical entities for which there is no reasonable alternative and also those with efficacy, quality of life and/or safety improvements, including better modes of delivery of active ingredients.

As new innovative pharmaceuticals possess significant additional benefits over alternative treatments, or are the only ones available to treat a particular disease, manufacturers may have some capacity to set different prices in each country, reflecting differences in the price sensitivity of demand. However, regulatory constraints, such as the use of international benchmarking by governments to set prices, may reduce the scope for them to do this.

Figure 4 **Results for new innovative pharmaceuticals[a]**



a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn.

Data source: PC estimates.

The results for Australia's top-selling new innovative pharmaceuticals presented in figure 4 show that compared with the results for all categories of pharmaceuticals:

- manufacturer prices in Australia are much closer to those in the comparison countries but prices in the US and the UK are higher than those in Australia by 104 per cent and 25 per cent respectively (based on the lower estimates);
- differences between the higher and lower estimates are smaller (mostly due to a higher proportion of direct matches and fewer manufacturers of each form); and
- large buyers in the US are able to obtain smaller discounts off list prices (between three and six per cent).

'Me-too' pharmaceuticals

'Me-too' pharmaceuticals are chemical entities for which therapeutic alternatives are available. These pharmaceuticals may face different levels of competition from therapeutic alternatives within a country and may be subject to different levels of price regulation. Therefore, it is difficult to arrive at in-principle predictions about relative prices across countries.

For Australia's top-selling 'me-too' pharmaceuticals, figure 5 shows that compared with all categories of pharmaceuticals:

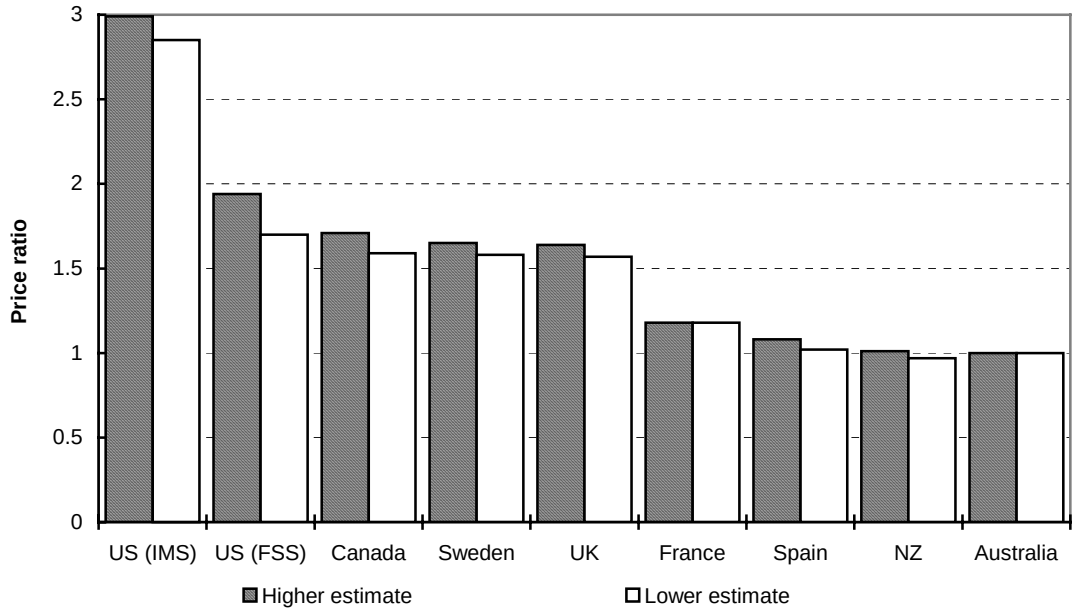
- manufacturer prices in Australia are lower than those in the comparison countries (except NZ based on the lower estimate of prices);
- very large discounts were obtained by large institutional buyers in the US (between 34 to 39 per cent). Prices for the top-selling Australian 'me-toos' are likely to be between 70 and 94 per cent higher in the US than in Australia; and
- the gap between prices in Australia and the comparison countries is greater for the 'me-too' category (based on the lower estimate of prices). Prices for the top-selling Australian 'me-toos' are around 60 per cent higher in Canada, the UK and Sweden (based on the lower estimates).

Generic pharmaceuticals

Generic pharmaceuticals are chemically-equivalent items and in this study include the originator brand. Studies for the US have found that as patents on originator brands expire, generic copies have been able to capture a significant share of the market at much lower prices. However, manufacturers of originator brands may prefer to maintain higher prices despite a reduction in market share, in order to preserve perceptions of higher quality. International trade in generics might be

expected to offer less scope for price differentiation across countries than is possible for patented (new innovative and 'me-too') pharmaceuticals.

Figure 5 **Results for 'me-too' pharmaceuticals, using IMS data[a]**



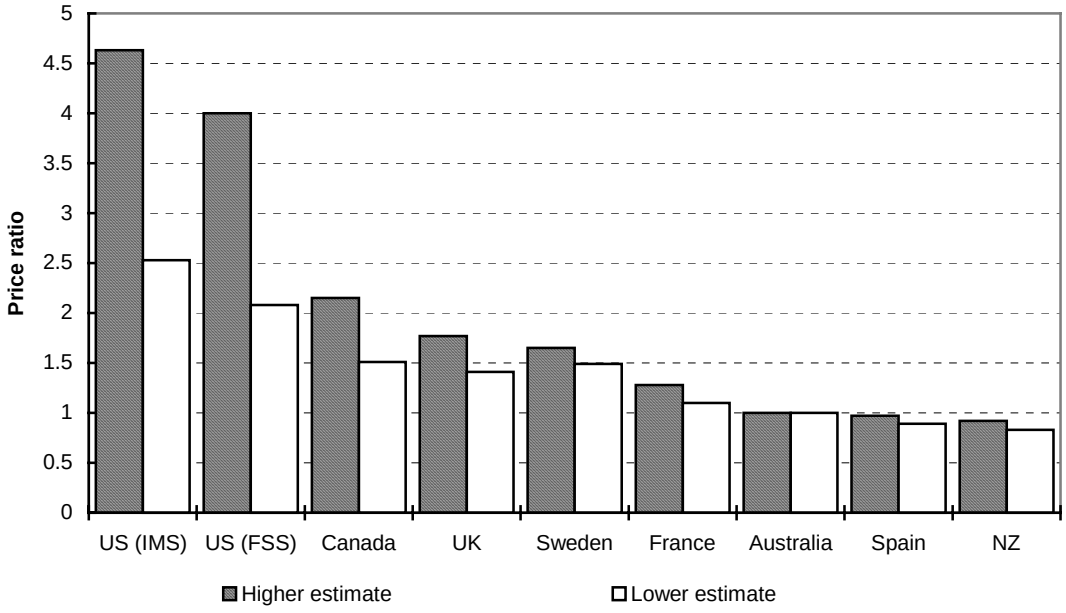
a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn.

Data source: PC estimates.

However, this expectation is not completely borne out by the results. Figure 6 shows that:

- while manufacturer prices for Australia's top-selling generics in Spain and NZ are below those in Australia, generic prices are between ten and 108 per cent higher (based on the lower estimates of IMS and FSS prices) in the US, Canada, the UK, Sweden and France;
- the range between the higher and lower estimates of manufacturer prices is greater for generic pharmaceuticals than for other categories. In part, this result is due to the inclusion of high-priced originator brands in the generic category. This effect is most pronounced for the US; and
- larger institutional buyers in the US can obtain discounts off manufacturers' list prices of between 14 and 24 per cent.

Figure 6 **Results for generic pharmaceuticals, using IMS data[a]**



a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn.

Data source: PC estimates.

Much of the observed large price range for generic pharmaceuticals was due to the availability of multiple manufacturer prices for many generic pharmaceuticals. For example, in some cases, the highest price for a generic pharmaceutical was several times the price of the cheapest. A comparison of higher and lower estimates with prices weighted by market shares for a sample of generic pharmaceuticals found that manufacturer price differences between Australia and the US, Canada and the UK are likely to be better reflected by the lower estimate of prices.

Even if the lower estimate of price comparisons is used, the significant price differences between Australia and the US, Sweden, Canada and the UK are surprising. For the UK, this result may be due, in part, to the use of list (not actual) prices. But this does not appear to be an important factor explaining the results for Sweden and Canada. Anecdotal evidence for these two countries suggests that discounting of generics is rare.

There are also some interesting differences between the results for individual categories. For instance:

- the gap between prices in Australia and the comparison countries (with the possible exception of NZ) is larger for 'me-too' pharmaceuticals than for other

categories (based on the more reasonable lower estimate of price comparisons); and

- discounts available to large purchasers in the US are also greatest for 'me-too' pharmaceuticals (ranging from 34 to 39 per cent compared with discounts of between 3 and 6 per cent for new innovative, and 14 and 24 per cent for generic pharmaceuticals).

Reasons for price differences

A number of potential reasons for the observed price differences were identified at a roundtable meeting of industry experts held to discuss the preliminary results. Two key ones were:

- differences in the broad features of pharmaceutical subsidy and cost-containment policies in Australia and the comparison countries; and
- specific features of Australia's cost-containment arrangements.

In addition, roundtable participants identified additional factors that may have contributed to the results for the individual categories, such as international price benchmarking.

Pharmaceutical subsidy and cost-containment policies

Some participants considered that differences in the broad characteristics of the subsidy and cost-containment policies in comparison countries may have influenced the results.

In very broad terms, it is difficult to find any obvious associations between the observed price differences and the types of subsidy and cost-containment policies adopted in the comparison countries. Large price differences were found for some countries that possess quite different subsidy arrangements (notably the US and Canada). But prices in Sweden and, to a lesser extent, France were also higher than in Australia even though they have similar subsidy arrangements.

Finding a correlation between the cost-containment mechanisms employed and the price differences was also problematic. The largest price differences were observed for those countries that allow relatively free pricing of pharmaceuticals — the US, the UK and Canada (at the Federal level). However, prices in Sweden also were significantly higher than Australia's, even though companies are required to negotiate a price before the product will be subsidised.

The difficulties in finding a close association between price differences and policy regimes suggest that other factors have also played a role. These could include differences in demand conditions, volume restrictions (such as restrictions on approved uses), delays due to marketing approval requirements, patent arrangements, the level of competition amongst pharmaceuticals within therapeutic groups, and production and marketing costs.

Specific features of Australia's cost-containment policies

Participants considered that the strong emphasis on cost-containment within Australia's subsidy arrangements, especially the requirement for economic evaluations and reference pricing, has had an important influence upon the results.

Economic evaluations involve an assessment of the relative costs and health benefits of a pharmaceutical, and a comparison of these with alternatives. Australia, NZ and the Canadian provinces of Ontario and British Columbia are the only jurisdictions to require companies to submit an economic evaluation with applications for listing new pharmaceuticals, or for increasing the price or clinical uses of items already listed. Prices in Australia were close to those in NZ but not to those in Canada.

In Australia, reimbursement prices (the maximum amount the Government pays) for defined sub-groups of therapeutically-equivalent pharmaceuticals are set using a comparatively strict form of reference pricing. These sub-groups may contain patented and generic pharmaceuticals. Reimbursement prices for all items in a particular sub-group are set on the basis of the lowest cost item. While a similar approach is used in NZ and British Columbia, it has not been applied in the other comparison countries.

To look at the possible contribution of these cost-containment mechanisms, the sample of 'me-too' pharmaceuticals was divided into those that were directly affected by reference pricing prior to 30 June 2000 — using the weighted average monthly treatment cost (WAMTC) methodology — and products that were not.

The results indicate that for all countries, except NZ, greater price differences were observed for those 'me-too' items subject to reference pricing, than for products that were not. This provides some support for the contention that Australia's reference pricing system has contributed to the reported price differences for 'me-too' pharmaceuticals. However, due to concerns about the representativeness of the sample, the extent of the contribution remains unclear.

Conclusions

It is difficult to identify robust specific explanations for the observed bilateral price differences. Rather, the price differences are probably due to a combination of influences, including systemic differences in health systems, pharmaceutical subsidy and cost-containment mechanisms, and production costs (including marketing and liability costs).

The overall results also may reflect the influence of factors affecting the prices of particular pharmaceuticals, or therapeutic groups, including differences in demand conditions, volume controls, patent arrangements, and competition from therapeutically similar molecules.

There is, nevertheless, some evidence to support the view that Australia's cost-containment arrangements may have contributed to keeping prices relatively low. The application of reference pricing in particular, may have been significant, although to what extent remains unclear.

1 Introduction

On 1 September 2000 the Productivity Commission was asked by the Commonwealth Government to undertake a research study into international pharmaceutical price differences. The terms of reference for the study direct the Commission to examine differences between the prices of pharmaceutical benefit items received by manufacturers in Australia and the prices of the same items in comparable overseas countries, and to identify as far as possible the reasons for any differences.

This study arose out of meetings of the Pharmaceutical Industry Working Group (PIWG). The PIWG was established to facilitate consultation between the pharmaceutical industry and the Commonwealth Government on the long-term operating and policy environment facing the industry.[1] This study was commissioned to inform these consultations, and to respond to concerns about previous price comparisons.

This report draws on information provided by IMS Health[2] and publicly available data sources in reporting the results of a comparison of prices for a sample of pharmaceuticals listed on the Pharmaceutical Benefits Scheme (PBS). The report also explores some of the many possible reasons for the observed price differences between countries. However, in doing so, the report does not seek to evaluate, or make recommendations on the PBS.

1.1 Background to the study

The health care system in Australia is an important part of Australia's economy. It provides a variety of services including hospitals, community services, nursing home services and health programs, and associated service providers such as general practitioners, medical specialists, nurses and pharmacists.

1 The Group comprises the Ministers for Industry, Science and Resources, and Health and Aged Care, officers of the two Commonwealth Departments, and representatives of the Australian pharmaceutical industry.

2 IMS Health is a private company specialising in the provision of marketing information to the pharmaceutical industry.

Pharmaceutical products are an integral part of this system.[3] Total government spending on pharmaceuticals accounted for over 15.3 per cent of total public spending on health in 1999-2000. Other significant components of public health expenditure in 1999-2000 were community health services (35 per cent) and acute care institutions (29 per cent) (ABS 2001a).

Moreover, pharmaceuticals are one of the fastest growing components of public health expenditure. For instance, between 1992-93 and 1999-2000 public spending on pharmaceuticals rose from just under 11.6 per cent of public expenditure on health to around 15.3 per cent (ABS 1999a, 2001a).

In Australia, around 75 per cent of all outpatient prescription pharmaceuticals are eligible for subsidisation under the PBS and the Repatriation Pharmaceutical Benefits Scheme (RPBS).[4] The PBS was established to provide the community with access to necessary medicines, which are affordable, available and of acceptable standards (box 1.1). In 2000-01, it is projected that the Commonwealth Government will spend around $4.2 billion subsidising pharmaceuticals, an increase of around $700 million over the previous 12 months. Overall, nominal expenditure under the scheme has risen by 261 per cent since 1990-91 (figure 1.1). In comparison, general prices in the economy have risen by 18.4 per cent over the same period (ABS 2001c).

Australia accounts for a small share of global pharmaceutical output (around one per cent in 1998). According to the European Federation of Pharmaceutical Industries and Associations (EFPIA 2000), Europe, the United States and Japan accounted for over 90 per cent of world pharmaceutical production in 1998 (by value).

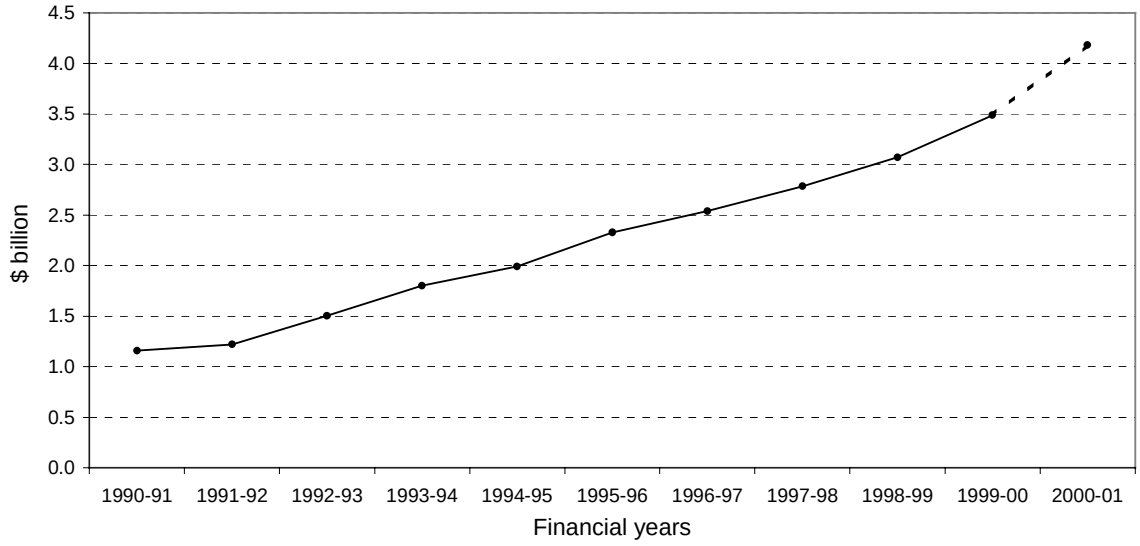
According to the Australian Pharmaceutical Manufacturers Association (APMA 2000), the local pharmaceutical industry comprises around 120 companies with an annual turnover of around $6 billion. The industry is dominated by subsidiaries of some of the largest multinational pharmaceutical enterprises but there are a small number of significant locally-owned companies. Nonetheless, the pharmaceutical industry accounts for around four per cent of Australia's total

3 The term 'pharmaceutical' is used to describe a large number of chemical entities that are designed to treat or prevent a variety of illnesses and conditions. Pharmaceutical products can be divided into items that are available only on prescription, and those that are available over the counter.

4 The RPBS is a separate system to the PBS that provides access to pharmaceuticals determined necessary to ensure the best treatment for entitled veterans, war widows and widowers. People eligible for the RPBS pay a maximum of $3.50 for prescribed medicines covered by the scheme. In 1998, over 90 per cent of RPBS prescriptions were for PBS-listed pharmaceuticals (DHAC 1999b).

business expenditure on research and development (ABS 1999b). The majority of pharmaceuticals supplied to the local market are manufactured in Australia, primarily from imported active ingredients (IC 1996). Australia is a net importer of medical and pharmaceutical products — in the 12 months ended March 2001, exports were valued at $2.1 billion and imports were worth $4.2 billion (ABS 2001b).

Figure 1.1 **Commonwealth Government cost of the PBS, 1990-91 to 2000-01[a]**



a The cost of the PBS to the Commonwealth Government is estimated to grow at 19.9 per cent in 2000-01.

Data sources: CDHFS (1996, 1995); DHAC (2001a, 2001b and pers. comm., 3 July 2001).

Given the significance of the pharmaceutical industry to Australia's economy and health care system, and the rapid growth in pharmaceutical spending, it is not surprising that pharmaceutical prices are a major issue for Australia.

Once a prescription pharmaceutical is approved for marketing in Australia, companies usually seek to have the item listed on the PBS. Because of the attraction of the scheme to consumers, it is usually necessary for the company to have the item listed on the PBS for viable marketing to occur (DHAC 1999b).

Box 1.1 **Australia's Pharmaceutical Benefits Scheme**

The PBS has been in operation since 1948. Initially, the scheme's coverage was limited largely to supplying products listed in the British Pharmacopoeia to pensioners, and 139 life-saving and disease-preventing pharmaceuticals to others in the community.

Since then, the coverage of the scheme has been extended. Currently, all members of the community are eligible for subsidies under the PBS. According to the Department of Health and Aged Care (DHAC 2001a), as at February 2001 the PBS covered 593 molecules, available in 1469 forms and marketed as 2351 different products (brands).[5]

The stated purpose of the PBS is to provide the Australian community with timely, reliable and affordable access to necessary and cost-effective prescription medicines.

In financial year 1999-2000, the cost to the Government of the PBS was $3.5 billion, representing an increase of 13.6 per cent over the previous year. In the same period, total expenditure on PBS-listed pharmaceuticals (Government plus patient contributions) was $4.1 billion. Concessional benefit prescriptions (that is, scripts written for holders of a Commonwealth concession card) accounted for more than 80 per cent of the Government expenditure on the PBS (DHAC , pers. comm., 3 July 2001). The cost to the Government of the PBS is expected to increase by a further 19.9 per cent in 2000-01 (DHAC, pers. comm., 3 July 2001).

Before a new pharmaceutical can be listed on the PBS, the supplier first must obtain marketing approval from the Therapeutic Goods Administration (TGA). The TGA analyses the product's quality, safety and efficacy before awarding marketing approval. The approval specifies, amongst other things, the approved uses (indications) for the pharmaceutical. Pharmaceutical manufacturers also must be licensed by the TGA and ensure that their manufacturing processes comply with principles of Good Manufacturing Practice.

Once approved for sale, suppliers may seek to have their products listed on the PBS by applying to the Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC is a statutory committee of independent experts that reviews applications against a number of criteria including: the need for the product; the outcomes and costs of a particular pharmaceutical when weighed against other available therapies; and whether any restrictions should be imposed on new listings (such as limits on the number of items that may be prescribed or restrictions on the indications for which a PBS subsidy is available).

(Continued next page

5 These figures exclude pharmaceuticals provided under special arrangements, such as section 100 pharmaceuticals. Section 100 pharmaceuticals are highly specialised items, used to treat chronic conditions and are restricted to supply through hospitals with access to specialised facilities (DHAC 2000, p. 251).

Box 1.1 (continued)

In reviewing applications for listing, the PBAC is required to consider both the effectiveness and cost of therapy involving the use of new pharmaceuticals. Under the *National Health Act 1953*, the PBAC cannot recommend listing unless the pharmaceutical provides 'a significant improvement in efficacy or a reduction in toxicity over the alternative therapy'. To this end, an important feature of Australia's system for listing new pharmaceuticals on the PBS is the reliance on requiring evidence that new pharmaceuticals offer significant benefits over those available from alternative forms of therapy. If the PBAC recommends that an item be listed on the PBS, the Pharmaceutical Benefits Pricing Authority (PBPA) will recommend a reimbursement price which may include a price-volume arrangement.[6] According to Professor David Henry (pers. comm., 14 May 2001) (a former member of the PBAC), the price at which a pharmaceutical is considered to be of acceptable cost-effective (that is, the cost of the item is justifiable based on the clinical outcomes which it is likely to deliver) by the PBAC has typically been the starting point for negotiations with manufacturers.

The reimbursement price is the maximum amount that the Government will reimburse to pharmacists, and it may be set with reference to the price of identical or similar pharmaceuticals that are already available under the PBS.

The PBPA recommends to the Government the price at which pharmaceuticals should be listed on the PBS. DHAC negotiates, on behalf of the Government, with pharmaceutical manufacturers the price of the pharmaceuticals using the PBPA recommendations as its basis. The Government then makes the final determination on whether to list a product at a particular price (although it cannot list a new pharmaceutical unless the PBAC has made a positive recommendation) (DHAC , pers. comm., 3 July 2001).

In some instances a company has the option, under the Brand Premium Policy and/or Therapeutic Group Premium (TGP) Policy, of charging a price above the reimbursement price agreed with the PBPA. However, patients must pay any difference between the company's price and the reimbursed price.

The PBPA also conducts annual reviews of the prices of products listed on the PBS. Also, suppliers may request a price review or seek to have pharmaceuticals already listed on the PBS approved by the PBAC for use to treat other conditions.

Sources: DHAC (2001a, 2001b and pers. comm., 3 July 2001); PBPA (2000).

6 Under a price-volume agreement, the agreed price of a pharmaceutical is based on a forecast volume of sales. If the actual sales volume exceeds the forecast, the price of the pharmaceutical is usually reviewed downwards.

Once listing has been recommended by the Pharmaceutical Benefits Advisory Committee (PBAC), the price of the pharmaceutical is negotiated with the company. The Pharmaceutical Benefits Pricing Authority is responsible for advising the Government on the price at which pharmaceuticals should be listed on the PBS.[7] Its objective is to secure a reliable supply of pharmaceuticals at the most reasonable cost to Australian taxpayers and consumers, consistent with maintaining a sustainable pharmaceutical industry in Australia (PBPA 2000).

It has been argued that the Australian Government has used its power to determine which pharmaceuticals will be eligible for subsidisation under the PBS to negotiate manufacturer prices for PBS-listed items that are significantly below prices in other countries (IC 1996).[8] While the use of buying power to hold down prices may benefit taxpayers and consumers, it has led to concerns about the potential for low prices to undermine investment in the pharmaceutical industry in Australia.

The results of this study are therefore intended to shed some light on how manufacturer prices in Australia, for PBS-listed items, compare with the prices received by pharmaceutical companies in comparable countries.

By themselves, the price comparisons results cannot be used to assess the attractiveness of the investment environment facing pharmaceutical companies operating in Australia. Assessing this broader issue would require an assessment of all of the factors that can affect the potential net returns to investment by pharmaceutical companies in Australia, such as the patent system, the quality and availability of skilled workers, the nature of links with educational and research institutions, the tax system, pharmaceutical evaluation processes, pharmaceutical subsidy and cost-containment mechanisms, and industry policy arrangements.

1.2 Scope of the study

The purpose of this study is to estimate, for selected comparator countries, differences in the prices received by manufacturers for pharmaceutical products listed on the PBS, and to examine the reasons for any differences.

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7 For most pharmaceuticals, the Government does not directly determine the manufacturer's price but rather, it negotiates a price that will be reimbursed to pharmacists (box 2.2). However, the Government does negotiate manufacturer prices for highly specialised pharmaceuticals (section 100 items).

8 In this report, the term manufacturer price is used to denote the prices received by companies which manufacture or supply pharmaceuticals to wholesalers and pharmacists. It can be distinguished from the prices charged by these buyers (which may include wholesale and retail mark-ups, wholesale and retail discounts, dispensing fees and other allowances).

The terms of reference require the Commission to compare prices for a group of countries that offer similar and dissimilar subsidy arrangements to Australia. The seven countries included for comparison are: the United States (US), the United Kingdom (UK), Canada, New Zealand (NZ), France, Spain and Sweden. The rationale for selecting these countries is outlined in chapter 3.

In any study of international pharmaceutical prices, the major requirement is to obtain reliable information on prices that is consistent across countries.

This study draws extensively upon information provided by IMS Health. IMS Health data have been used in most previous studies examining international price differences. Alternative sources of information are publicly available in many countries and, where possible, this information was used to supplement and verify data obtained from IMS Health. For example, information from the Federal Supply Schedule, which is maintained by the US Department of Veterans Affairs, was used to look at the potential impact on the price comparisons of manufacturer discounts offered to large buyers of pharmaceuticals.

Interpreting the results

The methodology employed in this study is described in more detail in chapter 3. However, several key features have important implications for the way the results of the study can be interpreted.

First, the study is confined to products listed on the PBS. As noted earlier, around 75 per cent of all pharmaceuticals prescribed outside of hospitals are eligible for subsidisation under the PBS. The study does not cover sales of unsubsidised over-the-counter (OTC) pharmaceuticals or prescription pharmaceuticals that are not listed on the PBS. *This study has been designed only to provide comparisons of prices for items that are available on the PBS.*

Second, the study uses a sample of pharmaceuticals comprising the top 150 PBS-listed molecules[9] ranked by total (government plus consumer) expenditure. These 150 molecules are available in 584 forms[10] and account for around 83 per cent of expenditure on PBS items. According to the Department of Health and Aged Care (DHAC), the PBS lists approximately 820 molecules (including highly specialised items) available in a large number of different forms. *Therefore,*

9 In this study, the term 'molecule' has been used to mean a generically-named pharmaceutical product, which in turn can be available in many forms.

10 'Forms' covers the different dosage types, strengths and pack sizes in which a particular molecule is available in Australia. For example, the pharmaceutical *simvastatin* is available in tablets with strengths of 5, 10, 20, 40 and 80 mg and in packs of 30.

while the study can be used to say something about international price differences for the top-selling PBS items, the results cannot be used to draw conclusions about price differences for those molecules not covered by the study.

Third, pharmaceuticals have been matched on the basis of dosage type, strength and pack size, to ensure as far as possible 'like-with-like' comparisons. In those instances where different prices were observed in comparison countries for an identical form or where the pack size was close to Australia's, higher and lower estimates of price comparisons were reported.

Consequently, the methodology used in this study permits country-specific, pair-wise comparisons of prices for those products covered by the study, and which are available in both countries.[11] *The results provide an indication of how Australian prices compare with those in each country covered by the study, based on Australian volumes purchased. They cannot be used to draw inferences about price levels across the comparison countries.*

Finally, this study reports the results of a comparison of prices at (or as close as possible to) 30 June 2000. Previous studies have utilised different methodologies and samples of pharmaceuticals. Some studies have attempted to cover a large number of countries but, as a result, have covered relatively few molecules. In undertaking this study, the Commission has attempted to achieve a broad coverage of the high volume molecules on the PBS, focusing on a smaller number of key countries. *Due to differences in methods, samples and data, the results are not directly comparable with those of previous studies discussed below.*

1.3 Previous studies

A significant body of literature exists on international comparisons of pharmaceutical prices. Much of this work was undertaken over the 1990s, and focused on prices in the US compared with a range of other countries (see, for example, GAO 1992, 1994, 2000c, Andersson 1995, Danzon and Kim 1998, and Danzon and Chao 2000). Danzon (1996) also gave evidence to the US Senate Committee on Health, Education, Labor and Pensions on, among other things, the key criteria necessary to conduct valid international comparisons of pharmaceutical prices.

As discussed above, it is commonly held that manufacturer prices in Australia for PBS-listed pharmaceuticals are lower than those in many other developed countries.

[11] The number of products available in all of the comparison countries was too small to allow meaningful comparisons on a multi-country basis (section 3.1).

This view is based on previous price comparison studies that have included Australia. These are listed in table 1.1, and were summarised by the Industry Commission in its inquiry into *The Pharmaceutical Industry* (IC 1996).

Table 1.1 **International pharmaceutical price comparisons**
Results of previous studies

Study	*Year of comparison*	*Countries in the sample*[a]	*Products in the basket*	*Australian prices*[b]
		no.	no.	%
PBPA 1996	1996	2[c]	165	91
APMA 1996	1995	18	38	73
Balasubramaniam 1995	nes	29	22	75
BIE 1991	1990	17	53	69
Parry & Creyke 1991	1990	nes	80	50
Peat Marwick 1991	1988	12	22	59
Parry & Thwaites 1988	1987	12	80	55
IAC 1986	1985	2[d]	9	73
Merck, Sharp & Dohme 1986	1985	20	17	47
APMA 1982	1982	13	58	56

a Sample includes Australia. **b** Percentage of international prices. All unweighted price comparisons except for IAC (1986). **c** Comparison country is the UK. **d** Comparison country is NZ. **nes** Not elsewhere specified.

Source: IC (1996).

On face value, the comparisons suggest that pharmaceutical prices in Australia have been anywhere from 47 to 91 per cent of the level of overseas prices.

Many of these previous studies suffer from significant methodological flaws, calling into question the accuracy of their results. For instance, the Industry Commission had particular concerns about the selection of countries in benchmark groups and the practice of aggregating all products in terms of a single, unweighted average price.

The Industry Commission concluded that Australian pharmaceutical prices were well below international prices but that the difference appeared to be declining over time. It also concluded that price differences were likely to be smaller for new innovative pharmaceuticals compared to items in other categories.

1.4 The Commission's approach

Although this study is not a formal public inquiry, the Commission has undertaken extensive consultations with, and encouraged input from, a number of interested parties.

After receipt of the terms of reference, the Commission held discussions with officials from Government (the Department of Industry, Science and Resources, and DHAC) and the pharmaceutical industry, including the Australian Pharmaceutical Manufacturers Association. The Commission also convened a roundtable meeting with interested parties to discuss its proposed approach to undertaking the study. This roundtable provided a number of valuable suggestions for improving the Commission's approach.

In late April 2001, the Commission circulated a work-in-progress report to a range of interested parties. Preliminary results were discussed at a further roundtable meeting held on 29 May 2001. This meeting provided an opportunity for industry and government officials to provide comments on the methodology, preliminary results and reasons for the observed price differences.

In addition, the Commission also sought information from sources in each of the comparison countries, on the subsidy and cost-containment policies prevailing in those countries. These sources provided a range of useful information and assisted the Commission in understanding the regulatory mechanisms affecting pharmaceutical prices in these countries.

The Commission would like to take this opportunity to thank the many people, in Australia and overseas who contributed through providing information and comment on aspects of the study.

Further details on the consultations undertaken by the Commission are set out in appendix A.

1.5 Outline of the report

The pharmaceutical industry is characterised by extensive government interventions affecting the demand and supply of pharmaceuticals. Chapter 2 discusses those government interventions in the industry which have direct implications for the international pricing of pharmaceuticals. Amongst other things, this discussion assists in identifying suitable countries to include in price comparisons.

The key features of the methodology for undertaking the comparison of manufacturer prices, and the results are set out in chapter 3. The chapter reports a comparison of manufacturers' prices as at 30 June 2000 for all categories of Australia's top-selling 150 molecules, as well as for individual pharmaceutical categories (new innovative, me-too and generics).

The terms of reference also require the Commission to explain, if possible, the reasons for any price differences. Chapter 4 identifies the principal methods that can be used to assess the results, and examines some of the many factors that may have contributed to the price differences identified in the previous chapter. Given the difficulties in attributing causes to the observed price differences, the chapter also identifies areas where further information and analysis are required.

2 Government interventions

Prior to examining the evidence on international price differences for pharmaceuticals listed on the Pharmaceutical Benefits Scheme (PBS), this chapter examines some of the government interventions that may give rise to price differences, drawing on examples from various countries. The chapter also attempts to identify an appropriate group of countries on which to base price comparisons.

Most major pharmaceuticals available in Australia are traded internationally. International trade normally tends to equalise manufacturer prices across various markets. However, a number of government interventions may affect pharmaceutical prices, such as patents, trade restrictions, pharmaceutical approval procedures, subsidies and cost-containment measures.

Differences across countries in the nature and effectiveness of these interventions may explain any observed inter-country price differences.

2.1 Patent protection

Patent protection (often combined with restrictions on parallel importing) may allow pharmaceutical manufacturers to price discriminate across markets, with higher prices charged in those countries and markets where demand is relatively insensitive to price changes.[1]

The process of developing a new pharmaceutical commonly involves the identification of potentially useful chemical substances, the synthesis and extraction of these substances, and their testing in animals, and ultimately in humans, to assess their therapeutic effects and commercial value. Due to the significant costs and lags involved in the identification, development and testing of pharmaceuticals, the industry looks to the patent system to provide it with a means to recoup these up-front expenditures (box 2.1).

1 Parallel importing occurs when an intermediary (usually a wholesaler or a retail pharmacist) buys a patented pharmaceutical in one country, and exports it to a second country, without the consent of the patent holder. To provide an incentive for parallel trade to occur, the price difference between countries must be sufficiently large to outweigh transport and other trade-related costs.

Box 2.1 **Pharmaceutical research expenditure**

The costs of manufacturing pharmaceuticals are considered to be low relative to total production costs (Schweitzer 1997, p. 101). According to Danzon, on average, R&D expenditure accounts for around 30 per cent, marketing cost accounts for around 25 per cent, and all manufacturing and distribution costs account for around 25 per cent of the total lifetime costs of creating, producing and distributing pharmaceuticals (cited in CSES 1999, p. 9).

According to the US Office of Technology Assessment, the cost of R&D per successful new pharmaceutical, at the time of market approval in 1993, was US$359 million (cited in Lofgren 1996, p. 89). Further, only around three out of ten pharmaceuticals marketed cover their development costs (Schweitzer 1997, p. 27).

A few countries account for a large share of the new pharmaceutical patents that are awarded around the world. The US has the highest proportion of patent applications at 61.6 per cent, followed by the European Union at 24.5 per cent, Japan at 4.8 per cent, and the rest of the world at 9.1 per cent (EFPIA 2000, p. 24).

Sources: CSES (1999); (EFPIA 2000); Lofgren (1996); Schweitzer (1997).

Patents may enable manufacturers to charge higher prices for some items and hence have implications for the international pricing of pharmaceuticals.

A patent confers monopoly rights on the holder by excluding others from making or selling a patented product without the holder's consent. In most developed countries (including Australia), the patent term for pharmaceuticals and for other products and processes, is 20 years.[2] The principal economic rationale for awarding patents is to stimulate investment in research and innovation. It is argued that, without patents, others may be able to imitate new products, thereby limiting the innovator's ability to recoup these research and development (R&D) expenditures.

Through enhancing the ability of companies to finance pharmaceutical R&D, patents may indirectly contribute to increased life expectancy, improvements in peoples' quality of life, and to the possible eradication of life threatening diseases. In exchange, patents may enable the holder to earn monopoly profits for a limited

2 Each country establishes its own intellectual property laws. A company that wishes to market a new product in several countries must obtain separate patents in each country. Many countries also permit period extensions to compensate for delays in obtaining marketing approvals. In Australia, if the period between the filing of the Australian patent application and the granting of marketing approval exceeds five years, the patent term may be extended by up to five years. In the United States (US), pharmaceuticals containing a new chemical entity never before approved by the Food and Drug Administration (FDA) may qualify for an extended patent term of up to five years (appendix B).

period through charging prices that appear to be high in relation to the unit costs of production.

At any time, there may be a number of companies developing new pharmaceuticals to treat a particular condition. The company which is first to patent and market a new 'breakthrough' pharmaceutical, which faces little or no competition from alternative therapies, may have the ability to exploit the advantage of being first onto the market, by charging a price which maximises its profits for the duration of the patent.

However, the ability of others to develop and market products with a different chemical structure but with the same or similar therapeutic effects (me-too products) may limit the ability of pharmaceutical patent holders to earn monopoly profits for the duration of the patent.[3]

Competition from 'therapeutic alternatives' is considered to be relatively widespread in the pharmaceutical industry. According to the Boston Consulting Group (BCG 1999, p. 8), because patent laws allow access to patent information after a short period, competitors can use this information to inform their own research. As a result, new pharmaceuticals tend to be followed by me-toos (competitive modifications of the originator). For the US market, the Congressional Budget Office estimated that a breakthrough pharmaceutical usually has between one and six years on the market before a me-too version is introduced (CBO 1998, p. xi).

In principle, companies will seek to set a price for patent-protected products that maximises their profit — taking into account the price sensitivity of demand for the pharmaceutical, the costs of developing and manufacturing it, and competition from broadly equivalent products (me-too pharmaceuticals). If the conditions facing the holder of a pharmaceutical patent vary across countries then the holder may want to set a different price in each country where the product is marketed.

For example, consumers in countries which have a strong preference for pharmaceuticals over other forms of treatment, may be less sensitive on average to price changes. Consequently, companies may be able to sustain higher prices in these countries compared to those where consumer preferences for pharmaceuticals are not as strong.

3 Generally, pharmaceutical patents cover the chemical composition but not the therapeutic uses. Therefore, other firms may be able to develop a chemically distinct but therapeutically similar pharmaceutical which also could be awarded a patent.

Demographic factors also may affect pharmaceutical consumption and therefore prices in a particular country. Older people (aged 65 and over) tend to account for a relatively large share of pharmaceutical consumption in developed countries. If older patients are on average less sensitive to prices, patent holders may seek to recover a larger share of their R&D costs in those countries with a larger share of older persons. However, the reverse may hold if older persons are actually more price sensitive. This could occur if the elderly tend to consume treatments for chronic rather than acute illnesses, and the price sensitivity of demand for pharmaceuticals designed to treat chronic illnesses is greater than that for acute forms of treatment.

In principle, as products move through their life-cycle, international price differences could be expected to diminish over time, despite inter-country differences in demand conditions, through mechanisms such as parallel trading.

However, manufacturers may be able to sustain the practice of setting different prices across countries because patent laws generally protect patented pharmaceuticals against parallel importation. Despite some legal debate it generally is considered that patent and design legislation in Australia provides the exclusive right over importation of a product to the patent holder (Revesz 1999, p. 44). Thus, if the price of a patented pharmaceutical product in Australia is above the price in another country, a foreign distributor could be in breach of the patent if it tried to import a product protected by an Australian patent (without the permission of the Australian patent holder).[4]

The World Trade Organization (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) attempts to harmonise intellectual property protection in most developed countries. The TRIPS agreement requires countries to grant patent protection to pharmaceutical products for a minimum period of 20 years. The agreement also encourages member countries to respect patent laws across countries, including enabling manufacturers of patented pharmaceuticals to prevent parallel trade in their products. There are important exceptions, including in the area of compulsory licensing.[5]

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4 Patent rights may be over-ridden by international trading agreements and/or national laws. For example, the European Union (EU) allows parallel trade within the Union. Under EU law, patent holders exhaust their exclusive rights to prevent movement of their products once they are placed on the market in any Member State. Unauthorised imports from outside the EU, however, are prohibited (Kanavos 1999b, pp. 161–162). In addition, NZ permits parallel importation of patented pharmaceutical products.

5 Under compulsory licensing, governments or a company may be permitted to manufacture and sell pharmaceuticals without the patent holder's permission. Compulsory licenses are generally issued on the basis of public interest considerations and are used mostly in developing countries.

In principle, when a pharmaceutical patent has expired in all countries, its price could be expected to converge internationally. Any attempt by a pharmaceutical company to charge a high price in one country would encourage buyers to import the product from lower-priced countries.

However, several factors may prevent complete convergence in generic prices, including the legislative, legal and regulatory obstacles that may discourage generic suppliers from entering a market (Goldberg 1997). Also, the imposition by one country of specific regulatory requirements may increase local prices relative to overseas prices if they increase costs for all domestically produced and imported generic pharmaceuticals (section 2.4).

In addition, advertising by manufacturers[6] and first-mover advantages may enable originator brands of generic pharmaceuticals to maintain high prices for sustained periods. According to Dong-Churl Suh (2000), an off-patent originator can maintain a high price and a significant share of the market because:

- patents, in effect, give an originator a first-mover advantage, especially if the originator invests heavily in promotional expenditures to develop brand loyalty; and
- new entrants incur high costs associated with disseminating the information necessary to assure consumers that their products are therapeutically equivalent to the original product.

2.2 Pharmaceutical subsidy arrangements

Pharmaceutical subsidy arrangements (including associated cost-containment mechanisms) is another key area of government intervention in the pharmaceutical industry. Most developed countries are similar to Australia in that governments, for social welfare and equity reasons, subsidise the consumption of prescription pharmaceuticals that have been approved for marketing by regulatory authorities.

The effect of subsidy arrangements on manufacturer prices is likely to depend on how subsidies are designed and administered.

Subsidy arrangements that provide universal coverage and subsidise an extensive list of pharmaceuticals are likely to stimulate a greater increase in demand for pharmaceuticals (and depending on the price, potentially increase the revenue of producers) compared to narrower subsidy schemes. The potential for an increase in

6 Most countries in the OECD prohibit direct advertising of pharmaceuticals to consumers (section 2.4).

the volume of sales encourages companies to submit their products for listing under a subsidy scheme.

Many Organisation for Economic Co-operation and Development (OECD) countries have established universal subsidy arrangements, covering an extensive range of products, that effectively enable the government to act as the principal purchaser of pharmaceuticals. These countries may have a positive list (companies must apply to have their products listed for subsidy), a negative list (where the government decides which products it will not subsidise) or a combination. Countries that control access to the subsidy list (positive list) may have relatively greater bargaining power compared to countries that agree to subsidise all new pharmaceuticals except those placed on a negative list. This could arise if it is relatively difficult to place products on the negative list (due to consumer and political resistance) and the list is relatively small.

The extent to which governments wish to use their power to negotiate lower pharmaceutical prices also may depend on the objectives of the government purchaser. For some governments, the principal objective may be to obtain access to necessary medicines at the lowest possible cost. Alternatively, some governments may choose not to use their buying power to negotiate the lowest possible prices. For instance, the UK Government may not be willing to use its bargaining power fully because one of its objectives is to encourage industry development (section 2.4).

There may be a direct relationship between the extent of subsidies and the downward pressure that governments may wish to exert on manufacturer prices through cost-containment arrangements, at least for patented (new innovative and me-too) pharmaceuticals. Cost-containment arrangements (such as price controls and prescribing guidelines) may be designed to lower manufacturer prices, to restrict the volume of sales of subsidised pharmaceuticals or to lower prices indirectly through influencing the price sensitivity of purchasers. Inter-country differences in the cost-containment mechanisms accompanying pharmaceutical subsidies may therefore give rise to international differences in manufacturer prices (section 2.3).

Before examining how differences in cost-containment mechanisms across countries may give rise to international price differences, it is worthwhile examining the main features of subsidy arrangements in OECD countries. This assists in identifying a suitable group of countries to include in price comparisons.

Pharmaceutical subsidy arrangements in the OECD

Pharmaceutical subsidy arrangements exist in all major OECD countries. The major differences, however, are with respect to:

- whether public or private arrangements predominate (that is, the percentage of the population covered by public or private schemes);
- eligibility for public subsidies (for example, the proportion of the population covered by the public subsidy scheme);
- the level of public subsidy offered (in terms of the size of subsidy list and the level of patient copayment);[7] and
- the type of subsidy list (positive, negative or both).

Australia has a public subsidy scheme for pharmaceuticals (the PBS), with universal coverage (all Australian residents and eligible foreign visitors, other than those treated by public hospitals). In 1996, the public sector accounted for around half of total expenditure on pharmaceuticals (table 2.1).[8]

In Australia, patients contribute around 20 per cent of the total cost of the PBS. Patients pay a maximum copayment for each PBS item, based on their welfare situation. There are two levels of maximum copayment, one for general patients ($21.90) and a lesser one for concessional patients ($3.50).[9] Copayments are generally not refundable from private health insurance.

Many developed OECD countries either rely on public pharmaceutical subsidy arrangements or have a mixture of public and private schemes. Within the group of countries where public schemes predominate, most are similar to Australia in that the subsidy arrangements provide universal coverage, with subsidies available on most pharmaceutical products, and patients are required to make some form of contribution towards the cost of purchases (table 2.1).

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7 Copayments are out-of-pocket contributions made by patients when purchasing a pharmaceutical. Copayments are intended to reduce unnecessary or excessive pharmaceutical consumption by making consumers bear at least part of the cost.

8 Private expenditure includes patient copayments for items subsidised under the PBS, pharmaceuticals supplied in private hospitals and non-PBS items purchased by consumers (including over –the-counter (OTC) products).

9 Individuals and families are protected from large overall expenses for PBS-listed medicines by an expenditure safety net. For general patients, once the eligible expenditure of a person and/or their immediate family exceeds $669.70 in a calendar year, the maximum patient copayment per item decreases from $21.90 to the concessional rate. For concessional patients, the $3.50 copayment per prescription item is removed once their total eligible expenditure exceeds $182 within a calendar year.

Table 2.1 **Characteristics of subsidy arrangements in selected OECD countries**

	Principal scheme[a]	*Eligibility for public subsidies*	*Is private insurance available?*	*Public share of pharmaceutical expenditure (per cent)*[b]	*Type of public copayment system*	*Private share of pharmaceutical expenditure (per cent)*[b]
	1999	**1999**	**1999**	**1997**	**1999**	**1997**
Ireland	Public	Universal	Yes	83.3	Fixed	16.2
Austria	Public	Universal	na	74.4 ('98)	Fixed	25.6 ('98)
Spain	Public	Universal	Yes	72.6	Proportional	27.4
Sweden	Public	Universal	No	71.3	Proportional	28.7
NZ	Public	Universal	No	70.9	Fixed	29.1
Germany	Public	Universal	Yes	70.0	Proportional	30.0
Netherlands	Public	Limited[c]	Yes	64.4 ('98)	Proportional	35.6 ('98)
UK	Public	Universal	No	64.2	Fixed	35.8
France	Public	Universal	Yes	58.2 ('98)	Proportional	41.8 ('98)
Australia	**Public**	**Universal**	**No**	**52.5**	**Fixed**	**47.5**
Finland	Public	Universal	na	48.1 ('98)	Proportional	51.9 ('98)
Belgium	Public	Universal	na	44.7	Proportional	55.3
Italy	Public	Universal	No	40.6	Proportional	59.4
Canada	Private	Mixed[d]	Yes	32.0 ('99)	Proportional	68.0 ('99)
US	Private	Limited[e]	Yes	15.4 ('98)	Mixed/ Proportional	84.6 ('98)

a Indicates whether a public or private pharmaceutical subsidy scheme covers the largest proportion of the population. **b** Pharmaceutical expenditure comprises prescription medicines, OTC products and expenditure on other medical non-durables (such as bandages, elasticised stockings, incontinence articles, condoms and other mechanical contraceptive devices). Pharmaceuticals consumed in hospitals are excluded. **c** High income earners in the Netherlands are excluded from statutory health insurance and must hold private health insurance. **d** Some provincial schemes in Canada are universal (eg Alberta, British Columbia and Quebec), while others are limited to particular groups (eg Ontario). Eligibility for Federal Government subsidies is limited to the First Nations and Inuit, war veterans and members of the Royal Canadian Mounties and armed forces. **e** The US Government generally subsidises pharmaceuticals for the poor (through Medicaid) and veterans of military service and members of the armed forces (through the Department of Veterans Affairs). Medicaid accounts for around 12 per cent of the US market by sales. Sales through the Department of Veterans Affairs account for approximately 1.5 per cent of the market. **na** Not available.

Sources: GAO (2000a); HC (2000); Jacobzone (2000); Kanavos (1999b); Ministry of Health and Long-Term Care (2001); OECD (1998).

Only the US and Canada appear to be significantly different from Australia in terms of eligibility for public subsidies. Private insurance schemes cover a large proportion of people in these countries, and eligibility for public pharmaceutical subsidies is limited to certain segments of the population.[10] Consequently, the shares of public expenditure in total US and Canadian pharmaceutical spending are low compared to Australia and many other countries.

10 In Canada, private plans funded around 62 per cent of sales of prescription medicines in 1995 (appendix B).

There is significant variation in the respective shares of the public and private sectors in funding pharmaceutical expenditure amongst the group of countries that provide universal pharmaceutical subsidies (table 2.1). For these countries, private insurance schemes exist in Ireland, Spain, Germany and France, which partly cover the cost to consumers of pharmaceuticals. In those countries without private insurance coverage, the private expenditure on pharmaceuticals reflects mostly consumer copayments and expenditure on non-subsidised products.

The predominant form of copayment system for the countries reported in table 2.1 is proportional to the final price.[11] A fixed or flat rate system exists for some of the countries, while the US may have a mixture of fixed and proportional systems.

Within the OECD, countries maintain a mix of positive and negative subsidy lists. However, many countries have a positive list only (including Australia, NZ, France, Canada, and the US). Some countries (such as the UK) subsidise all prescription pharmaceuticals once they have been approved for marketing but may decide to remove the subsidy on some products or groups of products (involving placing them on a negative list). Other countries (such as Sweden and Spain) have a combination of positive and negative lists.

2.3 Cost-containment policies

The introduction of new, more expensive pharmaceuticals, combined with growth in demand from aging populations, have caused government outlays on pharmaceuticals to increase rapidly in most OECD countries. Between 1990 and 1997, a number of OECD countries experienced average annual nominal growth rates in public expenditure on pharmaceuticals of eight per cent or more, including the US (13.5 per cent), Australia (11.4 per cent), Denmark (11.1 per cent), Austria (9.5 per cent), Ireland (9.0 per cent), Japan (8.0 per cent) and the UK (8.0 per cent) (OECD 2000).[12]

In response to growing budgetary pressures, governments have implemented a range of cost-containment measures. Some measures (such as price controls) may influence manufacturer prices directly. Others are designed to limit growth in demand by restricting the volume of sales for a given subsidy level. A third group of measures is designed to affect manufacturer prices indirectly by influencing the demand for pharmaceuticals (such as physician budgets and generic substitution

[11] Most countries also have safety net arrangements to protect individuals or families from large expenditure on pharmaceuticals.

[12] The expenditure figures also include spending on a wide range of other medical items, such as bandages, elasticised stockings, incontinence articles, and contraceptive devices.

policies). Taken together, differences in the nature and application of these cost-containment mechanisms may contribute to international price differences.

Price and profit controls

In most OECD countries, manufacturers are free to set the price of their pharmaceuticals when the product is launched in the market. However, if manufacturers want their pharmaceuticals subsidised by the government (or a private insurer in countries such as the US), they also may have to agree to accept a lower price for their products.

Reimbursement pricing system

In the past, direct price controls (involving the fixing of prices on a product by product basis) were relatively common in the OECD. However, most OECD countries have moved away from these controls in favour of reimbursement pricing systems.

Under reimbursement pricing systems, public or private pharmaceutical insurers set price ceilings for subsidised items (where the list of subsidised items is commonly referred to as a formulary). Insurers agree to cover or reimburse the cost of listed pharmaceuticals up to the ceiling (reimbursement price). Manufacturers are free to price above the reimbursement price but the patient usually must pay the difference between the reimbursement price and the manufacturer's price (Dickson and Redwood 1998, p. 472). Box 2.2 describes the relationship between reimbursement and manufacturer prices in Australia.

Most governments in the OECD have established reimbursement pricing systems. However, they may use different methods to set reimbursement prices. For example, reimbursement prices can be determined using information from: economic evaluations; reference pricing; and international price benchmarking.

Economic evaluation

Economic evaluations aim to examine the clinical and economic impact of pharmaceuticals, requiring an assessment of the costs and health benefits to patients. Costs may include those associated with follow-up visits to and from physicians, other pharmaceutical use (for example, to treat side effects), hospital out-patient visits, diagnostic and therapeutic procedures in hospital, and in-patient stays in hospital.

Box 2.2 **Reimbursement and manufacturer prices in Australia**

When a PBS-listed pharmaceutical is purchased, the patient pays a copayment to the pharmacist (up to a fixed amount), and any delivery and after hours fee, brand or therapeutic premium, or special patient contribution that may be applicable. The pharmacist in turn is reimbursed by the Government for any difference between the total patient copayment and the reimbursement price of the pharmaceutical. This reimbursement price set by the Government includes the manufacturer price, retail mark-ups (to wholesaler and pharmacist) and dispensing fees.

The mark-ups to retailers in Australia are a set percentage of the agreed price to the pharmacist. The dispensing fee also is a set amount per item. The greatest proportion of the Government's agreed price to pharmacists goes to the manufacturer (90 per cent) (DHAC 1999a, p. 11).

Although the reimbursement price (set by the Government) is not the same as the manufacturer's price, there is a strong relationship between the two. The Government sets the reimbursement price, taking into account what is charged by the manufacturer. The manufacturer, if it wants its product listed on the PBS, will negotiate a price that is acceptable to itself and the Government.

Sources: DHAC (1999a, 1999b).

There are four principal types of economic evaluation of pharmaceuticals. While the costs of a particular therapy usually are measured in monetary terms, the outcomes may be expressed in monetary or non-monetary terms (for example, lives saved). According to McKie et al. (1998), the main techniques are:

- cost-minimisation analysis, which compares the costs of two or more therapies with identical outcomes (for example, an identical reduction in mortality rates for patients);
- cost-effectiveness analysis, may be used where therapies have the same outcome, but the outcome can be achieved to different degrees (for example, the level of reduction in a patient's blood pressure). It aims to identify the most efficient therapy that minimises cost per unit of outcome (for example, minimise costs per life saved). A product may be considered to be cost-effective compared to alternatives if it is less expensive but just as effective as its comparator, more expensive while providing an additional benefit that is worth the extra cost, or it has the same cost but is more effective than its comparator;
- cost-benefit analysis, may be used to compare therapies that have multiple outcomes and these outcomes may be achieved to different degrees. Outcomes such as improvements in a patient's quality of life are expressed in monetary terms and compared with monetary costs. The objective is to select the therapy that provides the largest net monetary benefit; and

- cost-utility analysis, compares therapies that have multiple outcomes which may be achieved to different degrees. The quality of life is explicitly quantified and included in this analysis. Rather than using a monetary value, outcomes are expressed using a measure of the improvement in health status (usually the Quality Adjusted Life Years gained or QALYs).[13] The method is useful when evaluating alternatives that are life-extending, yet with significant side effects, such as chemotherapy. Alternative projects can be ranked to select the one that minimises cost per QALY gained.

Several countries require companies seeking listing for new products (or changes in prices or approved uses) to submit an economic evaluation. This analysis may form the basis for decisions about reimbursement prices. Economic evaluations are mandatory in very few countries, such as Australia (since 1993), NZ and some parts of Canada (British Columbia and Ontario). Economic evaluations have been undertaken on an ad hoc basis in the UK, Sweden, Spain and France.

The type of analysis used in Australia to establish or review reimbursement prices may depend on the characteristics of the pharmaceutical. For example, when deciding whether a new pharmaceutical is to be listed on the PBS, the manufacturer has to provide information to the Pharmaceutical Benefit Advisory Committee (PBAC) on the cost-effectiveness of its product relative to that of therapeutic alternatives. According to Birkett et al. (2001, p. 110), 37 per cent of pharmaceuticals listed on the PBS have been subjected to economic evaluation — most involving cost minimisation or cost-effectiveness analyses. However, the proportion of cost-utility analyses has been on the rise since 1996.

If an alternative therapy is not available, pricing negotiations for a new innovative product may consider the cost of production (including R&D) and prices in comparable countries. Price-volume agreements also may be used to determine the reimbursement price. Under a price-volume agreement, the agreed price of a pharmaceutical is based on a forecast volume of sales. If the actual sales volume exceeds the forecast, the price of the pharmaceutical is usually reviewed downwards.

In providing comments on the Commission's preliminary analysis, some roundtable participants considered that Australia's requirements for evidence-based economic evaluations are amongst the most stringent in the world.

In Australia, the use of cost-effectiveness analysis involves evaluating an extensive set of outcomes, including the changes in the use of resources (which includes

[13] Results are usually expressed as cost per QALY gained. QALYs express life years gained weighted by a utility index of health-related quality of life.

medical services that are not subsidised through the PBS) that are likely to result from the introduction of the proposed pharmaceutical (DHAC 1999c).[14]

According to Cookson (2000), there is a preference for 'hard' evidence from trials rather than 'softer' evidence used in economic modeling (unless used in conjunction with trial data) or less rigorous scientific evidence, such as observational studies and expert opinion. With the 'hard' trial-based evidence, Australia's listing and pricing committees prefer the results obtained from 'head-to-head randomised' control trials that directly compare the proposed pharmaceutical with the existing pharmaceutical therapy used by most prescribers in Australia for the same indication.[15]

In Australia, if a pharmaceutical that has been shown to be therapeutically more effective than its comparator and it is priced above the existing treatment, the manufacturer is requested to quantify the extra health benefits and weigh them against the higher cost. In doing so, patient-relevant outcomes are preferred (particularly final outcomes such as deaths prevented) based on a preliminary trial-based economic analysis, followed by a modelled analysis where appropriate (Birkett et al. 2001, pp. 107–108).

As noted above, Australia is one of the few countries to require companies seeking reimbursement for their products to submit an economic evaluation. In most other countries, similar issues to those considered in Australia are incorporated in decisions about reimbursement. For instance, in Spain and France, factors such as the degree of 'innovation' and the prices of therapeutically similar treatments are considered in pricing negotiations. The difference between Australia and these countries appears to be that in Australia these methods are central to decision-making and they are incorporated in a much more formal and rigorous way.

Reference pricing systems

A number of OECD countries establish reimbursement rates for new and established pharmaceuticals using a reference pricing system (box 2.3). Under a reference pricing system, reimbursement prices are commonly set for a group or cluster of similar or identical pharmaceuticals. Using this approach, pharmaceuticals that have the same chemical structure and/or those that are therapeutically

14 Manufacturers are encouraged to submit evaluations that are relevant to Australia, taking into account the unit costs, the patterns of resources used and the way in which the Australian health care system is funded (DHAC 1999c).

15 In circumstances where there is no pharmaceutical that can be used as a comparator, the main comparator would be the standard non-pharmaceutical therapy currently used to manage the indication (Birkett et al. 2001, p. 107).

interchangeable, may be grouped together to form a reference group. The government may set a single reference (benchmark) price for the entire reference group. If the reference price is set at the level of the lowest-priced item in the group, manufacturers of the higher priced items may be required to lower their price to the benchmark. In some cases, under the brand premium or therapeutic group premium (TGP) policies, manufacturers may be permitted to sell at a higher price (with the consumer paying the difference between the selling price and reference price). If they decide to sell at a higher price they face the risk of losing market share to the cheaper, more highly subsidised product.

Australia, based on the type of reference pricing system implemented, appears to have a relatively strict price control system in place for subsidised pharmaceuticals. The reimbursement prices for many items in Australia are determined by a reference pricing system, which has reference groups that may include patented products that are therapeutically interchangeable as well as generic products. Originally, six therapeutic groups were subject to the reference pricing system in Australia, using the weighted average monthly treatment cost (WAMTC) methodology.[16] However, pricing reviews for one group (selective serotonin re-uptake inhibitors (SSRIs)) were suspended in mid-1999 pending a review of this pricing methodology.[17] Of the remaining five, four are also subject to the TGP.[18]

Like Australia, NZ and British Columbia (in Canada) also define reference groups to include patented pharmaceuticals and off-patent pharmaceuticals that are therapeutically interchangeable with different active ingredients.

In contrast to Australia, most OECD countries with reference pricing systems define reference groups to include products that are off-patent and contain the same active ingredients (such as Italy, Sweden and Spain). For these countries, suppliers of originator brands may be unable to obtain significantly higher premiums for their products, compared to countries that do not implement a reference pricing system.

16 The WAMTC methodology is used to compare the treatment cost of therapeutically equivalent pharmaceuticals that are available in different dosage types, strengths and pack sizes. The aim is to adjust the prices of these pharmaceuticals so that their cost per month of treatment is equivalent (PBPA 2001, p. 6).

17 In 2001, pricing reviews for the remaining five were suspended as well, pending a review of the WAMTC pricing methodology.

18 Suppliers of pharmaceuticals in one of the four groups covered by the TGP are permitted to charge a premium, over the reimbursed price, which is paid by the consumer. The four groups under the TGP are: ACE Inhibitors and Calcium Channel Blockers for cardiovascular disease (hypertension), HMG CoA reductase inhibitors for lowering blood cholesterol and H2 receptor antagonists for peptic ulcers.

Box 2.3 **Price and profit controls in selected OECD countries**

Canada: Launch prices of patented products are reviewed at the federal level — prices should not be higher than the median price in seven other developed countries. Prices also are indexed to the CPI. The provinces also set reimbursement prices for subsidised products. Ontario uses a reference pricing system for most generics — reimbursing the lowest price offered in Canada. British Columbia sets reimbursed prices in reference to the product 'which is medically effective and the most cost effective as determined by current published scientific studies'. Therapeutically interchangeable/comparable pharmaceuticals (patent or off-patent) of different chemical structures can be clustered together.

France: The 'convention' (five-year contract) is the main method by which prices of reimbursed pharmaceuticals are set. Negotiations are based on sales forecasts, made at the therapeutic class level. If actual sales exceed the targets, firms are required to pay rebates. Prices of older products can be reduced in order to receive higher prices for newer products. Reimbursed prices are based on a number of factors including: prices of local comparators; prices of the product in other European markets; sales forecasts for the next three years; and the degree of 'innovativeness' of the product (the therapeutic improvement over existing products).

Germany: Until 1996, all listed pharmaceuticals (including patented items) were allocated to one of three reference groups: the same active ingredients (level 1), chemically different active ingredients (level 2); or pharmacologically comparable effects (level 3). The reimbursement price for a pharmaceutical in a particular reference group was then based on the price of all other pharmaceuticals in the group. Since 1996, new patented pharmaceuticals have not been included in the level 2 or 3 reference pricing groups until their patents expire.

Italy: Companies are free to set prices of pharmaceuticals unless reimbursement is sought. Prices of reimbursed products reflect the average price charged in all other European Community countries. Other factors taken into account include cost-benefit ratios, sales forecasts, number of patients, and financial factors such as related investments and increases in local employment. In 1996, a reference pricing system was introduced. Chemically equivalent pharmaceuticals must have the same price per unit of active ingredient. If prices are not lowered to the cheapest referenced value, the product is de-listed and the patient is required to pay the full price for the product.

NZ: The reference pricing system is similar to that used in Australia in that reference clusters can include patented and off-patent products. Since 1997, other methods have been introduced in an effort to reduce manufacturer prices for off-patent products, including the use of exclusive tenders and companies agreeing to reduce the price of certain products, in exchange for Government agreement not to tender the products.

(Continued next page)

Box 2.3 (continued)

Spain: The Government controls the prices of all prescribed pharmaceuticals. A range of factors are taken into account when setting the price of reimbursed products including the 'innovativeness' of the product and the prices of therapeutic equivalents available locally. Price-volume agreements are used frequently for more expensive products. A reference pricing system was introduced in 1999, applying only to products with a bioequivalent generic on the market.

Sweden: Reference pricing applies only to off-patent products (including originator brands). International price comparisons also are used to set the price of a pharmaceutical — aiming to award a 'European price'. Pricing of new innovative pharmaceuticals are usually accompanied by a price-volume agreement.

The Netherlands: Companies are not allowed to sell pharmaceuticals (including non-subsidised ones) at prices higher than the average of the pharmacy purchase prices of 'comparable' products in Belgium, France, Germany and the UK. In setting maximum prices, the Government can include the price of generics in the reference countries (even if the product is patented in the Netherlands).

UK: Companies are free to set prices for new products. But under a voluntary agreement, the Government regulates the profitability of pharmaceutical companies supplying branded products to the National Health Service under the Pharmaceutical Price Regulation Scheme. Under this scheme, firms are prevented from raising the prices of existing pharmaceuticals without Government permission.

US: Most government programs have some form of price control such as a mandatory rebate, discount, price cap or limit on price increases. In the private sector, managed care plans directly negotiate rebates from manufacturers based on their ability to use their formularies to steer members toward a particular pharmaceutical.

Sources: BCG (1999); DHAC (1999b); Dickson et al. (1998); Jacobzone (2000); Kanavos (1999b).

Since newer patented products can be priced against older off-patent products in countries such as Australia and NZ, it is possible that manufacturer prices for patented pharmaceuticals included in the reference pricing system in these countries may be lower than those in countries where the reference groups do not contain patented products. This effect may be most pronounced if the reimbursement ceiling for a reference group is fixed at the level of the lowest priced product in the group (Australia and NZ). In some countries, the reimbursement price may be set using an averaging process among the pharmaceuticals within a reference group (Germany and Sweden) (Burstall et al. 1999, p. 672).

Many OECD countries also may take a range of other factors into account, especially when determining reimbursement prices for new innovative products. These additional factors include: production and R&D costs; the therapeutic value of the product; evidence of clinical improvement (degree of innovation) of the

product over existing similar products; and price-volume agreements (box 2.3). The weights applied to other factors may differ across countries.

International price benchmarking

International price benchmarking (the practice of comparing pharmaceutical prices across countries for the purpose of determining reimbursement prices) is also commonly used in a number of OECD countries such as the Netherlands, Italy, Japan, France, Sweden, Spain and Canada, and to a lesser degree in Australia and NZ.[19] The widespread use of international reference pricing could be expected to reduce the scope for manufacturers of patented new innovative medicines to set different prices across countries based on differences in demand sensitivity. This could occur because a low manufacturer price in one country could be used to establish prices in other countries. With widespread use of international reference pricing, manufacturers may be more likely to set a single price across a number of countries at launch that will give the highest returns when all markets are taken into account.[20]

Direct price and profit controls

Some countries also use direct price and profit controls to supplement reimbursement pricing. For instance, prior to marketing, the prices of all pharmaceuticals (not just reimbursed products) must be approved by governments in Spain and Belgium. Manufacturers in the UK (although not subject to direct price controls) have entered into an agreement with the Government which involves capping profit levels on sales to the National Health Service (box 2.3 and appendix B).[21]

In the US market, manufacturers are largely free to set prices as they wish. However, most government programs that cover prescription pharmaceuticals (such

19 According to Danzon (1997) the use of international price benchmarking also has been proposed in the US. Under one proposal, the allowed prices of pharmaceuticals in the US would be based on the lowest price paid across 22 countries, including countries such as NZ. Several bills are before state legislatures in the US that would cap prices in those states at the price in Canada.

20 International price benchmarking also may provide companies with an incentive to post high list prices (especially in those countries that are used as international benchmarks) but to offer discounts and other less transparent forms of price reductions to buyers.

21 Countries such as Spain and France also implement some form of profit control, although this is not the only method used for price negotiations.

as Medicaid) use some form of price control.[22] These controls can take the form of mandatory discounts, price caps or limits on price increases (appendix B).

Other price control measures

A variety of other price control measures have been used from time to time by governments in the OECD. They include price freezes, across-the-board price reductions, price reductions for exceeding an agreed level of sales,[23] fixed expenditure budgets,[24] and performance requirements (Kanavos 1999a). For example, Germany, Italy, the UK (from 1993 to 1996) and Spain (from 1994 to 1997) have all used price freezes. Across-the-board price reductions have been used as a cost control method in Italy (2.5 per cent price cut in 1995), Spain (three per cent price cut in 1994), the UK (a price cut of 4.5 per cent in 1999) and Belgium (in 1996). The use of measures such as price freezes and price reductions by governments may contribute to the opening-up of price gaps between the countries that have used them and those countries that do not.

Governments also have used volume controls to contain costs. This may involve restricting the number of repeat prescriptions that may be used, limiting the uses (indications) on subsidised items, or requiring authorisation before a pharmaceutical can be prescribed for treating a particular condition. For example, in Australia, some pharmaceuticals may be approved for use to treat several conditions. However, the product may be subsidised for the treatment of only one of these conditions.

Performance requirements are widely used to establish reimbursement prices in the OECD (Kanavos 1999b). It involves governments setting reimbursement prices partly on the basis of a company's ability to increase the local employment level or the level of R&D investment undertaken locally. Higher prices may be awarded to companies that agree to undertake a certain level of local production or R&D. It could be expected that countries with relatively large pharmaceutical industries (such as the US, the UK, Switzerland, Germany, France, Sweden and Japan), therefore, may award relatively higher reimbursement prices to pharmaceuticals that are developed and manufactured locally.

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22 Government programs in the US cover only a small percentage of the total US market (appendix B).

23 Under this method, the government imposes a fixed budget for pharmaceutical expenditure and any excess on that budget is paid back by the industry. This method of controlling expenditure has been used in the UK, Germany, France, Italy and Spain.

24 Under a fixed budget system, governments seek to maintain a ceiling on total pharmaceutical expenditure through increasing or decreasing the number of subsidised pharmaceuticals available to consumers. This approach has been used in NZ (appendix B).

There are differing views about the effectiveness of the various methods of controlling prices. For instance, Danzon and Chao (2000, p. 314) argue that countries with strict forms of price control (such as Italy, France and Japan) tend to have lower prices than countries with relatively free pricing (such as the US, the UK, Canada and Germany). On the other hand, Dickson and Redwood (1998, p. 476) argue that while the introduction of reference pricing systems caused a once-off lowering in prices, they have not limited the rate of price increases.

Other cost-containment measures

In addition to price controls, governments and private insurers, in an attempt to contain costs, have implemented a variety of measures essentially designed to influence the demand for pharmaceuticals through altering the incentives facing consumers, physicians and pharmacists. Variations across countries in the types of mechanisms applied and their effectiveness could cause corresponding differences in the demand conditions facing companies and, therefore, may give rise to international price differences for patented pharmaceuticals that are subject to limited competition from me-too products.

One way in which governments and private insurers seek to influence consumer demand is through copayments (section 2.2). Demand for pharmaceuticals is considered to be more sensitive to price in countries where copayments are proportional to the final price because the out-of-pocket costs are linked to the total cost of pharmaceuticals. Under a fixed copayment system, the consumer may pay the same amount irrespective of the total cost of alternative pharmaceuticals. According to the OECD (2001, pp. 40, 44), a subsidy arrangement that fully covers the cost of pharmaceuticals may lessen the incentive to use cheaper alternatives.[25] Further, the higher the marginal payment between two products that are considered therapeutically comparable, the greater the incentive for consumers to use the cheaper substitute (OECD 2001, p. 44).

Many governments and private insurers also seek to influence the behaviour of physicians and pharmacists by employing a range of mechanisms in an effort to make physicians' prescribing decisions more sensitive to price (table 2.2).

Many countries have established prescribing guidelines in an effort to encourage physicians to prescribe rationally and consistently according to the pharmaceutical's

[25] For example, in countries such as France, the copayment policy may not affect consumer behaviour because consumers are able to seek reimbursement of most or all of the copayments through private insurance (Jacobzone 2000, p. 29).

indications and the therapeutic needs of their patients.[26] Several countries also have imposed spending limits on physicians (for example, through setting a budget for each physician or medical practice). Most governments also impose direct limits on the volume/repeats prescribed per day (or per physician).

Table 2.2 **Methods of influencing demand in selected countries**

Country	*Doctor*			*Pharmacist*
	Prescribing guidelines/possible sanctions	*Fixed budget/Global volume targets*	*Some type of individual control per physician, per episode or day*	*Generic substitution permitted*
Australia[a]	Yes/Sanctions may exist[b]	No	Yes	Yes
Canada	Yes (in some provinces)/ Sanctions may exist	No	Yes	Yes
France	Yes/Sanctions may exist	Yes	Yes	Yes
Germany	Yes/Sanctions may exist	Yes	na	Yes
Netherlands	Yes/No sanctions	No	Yes	Yes
NZ	Yes/No sanctions	No	Yes	Yes
Spain	Yes/No sanctions	No	No	Yes
Sweden	Yes/No sanctions	No	Yes	Yes
UK	Yes/No sanctions	Yes	na	Yes
US	Yes/Sanctions may exist	na	na	Yes

a From 1 January 2001, consumers in Australia have to provide proof of their eligibility for the PBS when collecting subsidised items from pharmacies. This enables the Health Insurance Commission (Wooldridge 2000) to identify and check each claimant's eligibility to receive a subsidy. **b** The HIC identifies medical practitioners whose servicing, ordering or prescribing appear abnormal when compared with their peers. Sanctions may be imposed if a medical practitioner has engaged in inappropriate practice (HIC 2001). **na** Not available.

Sources: BCG (1999); Burstall et. al. (1999); HIC (2001); Jacobzone (2000); Kanavos (1999b); Wooldridge (2000).

The success of these mechanisms in influencing physicians to prescribe more cost-effective treatments and to prevent over-prescribing has been questioned. For instance, Jacobzone (2000, p. 31) concluded that there has been limited economic effects from attempts to place responsibility for the over-consumption of pharmaceuticals and misplaced prescription onto prescribers.

In order to encourage more cost-effective spending on pharmaceuticals, most OECD countries also have implemented policies that encourage the use of cheaper-priced generics.

26 Although most OECD countries do not implement sanctions, countries such as France and Germany do have financial and/or contractual sanctions in place if physicians do not prescribe according to the guidelines (Jacobzone 2000, p. 75). In the US, a third party (such as a managed care plan) may influence prescribing habits of physicians more directly by making it mandatory for participating physicians to prescribe generics where possible.

Policies to encourage generic competition generally are administered at the production, the approval and/or the retail stage. At the retail stage, most countries allow pharmacists to dispense generic pharmaceuticals where possible. In Australia, unless the prescribing physician has explicitly indicated that substitution is not allowed, pharmacists are allowed to substitute a generic item for a brand name pharmaceutical if: the patient agrees to the substitution; and there is more than one brand available under the PBS identified as being interchangeable, and the physician prescribes a more expensive brand (DHAC 2000).[27]

Policies that speed up the launching of generics onto a market also may encourage manufacturers of originator brand pharmaceuticals, in their post-patent period, to provide more competitive prices. For example, generic producers in countries such as Canada can develop and stockpile copies of patented pharmaceuticals prior to patent expiry.

The Congressional Budget Office (CBO 1998) found the prescribing of generic copies over brand name products is more likely to lead to greater discounts being offered by the suppliers of brand name products in order to maintain market share. The study also found that as the number of generic manufacturers increased, the average price decreased.

Generics tend to have a larger market share where strong financial incentives are in place, with an impact on patients, pharmacists and/or prescribing physicians. The share of pharmaceutical markets held by generics varies across countries. Countries that are considered to have a relatively significant generic market include the US (approximately 43 per cent of prescription volumes in 1996), Canada (around 40 per cent of all prescriptions written in 1996-97), and the UK (51 per cent of filled prescriptions in 1994). Australia also is considered to have a fairly significant generic market but the exact share is not known (Jacobzone 2000).

Generic pharmaceuticals, however, make up a relatively small share of the market in France, Sweden and Spain (appendix B). As of January 2000, generic versions of off-patent products accounted for 5.6 per cent of all pharmaceutical packs prescribed in France, while the originator accounted for 10.3 per cent. In Spain, in December 1999, generic prescribing accounted for only 3.5 per cent of total outpatient prescriptions (EGA France 2001; EGA Spain 2001). In 1999, generic sales accounted for little more than five per cent of the Swedish pharmaceutical market (Kanavos 1999b).

[27] Although most OECD countries do not compel physicians to prescribe generics, in the US many private health insurance schemes make it mandatory for their physicians to prescribe generics where possible.

2.4 Other government interventions

A range of other government interventions may give rise to international price differences through influencing the availability and cost of supplying pharmaceuticals. This section considers four other interventions, namely:

- pharmaceutical evaluation processes;
- policies affecting the marketing of pharmaceuticals;
- product liability legislation; and
- industry policies.

Pharmaceutical evaluation processes

All OECD governments evaluate the safety, efficacy and quality of new pharmaceutical products before they may be supplied. The primary objective of such regulation is to protect consumers through ensuring that pharmaceuticals are: safe for human consumption; that they have the intended effect on users; and meet minimum quality standards. The justification for them is that many consumers may be unable to assess the relative safety, efficacy and quality of various products prior to use. Also, pharmaceutical evaluation procedures may minimise the cost to the community of acquiring information on these dimensions (IC 1996, p. 44).

Evaluation procedures may affect manufacturer prices directly by increasing costs, or indirectly, by reducing the effective life of pharmaceutical patents. The patent life in most countries starts from the date the patent application is filed (or is processed). If the manufacturer price of a patented product is linked to the effective patent life, then differences in the duration of pharmaceutical evaluation procedures could lead to variations in the effective patent life for a pharmaceutical and, therefore, differences in manufacturer prices across countries.

There is some evidence that the length of time involved in pharmaceutical approvals varies across countries. Schweitzer (1997) examined the issue of timing of pharmaceutical approvals in eight developed countries and found that Switzerland, the US, the UK, Canada and France were relatively fast in approving new pharmaceuticals, while Sweden, Germany and Italy tend to be slower. In Australia, from the time the drug is discovered and the first Australian patent is registered, to the time the pharmaceutical is approved for sale on the Australian market is said to take around 10–12 years (APMA 2000).

However, with the push to harmonise the evaluation process of pharmaceuticals across OECD countries, differences in evaluation periods may be diminishing.

Australia no longer develops its own standards for therapeutic goods (except for uniquely Australian products). Instead, it accepts international standards that allow the use of information developed overseas (IC 1996). The European Medicines Evaluation Agency (EMEA) was established in 1993 to coordinate the evaluation of new pharmaceuticals in all member countries in the EU. A new pharmaceutical needs only to go through one registration process, and one safety, efficacy, and labelling review. Once approved by the EMEA, the product can be put on the market in all European countries, with standardised labelling and dosage.

Pharmaceutical evaluation processes also can affect manufacturer prices through facilitating or delaying the entry of competing generic products. As noted above, some countries permit the pharmaceutical evaluation authorities to commence processing marketing applications for generics prior to the expiry of patents on the originator pharmaceutical. The effect of this is to speed generic entry once patents expire.

Some countries such as the US also have strict regulations and standards on the manufacturing facilities of pharmaceutical companies. The US Food and Drug Administration (FDA) regularly inspects the manufacturing facilities of all pharmaceutical companies (including generic pharmaceutical companies) and can recall any marketed product that does not meet production standards. Each manufacturing plant must comply with FDA standards known as Good Manufacturing Practices.

Marketing costs

Most governments allow manufacturers to market pharmaceuticals to doctors (through medical journals and visits from sales representatives). Advertising enables manufacturers to distinguish their products in an effort to influence potential buyers. Advertising costs can form a large share of the cost of producing and marketing pharmaceuticals. Some studies have suggested that marketing costs can account for nearly one-quarter of total costs (box 2.1).

In addition, direct advertising to consumers also is allowed in the US via consumer magazines, the television and the internet.[28] In Australia, and most European countries, direct marketing to consumers is prohibited for prescription pharmaceuticals.

28 Direct to consumer advertising also is permitted in NZ and, to some extent, in Canada.

If allowing direct-to-consumer advertising causes a net increase in advertising and marketing costs, differences in the regulation of advertising may contribute to cost differences.

Liability costs

High liability costs in the US have been stated as one of the possible reasons why pharmaceutical prices are relatively higher in the US compared to other developed countries like Canada (Manning 1997). Further, with recent legislative changes in the US which make it easier for injured parties to take action against pharmaceutical manufacturers, the costs associated with bringing a new pharmaceutical into the US market also are likely to be higher because of the further research required to ensure safety (Schweitzer 1997, p. 36).

Industry policy

Governments generally recognise that their interventions in pharmaceutical markets affect returns to pharmaceutical manufacturers, and therefore incentives to invest in production and R&D. Hence, some countries have established policies that seek to attract investments by pharmaceutical companies.

One way governments can do this is through taking domestic activity into account when establishing reimbursement prices (section 2.3). For example, the French Government takes proposed R&D investments into account when negotiating pricing contracts for pharmaceuticals (Kanavos 1999b).

The UK Government recognises the cost of R&D within the prices paid for NHS medicines — reflecting both a contribution to the worldwide cost of R&D and a 'desire to provide an incentive for success in R&D' (DoH 1999a). The Pharmaceutical Price Regulation Scheme (PPRS) recognises the pharmaceutical industry's contribution to the UK economy and seeks to encourage its competitive efficiency, both in the UK and abroad. The PPRS also encourages R&D into new pharmaceuticals for the benefit of NHS patients — with a commitment to 'minimum interference' allowing companies the freedom to succeed in their R&D activity (DoH 1999a). According to Kanavos (1999b, p. 179), the most recent PPRS contract (valid from 1999 to 2004) is likely to grant a higher than average return on capital[29] for larger companies with a long established presence in the UK.

[29] A more detailed description on 'return on capital' is discussed in appendix B.

However, some governments also provide general and industry-specific forms of support to the pharmaceutical industry (for example, through tax concessions and R&D subsidies). By reducing production and R&D costs, inter-country differences in the nature and significance of assistance to the pharmaceutical industry may contribute to international price differences.

In Australia, the Government has developed the Pharmaceutical Industry Investment Program (PIIP). The PIIP seeks to compensate participating pharmaceutical companies, in part, for the impact on activity of the Government exercising its purchasing power under the PBS. It does so by paying higher prices on nominated products supplied by the participating companies in return for those companies meeting commitments to undertake certain activities in Australia, including manufacturing and R&D.

Some countries do not take industry development considerations into account in setting reimbursement prices and do not offer assistance targeted at the pharmaceutical industry. For example, according to Pharmac (NZ, pers. comm., 6 February 2001), there are no specific industry assistance programs targeting the pharmaceutical industry in NZ.

2.5 Conclusion

Patents play an important role in the pharmaceutical industry through providing the means for companies to recoup the costs of discovering and developing new products. Patents may enable companies to set prices in a particular country which are, to some extent, independent of those in other countries.

At the same time, there will be a host of factors that will limit the ability of companies to set different prices in each country. For example, competition from patented therapeutic substances may reduce the effectiveness of patents. Also, the use of international benchmarking to establish reimbursement prices in some countries may reduce the scope for differentiating prices across countries.

It is difficult to arrive at a definitive assessment of the net effect of various factors on international pharmaceutical price differences. There are so many government interventions in the pharmaceutical industry that it is hard to predict whether prices for patented new innovative and me-too pharmaceuticals will be higher or lower in Australia.

Provided barriers to trade are low, it might be expected that manufacturer prices for generic pharmaceuticals in Australia will be comparable to those in other countries. However, countries may impose different regulatory requirements on suppliers of

pharmaceuticals that affect production costs and/or competition between suppliers of generics.

The terms of reference require that the study includes a group of countries with similar and dissimilar subsidy arrangements.

The US, Canada and to some extent the UK are most dissimilar to Australia in terms of their subsidy and cost-containment arrangements. The US and Canada are quite different to Australia due to the limited coverage of their public subsidy arrangements. While Australia and the UK both offer pharmaceutical subsidies to all citizens, the UK is dissimilar because it allows relatively free pricing of subsidised pharmaceuticals.

Many other OECD countries are similar to Australia in that the public sector provides universal pharmaceutical subsidies, and a variety of cost containment mechanisms are used to influence pharmaceutical prices and quantities. However, there are many differences between these countries in terms of the types of mechanisms used and the level of pressure applied to prices by governments.

3 International price comparisons

The principal purpose of this study is to estimate, for a group of countries, differences in the prices received by manufacturers for pharmaceutical products listed on the Pharmaceutical Benefits Scheme (PBS).

This chapter reports the results of a comparison of Australian manufacturer prices with the prices of the same items in seven other countries. The comparison countries are Canada, France, New Zealand (NZ), Spain, the United Kingdom (UK) and the United States (US).

Before examining the results in detail, the next section identifies the key features of the methodology used to undertake the price comparisons. Sections 3.2 and 3.3 report the results of the price comparisons using the categories defined in the terms of reference, and using therapeutic groups respectively. The sensitivity of the price comparisons to key aspects of the methodology is discussed in section 3.4. The findings are then summarised in section 3.5.

3.1 Methodology

In comparing the prices of PBS-listed items with those in overseas countries, a number of methodological issues need to be addressed. Factors that influence the development and interpretation of price comparisons include:

- choosing the basket of pharmaceuticals for comparison;
- choosing pharmaceuticals in the basket;
- matching pharmaceuticals;
- choosing countries;
- prices used;
- converting prices to a common currency; and
- weighting manufacturer prices.

The following sections briefly discuss each issue and the approach adopted. A more detailed discussion of the issues and methodology is contained in appendix C.

Choosing the basket of pharmaceuticals for comparison

The terms of reference require that the study examine price differentials for items listed on Australia's PBS. A broader study of pharmaceutical prices in Australia would encompass non-PBS pharmaceuticals in the comparison. This could allow for inferences to be drawn on the impact of the PBS on prices for PBS-listed items and the broader pharmaceutical market.

However, cost and time constraints precluded a broader study. Instead, the comparison is limited to prices for a sample of PBS-listed pharmaceuticals. In doing so, conclusions cannot be drawn about the impact of the PBS on Australia's overall pharmaceutical market. Inferences can only be drawn about those pharmaceuticals listed on the PBS and included in the study.

Choosing pharmaceuticals in the basket

There are approximately 820 molecules listed on the PBS. Each of these molecules is available in a number of different forms (dosage type, strength and pack size). The practicalities of data availability preclude including all these pharmaceuticals in the price comparison. Hence, it was necessary to identify a sample of PBS-listed items for comparison.

Examination of PBS expenditure data shows that a small number of molecules accounts for a large share of total expenditure under the scheme[1] (appendix C). As such, the top 150 PBS-listed molecules (ranked by total expenditure during 1999-2000) were selected for the price comparisons.[2] These molecules account for 84 per cent of total expenditure under the PBS.

In taking this approach, firm conclusions cannot be drawn about the general level of prices for PBS-listed pharmaceuticals between Australia and the comparison countries. This is because the sample of pharmaceuticals may not be representative of the entire PBS market. Instead, inferences can only be drawn for those pharmaceuticals selected.

The terms of reference require that the basket of PBS pharmaceuticals examined includes three categories:

1 Total expenditure is defined as the sum of patient and government contributions.

2 The composition of the top 150 PBS-listed molecules ranked by total expenditure in 2000-01 is likely to have changed since 1999-2000 with the listing of new molecules. Changes in the pattern of expenditure on pre-existing PBS molecules also can affect the composition of the top 150 molecules.

- *new innovative* (that is, chemical entities for which there is no reasonable alternative and also those with efficacy, quality of life and/or safety improvements, including better modes of delivery of active ingredients);
- *me-toos* (that is, chemical entities for which therapeutic alternatives are available);[3] and
- *generics* (that is, chemically equivalent items, including the originator brand).

The terms of reference also specify that there be at least ten major forms in each of these categories.

The top 150 molecules included in the price comparison were categorised by the Department of Health and Aged Care (DHAC). The molecules are listed in appendix D. The me-too and generic categories account for the majority of molecules and around 90 per cent of expenditure on the 150 top-selling PBS-listed molecules (table 3.1). To ensure an adequate sample, some molecules listed part-way through 1999-2000 were included in the new innovative category based on their annualised expenditure.

Table 3.1 **Molecules and expenditure share by pharmaceutical category, Australia, 1999-2000**

Category	*Molecules*	*PBS expenditure share*
	no.	%
New innovative	21	10.3
Me-too	49	45.5
Generic	80	44.2
All	150	100.0

Source: PC estimates.

The molecules were classified into these categories as at 30 June 2000 (section 3.4). Their current status may have changed reflecting the expiry of patents and/or the launch of new alternative pharmaceuticals.

Matching pharmaceuticals

Pharmaceuticals are marketed to consumers in a wide variety of forms. Therefore, the forms of a particular molecule can differ across countries by the dosage type (for example, tablets, syrups and injections), by strength (the amount of active

3 Although most new innovative and me-too pharmaceuticals are on-patent, some items may be off-patent but not subject to competition from generic versions. Information on the patent status of all pharmaceuticals in the sample was unavailable.

ingredient) and by the pack size. In Australia, 584 different forms of the top 150 PBS-listed molecules were identified for 1999-2000.

The approach adopted by this study was to seek direct matches for each of the 584 forms of Australia's 150 top-selling molecules in each comparison country (that is, form matching). The form matching approach is designed to achieve meaningful results through ensuring that, where possible, 'like with like' price comparisons are undertaken. For instance, alternative approaches used in some previous studies have directly compared prices associated with different delivery methods such as injections, inhalers, tablets and syrups, despite possibly significant differences in both the costs of producing these forms, and their clinical uses. Also, this study compares prices at the level of individual packs rather than per tablet or other measurement unit (appendix C). The relationship between prices and pack sizes is determined by the interaction of demand and supply conditions in each market and therefore may vary across countries. Comparing prices at the pack level avoids the need to make simplifying assumptions about the relationship between prices and pack sizes.

That said, the practicalities of matching many hundreds of forms necessitated making some assumptions. While an attempt was made to match identical dosage types, there often are many different forms within a particular dosage type. For example, many types of tablets and capsules may be available in slightly different forms, such as standard, slow-releasing or enteric-coated. In such cases, prices for different forms within a given dosage type were considered comparable.

For some dosage types (for example, injections and inhalers), it was more difficult to find direct matches in the comparison countries. As a result, there were relatively fewer matches for these items than was achieved for tablets and capsules. The ability to obtain direct matches for dosage types also was constrained by the preference for different delivery methods in the comparison countries. For example, suppositories tend to be more commonly used in some European countries than in Australia.

In a number of instances, a direct match on the pack size available in Australia could not be obtained for the overseas countries. Also, in some countries, there were many manufacturers of the same form charging significantly different prices. When overseas volume data were available, a weighted average price for that form of pharmaceutical was calculated (section 3.2).

Higher and *lower* estimates of prices were reported when Australia's pack size was not available in the comparison country or there were multiple prices for the same form without corresponding volume data in the comparison country. This avoided

the need to make assumptions about the relationship between price and pack size or to average the range of prices for the same form of a molecule.

Because only 18 forms could be matched across all comparison countries, the study used a bilateral matching procedure. This approach achieves a much higher number of matches, increasing the robustness of the price comparisons. It also means that the sample for each pair-wise comparison is uniquely determined by the availability of matched forms.

An important implication of using the bilateral (pair-wise) approach is that conclusions about the prices of the top selling PBS-listed molecules cannot be drawn across the comparison countries. For example, the price ratios for the US relative to Australia and the UK relative to Australia cannot be used to draw inferences about the level of pharmaceutical prices between the US and the UK. This is because the sample for each pair-wise comparison is different, depending on the ability to match pharmaceuticals. In addition, a comparison of, say, US and UK prices using these results would be based on Australian consumption patterns, which are likely to be very different to US and UK consumption patterns.

Choosing countries

The terms of reference state that the group of comparable countries to be considered should include a sample of those that offer similar pharmaceutical subsidy arrangements as Australia and those that adopt different arrangements.

The terms of reference do not specify how many countries should be included in the study. The Commission decided to focus on a small group of countries, thereby permitting a larger number of pharmaceuticals to be included in the study.

The group of comparable countries includes those middle and high income countries with well-developed health care systems. Within this group, the factors used to distinguish between countries which have similar and dissimilar subsidy arrangements included:

- whether public pharmaceutical subsidy or private insurance arrangements dominate;
- eligibility for public subsidies (for example, the proportion of the population covered by the public subsidy scheme);
- the level of public subsidy offered (in terms of the size of the subsidy list and the level of patient copayment); and
- cost-containment measures used by government and private insurers (especially the degree of freedom that companies have to set prices).

As discussed in chapter 2, those countries that are most dissimilar to Australia are the US, the UK and Canada. Amongst the large group of Organisation for Economic Cooperation and Development (OECD) countries with similar subsidy arrangements, the Commission decided to focus on Sweden, NZ, France and Spain. These four countries differ from one another in the nature of the cost-containment mechanisms used and in the stringency with which they are applied. Sweden appears to be the least stringent of this group, possibly because it has a reasonably large domestic pharmaceutical industry. It appears that NZ has the most stringent approach to cost-containment, while France and Spain occupy an intermediate position.

Prices used

The terms of reference specify that price comparisons should be made at the ex-factory (manufacturer) level.

For all comparison countries except Sweden, manufacturer prices for pharmaceuticals were obtained from IMS Health. For Sweden, manufacturer prices were unavailable from IMS Health directly and therefore were obtained from the National Social Insurance Board (the *Riksförsäkringsverket,* RFV).

IMS Health reports manufacturer prices for the relevant countries, which it says are derived mostly from surveys of wholesalers (table 3.2). In some cases, manufacturer prices are collected by the surveys while, in other cases, wholesale prices are collected. In the latter case, manufacturer prices are estimated using a maximum or average wholesale mark-up (varying from a maximum of 12.5 per cent in the UK to an average of around five per cent in the US) (IMS Health, pers. comm., February 2001). Potentially, the use of maximum wholesale margins introduces a small source of bias in the reported manufacturer prices since some wholesalers may charge less than the maximum to some purchasers. The Commission was unable to readily identify the prevalence of discounted wholesale margins.

The manufacturer prices obtained from IMS Health can be considered to be the maximum potential prices received by manufacturers. They are usually obtained from wholesale or manufacturer price lists (and are not actual invoice prices). In

some countries (such as the US), larger/institutional buyers obtain substantial discounts off published list prices (section 3.2).[4]

Table 3.2 **Description of IMS Health manufacturer price data**

Country	*Data source and market coverage*	*Level of price collected*	*Conversion to manufacturer price*
Canada	Survey of pharmacies and hospitals (3% and 15% of total establishments)	Wholesale price to retailers	Converted to manufacturer price (average mark-up not specified)
France	Survey of wholesalers and pharmacies (market coverage not specified)	Manufacturer price to wholesalers	..
Spain	Survey of pharmacies and wholesalers (covers over 80% of the market)	Manufacturer price to wholesalers	..
UK	Survey of wholesalers and retailers (covers 83% of the market)	Wholesale price to retailers	Converted to manufacturer price (average mark-up is 12.5%)
US (retail channel)[a]	Survey of wholesalers and warehouses owned by retailers (covers 98% of sales from these sources)	Wholesale price to retailers	Converted to manufacturer price (average mark-up is 5%)
NZ	Survey of wholesalers and pharmacies (covers around 80% of the market)	Manufacturer price to wholesalers	..

a According to IMS Health, the retail channel accounts for 64 per cent of pharmaceutical sales in the US. The principal retail outlets are: chain and independent pharmacies; mass merchandise stores; proprietary stores; and foodstores with pharmacies. **..** Not applicable.

Source: IMS Health (pers. comm., February 2001).

Government agencies in a number of countries publish the prices they pay for pharmaceuticals. For example, in the US, the Federal Department of Veterans Affairs maintains a catalogue of manufacturer pharmaceutical prices, known as the Federal Supply Schedule (FSS). The prices negotiated under the FSS are intended to equal or better the prices manufacturers charge their 'most-favoured' non-federal customers under comparable terms and conditions (GAO 2000c). Hence, the FSS provides an indication of prices obtained by larger/institutional buyers in the US.

4 Hospitals also may be able to obtain substantial discounts from manufacturers. However, special factors may motivate the pricing of pharmaceuticals to hospitals. For example, manufacturers may choose to subsidise hospital sales in order to encourage trainee doctors to prescribe their products, or to get patients onto a particular treatment which they are then likely to continue once they leave the hospital. Due to the special features of the hospital market and a lack of hospital sales data in some of the comparison countries, hospital prices were excluded from this study (appendix C).

Information on pharmaceutical pricing in the US indicates that FSS prices may not, in fact, be the lowest price obtained by some buyers (appendix C).

Converting prices to a common currency

Price comparisons across countries require conversion of local currency prices into a common currency. For this study, official exchange rates were used to convert local currency prices into Australian dollars (table 3.3). This is because exchange rates provide the most relevant information for examining the revenue and cost implications for pharmaceutical companies and the Commonwealth Government respectively, of pricing PBS-listed molecules at international, rather than Australian, levels.

Table 3.3 **Average exchange rates[a]**

$1A=	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
June 2000	0.5941	0.8756	0.3929	5.1985	4.1062	104.0875	1.2615

a Each exchange rate is calculated as the average of the buying and selling rate for the month of June.

Source: ABS (2000).

Official exchange rates also are one factor taken into consideration by the Pharmaceutical Benefits Pricing Authority (PBPA) in reviewing the prices of pharmaceuticals under the PBS.[5]

An alternative conversion procedure is to use purchasing power parities (PPPs). These conversion factors are designed to reflect the purchasing power of a currency within its national market. They serve two purposes — to convert one currency into another (usually US dollars) and to adjust for differences in relative price levels (taking into account traded and non-traded goods and services).

However, the decision not to use PPPs reflects the purpose of this study which is to compare the prices that manufacturers receive for pharmaceuticals in Australia under the PBS with those obtained overseas. Exchange rates are appropriate conversion factors as they reflect the purchasing power of a national currency on international markets for traded goods, such as pharmaceuticals. The use of PPPs might be appropriate if the purpose were to assess the broader welfare implications of price differences (such as whether consumers are better off under Australian or overseas prices).

5 Consideration of official exchange rates occurs under 'factor g' in reviewing prices for existing and new pharmaceuticals (PBPA 2000).

For the results presented in the following section, the exchange rates applied were the average exchange rates for the month of June 2000. This month was chosen as it is the closest average exchange rate to the time period over which the pharmaceutical prices were collected. The sensitivity of the results to this exchange rate assumption is explored in section 3.4.

Weighting manufacturer prices

The terms of reference require the Commission to calculate some form of weighted average price. This is required to ensure that the results are not distorted by the inclusion of forms which have a large price differential but account for a small share of the market.

A number of weighting systems could be applied, including the volume of sales in Australia and the number of PBS scripts (appendix C). According to Pekarsky (pers. comm., May 2001), the PBS script data understate actual volumes for some pharmaceuticals because they do not include scripts priced below the patient copayment and some items commonly dispensed through hospitals. Consequently, if PBS scripts are used, the weights on these pharmaceuticals are likely to be biased downward. The sales volume data also do not record items dispensed through hospital pharmacies. Despite this limitation, these data are considered more comprehensive than the PBS scripts data. As such, the results in the following section are reported using the volume of Australian sales to weight prices. Results with prices weighted by the number of PBS scripts can be found in appendix E. The results differed little between the two systems.

The price comparisons are reported using a ratio of prices between Australia and each comparison country. These ratios were calculated by dividing an overseas revenue estimate by an estimate of Australian revenue for those forms that were available in both Australia and the comparison country.[6] The overseas revenue estimate is derived by multiplying overseas prices for each matched form by the corresponding Australian sales volumes. This yields an estimate of the revenue that could have been obtained by pharmaceutical companies if they had sold their Australian volumes at the overseas prices. Similarly, the Australian revenue

6 The formula for the price ratio is:

$$P = \frac{\sum_{i=1}^{n} P_{ji} Q_{Ai}}{\sum_{i=1}^{n} P_{Ai} Q_{Ai}}$$

where $P_{i,j}$ = price of pharmaceutical i in country j; $P_{i,A}$ = price of pharmaceutical i in Australia; and $Q_{i,A}$ = quantity of pharmaceutical i in Australia.

estimate is derived by multiplying Australian prices, for the same forms, by the Australian sales volumes. The price ratio therefore provides an indication of how the revenues of companies operating in Australia would change if they had been able to achieve overseas prices (rather than Australian prices) on their Australian sales.

However, the sales volumes also act as weights on the prices. For example, a high-priced item may make a small contribution to the revenue estimates for Australia and comparison countries if it has a low volume of sales in Australia. If the index is greater than one, it indicates that Australian prices are, on average, below those in the comparison country. Conversely, a value of less than one shows that Australian prices are above those in the comparison country.

3.2 International price comparisons

In this section, the price comparisons with the seven overseas comparator countries are presented. Initially, price comparisons are reported for all 150 PBS-listed molecules and then for each of the three categories of pharmaceuticals: new innovative; me-too; and generic. Prices paid by larger/institutional buyers are then estimated for some of the comparison countries. Finally, this section examines factors contributing to the large observed differences between the higher and lower estimate of prices.

List price comparisons

The following results are based on 'list' prices, or the maximum prices received by pharmaceutical companies. As noted above, a value greater than one indicates that manufacturer prices for the matched forms in the comparison country are greater than the prices of those items in Australia. Furthermore, the higher and lower estimates of prices reflect differences in pack sizes and the existence of multiple manufacturer prices for some matched forms.

In interpreting the price comparisons, it is worth reiterating some of the major qualifications, namely that the conclusions:

- are valid only for the top selling PBS-listed molecules in each category; and
- cannot be used to compare price levels across the comparison countries, as bilateral comparisons were undertaken.

In addition, the robustness of the results for the various categories is likely to be positively related to the size of the sample and the level of matching. This means that greater levels of confidence can be placed on the results for all categories than

for the sub-categories. And, for any category, more confidence can be placed on the price ratios which achieved a relatively high number of matches and coverage of Australian revenue.[7]

The results cannot be used to predict the change in pharmaceutical company revenue or government subsidies if the observed overseas prices were to prevail in Australia. Any change in manufacturer prices in Australia would be likely to induce corresponding changes in quantities demanded and supplied which may offset the revenue and government subsidy effects of price changes.

All categories

Manufacturer prices in Australia for the 150 top-selling PBS-listed molecules are low compared to all countries except NZ and Spain (table 3.4 and figure 3.1).

Table 3.4 **Price ratios for all categories, list prices[a]**

	Unit	*Aust*	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
Higher estimate	ratio	1.00	3.48	1.81	1.64	1.57	1.17	1.02	0.98
Lower estimate	ratio	1.00	2.62	1.51	1.48	1.48	1.12	0.96	0.92
No. of matches	no.	584	273	242	326	187	176	204	266
Coverage[b]	%	100	64	56	80	50	41	56	66

a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn. **b** Coverage shows the percentage of total Australian manufacturer revenue for the 150 molecules accounted for by the matched forms.

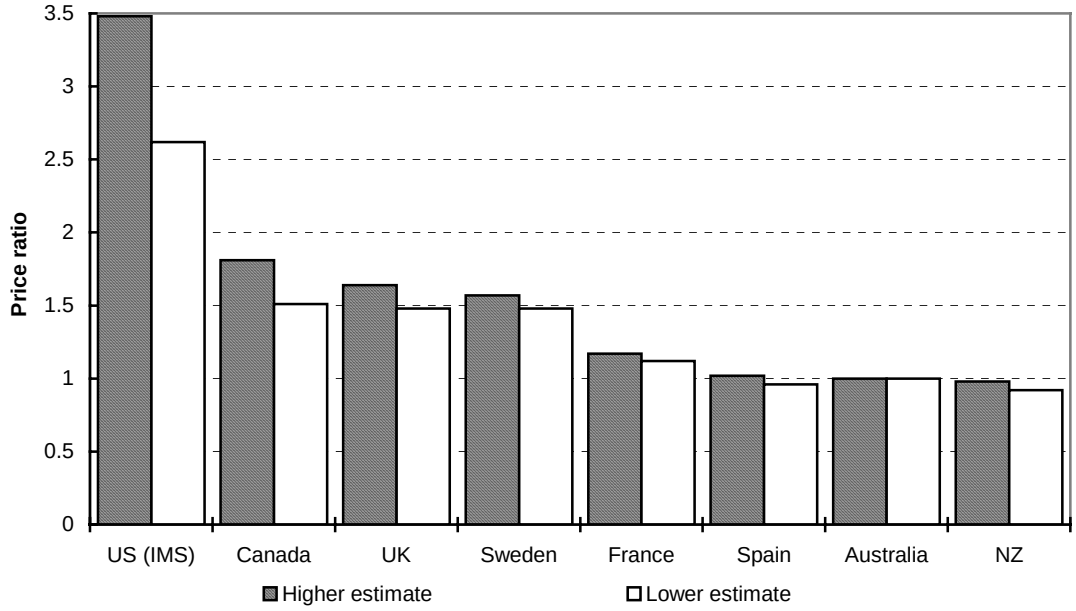
Source: PC estimates.

A very large price gap is observed for the US, where list prices are around 250 per cent higher than those in Australia based on the higher estimate of manufacturer prices, and still more than 160 per cent higher based on the lower estimate. Manufacturer prices in Canada, the UK, Sweden and France also are greater than those in Australia (between 12 and 51 per cent based on lower estimates).

Manufacturer prices in Spain and NZ are about the same, or slightly lower than Australia's.In the US, Canada, the UK and Sweden there is a marked difference between the higher and lower estimates of prices. As discussed later in this section, this is mainly due to large differences in the prices charged by the multiple manufacturers of generic pharmaceuticals in these countries.

7 The results of statistical tests of the significance of price differences are reported below.

Figure 3.1 **Price ratios for all categories, list prices[a]**



a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn.

Data source: PC estimates.

The number of matched forms for each of the seven countries varied between a low of 176 (France) to a high of 326 (UK). Except for France, matched forms accounted for around half or more of Australian manufacturer revenue for the top 150 molecules.

In order to examine the robustness of these results, statistical tests were applied to the unweighted price ratio series for each comparison country relative to Australia (appendix E).[8] The tests generally support the weighted price ratios reported in table 3.4. They indicate that price differences with Australia are statistically significant (at the one per cent level of significance) for all comparison countries except NZ.

New innovative pharmaceuticals

New innovative pharmaceuticals are chemical entities for which there is no reasonable alternative, as well as those with efficacy, quality of life and/or safety improvements, including better modes of delivery of active ingredients.

8 Caution needs to be exercised in interpreting the results of statistical tests because of the approach to sampling used by this study (appendix E).

As these pharmaceuticals possess significant additional benefits over alternative treatments or are the only ones available to treat a particular disease, it could be expected that manufacturers typically will have the ability to set different prices in each country, reflecting differences in the price sensitivity of demand. However, regulatory constraints, such as the use of international benchmarking to set prices, may limit the ability of manufacturers to differentiate prices across countries (chapter 2).

Compared to all categories, manufacturer prices in Australia for the top-selling new innovative molecules are closer to those in the comparison countries (table 3.5 and figure 3.2).

Table 3.5 **Price ratios for new innovative pharmaceuticals, list prices[a]**

	Unit	*Aust.*	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
Higher estimate	Ratio	1.00	2.17	1.09	1.26	1.17	0.92	0.85	1.00
Lower estimate	Ratio	1.00	2.04	1.09	1.25	1.10	0.92	0.85	1.00
No. of matches	no.	79	37	29	39	39	24	19	27
Coverage[b]	%	100	67	47	72	60	50	41	48

a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn. **b** Coverage shows the percentage of total Australian manufacturer revenue for new innovative molecules accounted for by the matched forms.

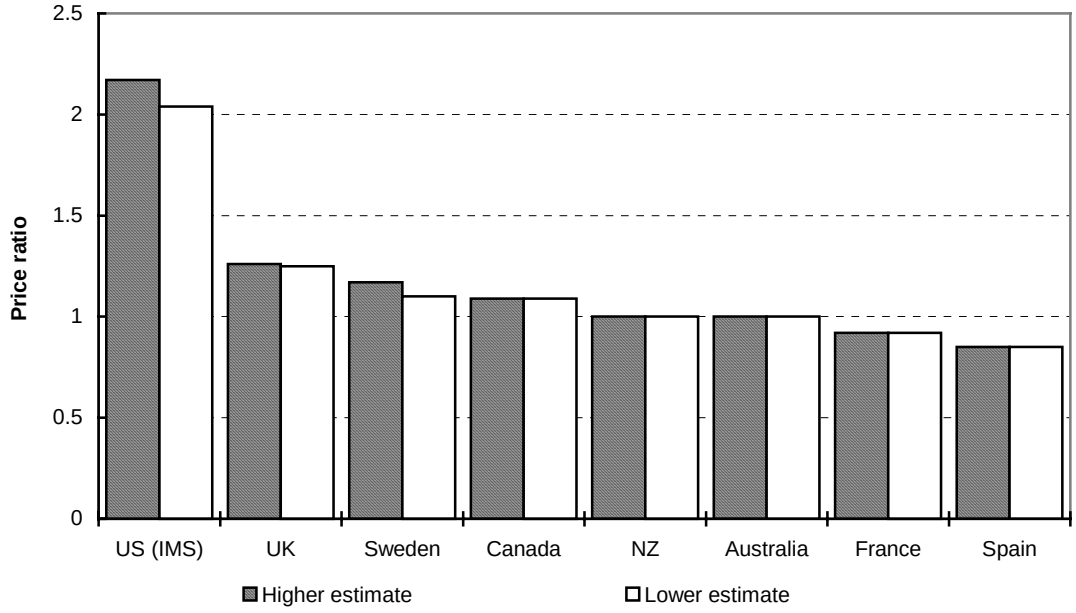
Source: PC estimates.

The price gap for new innovative pharmaceuticals is still significant for the US, where prices for matched forms are around double those in Australia. Prices in the UK also are greater than in Australia, but the gap is less than for all categories. Prices in Australia are close to those in Canada and Sweden, the same as those in NZ, and just above those in France and Spain.

Compared to all categories, France moves from being slightly more expensive than Australia to cheaper for new innovative pharmaceuticals. Prices in Spain also are lower, at around 85 per cent of Australian prices.

In all comparison countries, the number of matched forms is nearly double that required by the terms of reference (ten), and for the US, the UK and Sweden more than 30 matches were achieved. That said, the matches obtained for Spain, NZ and Canada were relatively low among the comparison countries and, in each case, covered less than 50 per cent of Australian revenue.

Figure 3.2 **Price ratios for new innovative pharmaceuticals, list prices[a]**



a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn.

Data source: PC estimates.

Statistical tests lend support to the weighted price ratios reported in table 3.5. The tests indicate that price differences with Australia are significant for most comparison countries (at the five per cent level of significance). For NZ and Canada, the test results suggest that prices are statistically the same as prices in Australia at the five and one per cent levels. In the case of France, prices were found to be statistically the same as Australian prices at the one per cent level. Based on the lower estimate, the weighted price ratios also show that prices in NZ, France and Canada are closest to Australian prices for this category.

Me-too pharmaceuticals

Me-too pharmaceuticals are defined as chemical entities for which therapeutic alternatives are available. It is difficult to arrive at in-principle predictions about relative prices for these pharmaceuticals across countries. For instance, the level of competition facing the same me-too pharmaceutical from therapeutic alternatives may vary across countries. In addition, the same me-too pharmaceuticals may be subject to differing regulatory constraints.

Manufacturer prices in Australia for the top selling me-too pharmaceuticals are lower than those in all comparison countries except NZ, where prices are essentially equal to Australia (table 3.6 and figure 3.3). For most countries (the US, Canada, the UK and Sweden), prices are at least 57 per cent higher than those in Australia. Australian prices are much closer to those in France, Spain and NZ.

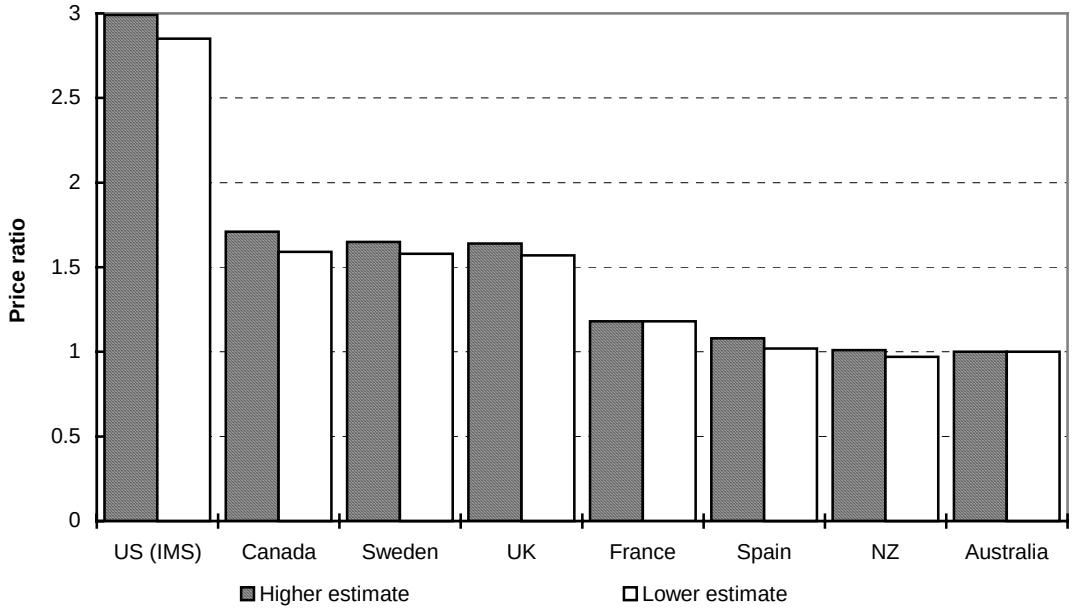
Table 3.6 **Price ratios for me-too pharmaceuticals, list prices[a]**

	Unit	*Aust*	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
Higher estimate	Ratio	1.00	2.99	1.71	1.64	1.65	1.18	1.08	1.01
Lower estimate	Ratio	1.00	2.85	1.59	1.57	1.58	1.18	1.02	0.97
No. of matches	no.	153	79	73	113	62	66	79	78
Coverage[b]	%	100	64	76	92	55	47	66	75

a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn. **b** Coverage shows the percentage of total Australian manufacturer revenue for me-too molecules accounted for by the matched forms.

Source: PC estimates.

Figure 3.3 **Price ratios for me-too pharmaceuticals, list prices[a]**



a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn.

Data source: PC estimates.

As discussed later in this section, the available evidence indicates that actual manufacturer prices are likely to be closer to the lower estimate of prices than the

higher estimate. On this basis, it appears that the greatest price gap with Australia for each comparison country occurs for me-too pharmaceuticals.

For all countries except France, the matches accounted for more than 50 per cent of Australian revenue for me-too pharmaceuticals. For five countries, the market coverage equalled or exceeded 64 per cent.

The results of statistical tests align closely with the weighted price ratios in table 3.6. The tests indicate that price differences with Australia are statistically significant for all comparison countries (at the one per cent level of significance) except for NZ and Spain. The weighted price ratios show that prices in NZ and Spain are nearest to Australian prices for me-too pharmaceuticals.

Generic pharmaceuticals

Generic pharmaceuticals are defined as chemically equivalent items and in this study include the originator brand. Studies for the US have found that as patents on originator brands expire, generic copies have been able to capture a significant share of the market at much lower prices (see, for example, CBO 1998). However, manufacturers of originator brands may prefer to maintain higher prices when a pharmaceutical's patent protection has ended despite a reduction in market share, in order to reinforce perceptions of higher quality. International trade in generics may offer less scope for price differentiation than is possible for patented pharmaceuticals (new innovative and me-too), and therefore may be expected to result in smaller international price differences.

However, this expectation is not borne out by the results.

Manufacturer prices in Australia for the top selling PBS-listed generic pharmaceuticals are lower than those in several countries (the US, Canada, the UK, Sweden and France) but higher compared to Spain and NZ (table 3.7 and figure 3.4).

The results indicate significant price differences between Australia and most comparison countries. Based on the lower estimate, manufacturer prices in the US are more than double Australian prices. Prices in Canada, the UK, Sweden and France are higher by 10 to 51 per cent. Prices in Spain and NZ are less than those in Australia, the largest differential being some 17 per cent in NZ, based on the lower estimate of prices.

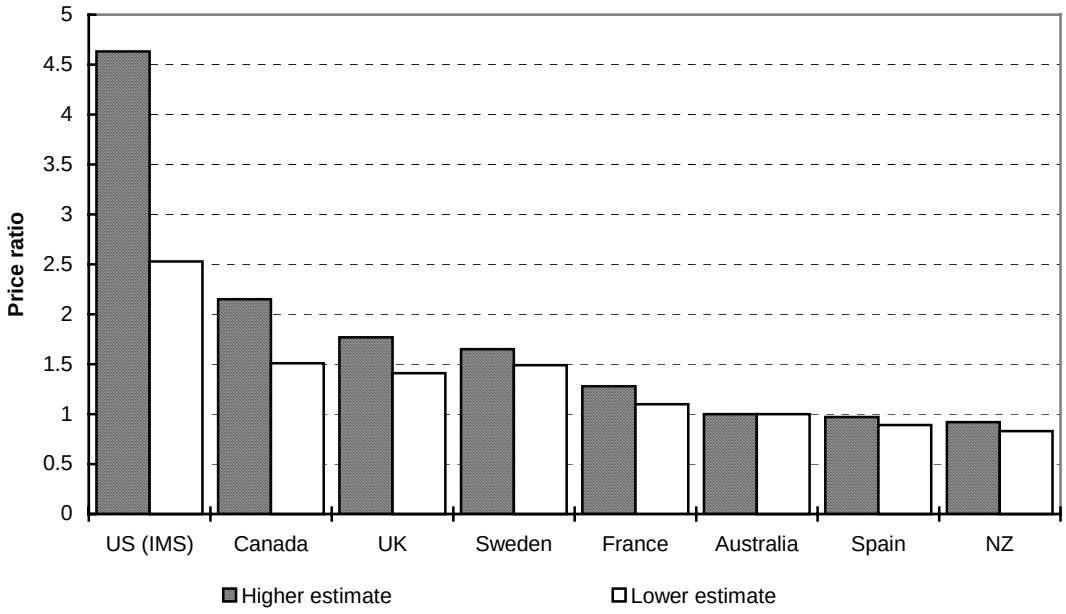
Table 3.7 **Price ratios for generic pharmaceuticals, list prices[a]**

	Unit	*Aust*	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
Higher estimate	ratio	1.00	4.63	2.15	1.77	1.65	1.28	0.97	0.92
Lower estimate	ratio	1.00	2.53	1.51	1.41	1.49	1.10	0.89	0.83
No. of matches	no.	352	157	140	174	86	85	106	161
Coverage[b]	%	100	62	56	67	41	29	48	62

a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn. **b** Coverage shows the percentage of total Australian manufacturer revenue for generic molecules accounted for by the matched forms.

Source: PC estimates.

Figure 3.4 **Price ratios for generic pharmaceuticals, list prices[a]**



a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn.

Data source: PC estimates.

As noted earlier, the reliability of the price ratios depends in part on the number of matches and the market coverage of matched pharmaceuticals. The number of matches achieved for Sweden and France, and to some extent Spain, are relatively low.[9] But while the market coverage for Spain and Sweden was less than

9 The difficulty experienced in matching generics in Sweden, France and Spain may reflect the relatively small market share of generics in these countries relative to countries such as the US and the UK (appendix B).

50 per cent, in the case of France, the coverage was very low (only 29 per cent of Australian revenue).

Statistical tests for this category indicate that price differences with Australia are significant for most comparison countries. However, based on the lower estimate of prices, the tests found that generic prices in NZ and France are not statistically different from Australian prices (at the one and five per cent levels of significance), even though the weighted price ratios for NZ and France show a 17 per cent and ten per cent difference respectively.

Prices paid by larger/institutional buyers

As discussed in section 3.1, the manufacturer prices obtained from IMS Health can be considered to be the maximum potential prices received by manufacturers. However, in some countries (such as the US), larger/institutional buyers are able to obtain discounts off these published list prices. In order to assess the significance of discounts for the price comparisons using IMS Health data, information was sought on the prevalence of discounting in Australia and the comparator countries.

In discussions with pharmaceutical companies, it was stated that discounting by manufacturers does occur in Australia. Discounts (usually in the form of free stock) are offered by some manufacturers to pharmacists in order to encourage them to stock and dispense generic pharmaceuticals. Such manufacturer discounts usually are available only on direct sales of generic pharmaceuticals to pharmacists.

As the manufacturer prices for Australia do not account for these discounts, there is likely to be some upward bias in the Australian manufacturer prices. However, since most pharmaceuticals are distributed through wholesalers in Australia, the net impact of failing to account for discounts on companies' direct sales to pharmacists is likely to be minimal.[10]

Evidence indicates that larger/institutional buyers in the US can negotiate substantial discounts off IMS Health list prices for Australia's top selling PBS-listed molecules (table 3.8). For all categories, the estimated discount using FSS prices is around 24 per cent based on the higher estimate of prices and even greater at 31 per cent based on the lower estimate (appendix E).

10 According to IMS Health (pers. comm., April 2001), direct sales from manufacturers to retail pharmacies account for only three per cent (by value) of their total sales. Around 86 per cent of manufacturers' sales are to wholesalers. The remainder are to hospitals (nine per cent) and governments and others (two per cent).

However, the level of discounts varies considerably across categories. The largest discounts occur for me-too pharmaceuticals, at between 34 to 39 per cent. In contrast, for new innovative pharmaceuticals, estimated discounts are only around three to six per cent.

Table 3.8 **Estimated discounts for larger/institutional buyers in the US**

	Higher estimate		*Lower estimate*	
Category	*Price ratio*	*Discount (per cent)*	*Price ratio*	*Discount (per cent)*
All	2.49	24	1.84	31
New innovative	1.94	6	1.86	3
Me-too	1.94	34	1.70	39
Generics	4.00	14	2.08	24

Source: PC estimates.

The use of FSS prices provides a more accurate indication of the price differences between Australia and the US than the IMS list prices. However, FSS prices are likely to provide a conservative estimate of the discounts available in the US. The General Accounting Office (GAO 1997, 2000a) noted that FSS prices may not be the lowest available in the US market (appendix C). For instance, buyers such as Health Maintenance Organisations (HMO) may be able to negotiate larger discounts due to their ability to shift volumes towards lower-priced pharmaceuticals. However, as information on HMO prices is confidential, the FSS is currently the best source of public information on discounts in the US. If HMO discounts were taken into account, it is likely that the price differences would be further narrowed but not eliminated entirely.

The Commission also received qualitative information on discounts from the pharmaceutical industry in Canada and Sweden.

Canada's Research-based Pharmaceutical Companies[11] (Rx&D, pers. comm., 11 April 2001) considers that some discounting of prescription products does occur in the form of offers of free goods to pharmacists but that the practice is confined to generic companies. Rx&D considered that any offers of discounts to selected customers on patented pharmaceuticals would likely lead to complaints to the Patented Medicines Prices Review Board (PMPRB) which has the power to investigate instances of excessive pricing (appendix B). As a result, discounting practices are deterred by the possible intervention of the federal regulator.

11 Canada's Research-based Pharmaceutical Companies (Rx&D) is the national industry association representing research-based pharmaceutical companies in Canada. It was previously known as the Pharmaceutical Manufacturers Association of Canada.

The Swedish Association of the Pharmaceutical Industry (LIF) also indicated that there are no significant discounts for pharmaceuticals in Sweden (LIF, pers. comm., 3 March 2001). This view is supported by the Swedish National Social Insurance Board which noted that, while discounts could be negotiated for reimbursed products, the pharmaceutical companies rarely accept discounts (RFV 2000b).

There is some evidence that significant discounts may be available in the UK market. For instance, a discount inquiry conducted by the UK Department of Health in 1998 examined the difference between reimbursement prices and prices paid by pharmacists for generic pharmaceuticals. The inquiry suggested a discount of over eight per cent for branded (originator) off-patent molecules and around 24 per cent for generic molecules (UK Department of Health, pers. comm., 28 February 2001). The Commission was unable to obtain information on discounts in the UK market for June 2000. However, the evidence from the earlier discount inquiry for generic pharmaceuticals suggests that actual prices for some pharmaceuticals in the UK may be well below those reported by IMS Health.

The Commission was unable to obtain information on the availability of discounts in France, Spain and NZ.

Difference between higher and lower price estimates

As discussed in the previous section, higher and lower estimates of prices were reported due to the issues of different pack sizes and multiple manufacturer prices.

The difference between the higher and lower estimates of prices (price range) tends to be greater for those countries with the largest price gap with Australia (tables 3.4 and 3.7). Based on the results for all categories of pharmaceuticals, the US has both the largest price ratio (3.48) and the greatest price range (25 per cent). In France, where prices for all categories are some 12 to 17 per cent higher than Australia, the price range is around four per cent (table 3.9).

Table 3.9 **Price range between higher and lower estimates, per cent[a]**

Category	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
All	25	17	9	6	4	6	5
New innovative	6	1	0	6	0	0	0
Me-too	5	7	4	4	0	6	4
Generics	45	30	21	10	15	8	10

a The price range is measured as the difference between the higher and lower estimates, expressed as a percentage of the higher estimate of prices.

Source: PC estimates.

In all seven countries, generic pharmaceuticals account for the largest share of the price range observed for all categories of pharmaceuticals. For new innovative pharmaceuticals, there is a price range of six per cent or less. In contrast, the price range for generics in the US, Canada and the UK varies from 21 to 45 per cent.

For the US, Canada and the UK, somewhere between 40 and over 80 per cent of the price range is explained by the availability of multiple manufacturer prices for the same form (appendix E). The contribution of multiple manufacturer prices to the price range in the US, Canada and the UK highlights the variety of prices available for generic pharmaceuticals in these countries. In a small number of instances, the highest price for a generic pharmaceutical was more than ten times the price of the cheapest.

In a number of cases, it was found that the highest-priced generic pharmaceutical is more expensive for Australia while the lowest-priced is cheaper. Table 3.10 shows that for those generic forms that were matched with the US (157 in total), prices in the US were higher than those in Australia for 147 forms, and ten were lower, based on the higher estimate of prices. But for the lower estimate of price comparisons, it was found that US prices were higher than Australia's for 99 forms, whereas for 58 forms, US prices were actually below Australia's.

Table 3.10 **Higher and lower prices for generic pharmaceuticals**

	US	*Canada*	*UK*
	no.	no.	no.
Prices higher than Australia			
Higher estimate	147	113	133
Lower estimate	99	84	109
Prices lower than Australia			
Higher estimate	10	27	41
Lower estimate	58	56	65

Source: PC estimates.

If overseas volume information were available in instances where the Commission found multiple manufacturer prices in the comparison country, it would be possible to provide more precise estimates of price comparisons. This is because the overseas volume information could be used to calculate a weighted average price.

Overseas volume information was obtained for a sample of pharmaceuticals and used to assess whether the actual price gap is likely to be closer to the lower range of prices than to the higher estimate (box 3.1). Based on a small sample of pharmaceuticals, the evidence suggests that the higher-priced forms of generics capture only a small share of the market in the US, Canada and the UK. In turn, this

suggests that the average prices paid by buyers (and hence average revenue to companies) in these countries are likely to be closer to the lower estimates.

Box 3.1 **Highest and lowest prices for generics in the US, Canada and the UK**

Many of the generic pharmaceuticals in the US, Canada and the UK are characterised by a wide variety of manufacturers and prices. The Commission obtained overseas volume data from IMS Health for some of the generic molecules included in the price comparisons. When possible, volume data were used to weight the range of prices. These provide a more accurate measure of the average prices that companies receive.

To examine the issue of where actual prices lie within each range, higher and lower estimates of prices were calculated for those forms for which prices were weighted by volume data (see table).

Price ratios for selected pharmaceuticals, the US, Canada and the UK

Country	*No. of forms*	*Higher estimate*	*Lower estimate*	*Weighted price ratio*
US	8	3.81	1.93	2.19
Canada	7	3.93	1.47	1.82
UK	12	3.36	1.80	2.16

Based on this small sample, the actual prices and revenues received by manufacturers are likely to be closer to the lower estimate of prices than the higher estimate. For example, in Canada, the volume weighted price ratio of 1.82 is 24 per cent greater than the lower estimate of prices and 54 per cent below the higher estimate.

Source: PC estimates.

3.3 Price comparisons by therapeutic group

All pharmaceuticals are classified under an internationally recognised system of Anatomical Therapeutic Chemical (ATC) codes (box 3.2). The ATC system provides a method of grouping certain pharmaceutical products according to criteria such as anatomical site of action, indications, therapeutic use, chemical composition and mode of action.

Each matching form of Australia's 150 top-selling PBS items can be allocated to its anatomical site of action (hereafter ATC group) and price comparisons undertaken. The results assist in identifying which types of pharmaceuticals account for the observed price differences reported in section 3.2.

Box 3.2 **Anatomical classifications**

The major ATC groups identified by their anatomical site of action (with examples of their therapeutic uses) are:

- alimentary tract and metabolism (digestive system disorders, ulcers and diabetes);
- antineoplastic and immunomodulating agents (various cancers, leukemia and multiple sclerosis);
- blood and blood forming organs (blood clots, angina, and stroke and heart attack prevention);
- cardiovascular system (heart disease and hypertension);
- dermatologicals (anti-fungals, psoriasis, treatment of burns, dermatosis and severe acne);
- general anti-infectives for systemic use (bronchitis, bacterial infections, tuberculosis, AIDS, sexually transmitted diseases and influenza vaccine);
- genito urinary system and sex organs (pituitary and testicular disorders, menopause and infertility);
- musculo-skeletal system (arthritis and osteoarthritis);
- nervous system (pain relief, migraine, epilepsy, mental disease and depression);
- respiratory system (asthma and pulmonary disease);
- sensory organs (eye infections and glaucoma);
- systemic hormonal preparations, excluding sex hormones (various pituitary and thyroid disorders, and endometriosis); and
- various (includes drug dependence, diagnostic tests and lactose intolerance).

Source: DHAC (2000).

For each ATC group, table 3.11 shows whether Australian manufacturer prices for the top-selling PBS-listed pharmaceuticals are higher or lower than those in the comparison countries.[12] The table also shows the results for all categories (from table 3.4) to enable comparisons across ATC groups for each comparison country.

Differences in manufacturer prices between Australia and each of the comparison countries can vary significantly, depending on the ATC grouping of the matched pharmaceuticals (table 3.11).[13] For example, based on the lower estimates for Canada, price differences for different ATC groups ranged from 0.5 (for systemic

12 The results cannot be used to draw conclusions about differences in manufacturer prices for all pharmaceuticals in an ATC group because the sample of items used may not be representative of the entire PBS market for that group.

13 The full results showing higher estimates are contained in appendix E (table E.38).

hormonal preparations) to 2.0 (for items in the respiratory system group). Prices in Sweden, the UK and the US were the same or higher than Australian prices for all ATC groups. Other countries have a mix of higher and lower priced ATC groups.

Table 3.11 **Price ratios for ATC groups, list prices, lower estimates[a]**

ATC group	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
All categories (from table 3.4)	2.6	1.5	1.5	1.5	1.1	1.0	0.9
Alimentary tract and metabolism	3.7	1.6	1.7	1.9	1.3	1.1	0.7
Antineoplastic and immunomodulating agents	1.5	1.0	1.0	1.0	0.8	0.5	0.7
Blood and blood forming organs	1.8	1.4	1.1	1.2	1.2	1.0	1.4
Cardiovascular system	2.5	1.6	1.5	1.3	1.2	1.0	0.9
Dermatologicals	4.0	1.5	1.0	1.0	0.9	0.7	0.7
General anti-infectives for systemic use	2.0	0.9	1.4	1.3	1.0	0.8	0.9
Genito urinary system and sex organs	4.2	1.3	1.5	1.4	0.9	1.0	1.4
Musculo-skeletal system	2.1	1.6	1.6	1.9	1.0	0.8	0.8
Nervous system	2.3	1.3	1.4	1.4	1.0	1.1	1.2
Respiratory system	4.1	2.0	1.7	2.8	1.4	1.1	1.2
Sensory organs	1.8	1.1	1.2	1.1	0.8	0.7	0.9
Systemic hormonal preparations, excluding sex hormones	2.4	0.5	1.0	1.0	0.8	0.5	0.7
Various	1.4	1.4	2.2	nm	1.2	0.4	1.3

a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn. Figures in this table are based on lower estimates of prices. The price ratios reported with a value greater (lower) than one indicates that manufacturer prices for the matched forms in the comparison country are greater (lower) than the prices of those in Australia. **nm** No matches were identified in this category.

Source: PC estimates.

It also is possible to estimate the contribution of particular ATC groups to the overall results reported in section 3.2. Table 3.12 shows the percentage contribution

that pharmaceuticals in specific ATC groups make to the overall results for each comparison country.[14]

Table 3.12 **Contributors to price gap with Australia, ATC groups, lower estimates[a]**

ATC group	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
	%	%	%	%	%	%	%
All categories (from table 3.4)	162.3	50.7	48.1	47.7	11.9	-3.6	-7.6
Alimentary tract and metabolism	44.4	8.6	12.2	16.3	4.7	1.4	-4.7
Antineoplastic and immunomodulating agents	2.6	-0.1	0.2	0.3	-1.8	-2.3	-1.5
Blood and blood forming organs	0.9	1.4	0.2	0.9	0.2	0.0	0.1
Cardiovascular system	59.7	24.0	19.3	12.8	7.8	-1.5	-4.3
Dermatologicals	7.4	0.5	0.1	0.0	-0.1	-0.5	-0.5
General anti-infectives for systemic use	8.0	-1.0	2.6	2.1	0.2	-1.3	-0.7
Genito urinary system and sex organs	6.0	0.4	0.4	0.6	-0.1	0.0	0.3
Musculo-skeletal system	4.0	2.5	2.1	2.6	0.0	-0.6	-0.6
Nervous system	22.9	3.2	6.2	6.1	-0.4	1.4	3.0
Respiratory system	4.2	10.7	4.0	5.9	2.0	0.6	1.4
Sensory organs	1.6	0.1	0.2	0.2	-0.5	-0.5	-0.2
Systemic hormonal preparations, excluding sex hormones	0.4	-0.1	0.0	0.0	-0.2	-0.1	0.0
Various	0.3	0.4	0.7	0.0	0.2	-0.3	0.2

a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn. Figures in this table are based on lower estimates of prices. A positive (negative) value indicates that the relevant group of pharmaceuticals made a positive (negative) contribution to price differences; that is, Australian prices were lower (higher) than those in the comparison country.

Source: PC estimates.

14 The contribution of an ATC group is equal to the share of price differences for that particular ATC group in price differences for all ATC groups, and is calculated using the formula:

$$C_j = \frac{\sum_{i=1}^{n_j} Q_{Aij}(P_{Oij} - P_{Aij})}{\sum_{j=1}^{14}\sum_{i=1}^{n_j} P_{Aij}Q_{Aij}}$$

where: P_{Oij} = price of pharmaceutical i, within ATC group j, in the comparator country; P_{Aij} = price of pharmaceutical i, within ATC group j, in Australia; and Q_{Aij} = quantity of pharmaceutical i, within ATC group j, in Australia.

Positive (negative) figures within table 3.12 indicate the relevant ATC group made a positive (negative) contribution to aggregate price differences — that is, Australian prices were lower (higher) than those in the comparison country. For instance, table 3.12 shows that prices in the US for all categories (based on the lower estimate) were about 162 per cent above Australian prices. Three ATC groups accounted for a large share of this difference. One group (cardiovascular system) accounted for around 60 percentage points (or 37 per cent) of the overall difference.

From these results, it appears that a relatively small number of ATC groups have a large influence on the overall results (driven by both their large share of Australian expenditure and the size of observed price differences). Four ATC groups accounted for over 70 per cent of the total expenditure on Australia's 150 top-selling PBS molecules. These influential ATC groups are:

- cardiovascular (which accounted for 34 per cent of Australian expenditure);
- alimentary tract and metabolism (14 per cent of Australian expenditure);
- nervous system (15 per cent of Australian expenditure); and
- respiratory system (nine per cent of Australian expenditure) (appendix E).

Australian manufacturer prices for these four groups were found to be below those in the comparison countries in nearly all cases. The exceptions are for cardiovascular items (Spain and NZ), alimentary tract and metabolism items (NZ), and nervous system pharmaceuticals (France).

In most cases, the results for cardiovascular pharmaceuticals seem to have the largest effect on the results for all categories. Moreover, Australian manufacturer prices for this group appear to be well below those for all countries, with the exception of Spain and NZ (table 3.11).

It is possible to examine the contribution that different categories of pharmaceuticals make to the estimated price differences for the four key ATC groupings.

The contribution of different pharmaceutical categories to the aggregate price differences for each of the four influential ATC groups is shown in table 3.13. As noted earlier, cardiovascular system pharmaceuticals accounted for around 60 percentage points of the overall price difference for the US. The table shows that me-too pharmaceuticals accounted for nearly all of this contribution (around 52 percentage points).

Table 3.13 **Contributors to price gap with Australia, influential ATC groups, lower estimates[a]**

ATC group		*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
		%	%	%	%	%	%	%
Cardiovascular system	Generics	7.8	6.9	2.8	1.8	-0.6	-0.7	-0.9
	Me-too	51.8	17.2	16.5	11.1	8.5	-0.7	-3.4
	New	nm	nm	0.0	nm	-0.1	nm	nm
	All	59.7	24.0	19.3	12.8	7.8	-1.5	-4.3
Alimentary tract and metabolism	Generics	27.5	6.1	6.0	8.4	3.8	1.9	-3.3
	Me-too	13.7	2.4	5.2	7.3	0.9	-0.4	-1.5
	New	3.2	0.1	1.0	0.5	0.0	-0.1	0.0
	All	44.4	8.6	12.2	16.3	4.7	1.4	-4.7
Nervous system	Generics	3.7	-0.4	0.0	0.6	0.0	-0.8	-0.3
	Me-too	14.0	2.7	4.7	5.8	0.4	2.9	3.1
	New	5.2	0.9	1.5	-0.3	-0.9	-0.7	0.3
	All	22.9	3.2	6.2	6.1	-0.4	1.4	3.0
Respiratory system	Generics	0.1	3.5	0.2	0.5	0.8	-0.3	0.1
	Me-too	4.1	7.3	3.8	5.4	1.2	0.9	1.3
	New	nm	nm	nm	nm	nm	nm	nm
	All	4.2	10.7	4.0	5.9	2.0	0.6	1.4

a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn. Figures in this table are based on lower estimates of prices. A positive (negative) value indicates that the relevant group of pharmaceuticals made a positive (negative) contribution to price differences (that is, Australian prices were lower (higher) than those in the comparison country). **nm** No matches were identified in this category.

Source: PC estimates.

The general pattern emerging from these results is that price differences for me-too pharmaceuticals in the cardiovascular, nervous and respiratory systems account for the largest share of the observed price differences with Australia for most comparison countries.

For the cardiovascular group, me-too pharmaceuticals account for the largest share of price differences between Australia and all comparison countries, with the exception of Spain. This reflects the large share of me-too cardiovascular pharmaceuticals in total Australian expenditure on the top 150 molecules (around

27 per cent). Generic pharmaceuticals also make a significant contribution to the comparisons for the US and Canada.

The contribution of me-too pharmaceuticals also outweighs that of other categories for pharmaceuticals acting on the nervous system (except for France) and the respiratory system.

Generic pharmaceuticals make the largest contribution to the results for alimentary tract and metabolism pharmaceuticals (with a significant contribution from me-too pharmaceuticals in Sweden, the UK and the US).

The influence of new innovative pharmaceuticals is low overall, reflecting their relatively small share of total expenditure in Australia. However, the contribution of new innovative pharmaceuticals is most pronounced for pharmaceuticals acting on the nervous system.

3.4 Sensitivity of results

The number of methodological choices associated with pharmaceutical price comparisons means that a wide variety of results (and interpretations) can be obtained depending on the approach taken to each issue. The methodological choices made in this study were guided by the purpose of the study, the requirements of the terms of reference, and data and time limitations.

However, two areas where different values could be used for a given methodological issue are the choice of exchange rate and classification of molecules, as discussed below.

Exchange rates

Due to fluctuations in exchange rates through time, the price ratios could be sensitive to the choice of time period over which the exchange rate is obtained.

In response to the preliminary results, the Commission received a number of comments regarding the choice of exchange rate period. One respondent asked whether fluctuations in exchange rates over time had influenced the price comparisons. Another respondent contended that the use of recent point estimates of exchange rates was not appropriate, arguing that the relevant exchange rates were those which applied when listing decisions were made.

Apart from the logistical difficulties in matching exchange rates that applied when listing decisions were made, the purpose of the study is to compare the prices that

manufacturers receive at a particular point in time. Given this purpose, it is appropriate to use an average exchange rate for the month of June 2000 to estimate the price ratios reported in section 3.2 because they closely matched the time period over which the pharmaceutical prices were collected.

To assess the sensitivity of the results, the price ratios for all categories were recalculated using a number of different exchange rate periods (table 3.14). This analysis showed that, while the variation in price ratios increased as the exchange rate period was lengthened, the choice of exchange rate period did not significantly affect the price comparison results. This is because the average exchange rates for different periods were relatively stable over the 24 months to June 2000.

Table 3.14 **Sensitivity of price ratios to different exchange rates[a]**

Time period	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
	%	%	%	%	%	%	%
30 June 2000	-1.4	-1.7	-0.8	-2.3	-1.1	-1.2	-1.6
Three months to June 2000	0.6	0.5	2.2	-0.4	-0.9	-1.0	2.6
1999-2000	-5.6	-5.3	-0.4	-2.9	-0.4	-0.4	1.1
1998-99 to 1999-2000	-5.3	-6.2	1.4	-0.2	5.2	5.2	3.9

a A negative (positive) value indicates that the price ratio would decrease (increase) by that percentage if that exchange rate was used instead of the average for June 2000.

Source: PC estimates.

Using the average exchange rate for the three months to June 2000 and as at 30 June 2000, prices in all countries differ by less than three per cent.

Applying the average exchange rate for 1999-2000, prices differ by less than three per cent in the UK, Sweden, France, Spain and NZ compared to the average exchange rate for June 2000. In the US and Canada, prices were around five to six per cent lower with the average exchange rate for the 1999-2000 financial year. This reflects the general depreciation of the Australian dollar against these currencies during 1999-2000.

Using the average exchange rate over the years 1998-99 and 1999-2000, prices in Canada and the US were about five to six per cent lower whereas prices in France, Spain and NZ were around four to five per cent higher. While the use of this exchange rate period reduces the price differences between Australia and the North American countries, the price differences remain significant for all categories. For Spain and NZ, there were some reversals in relative price levels with Australia, but these changes were small. For example, in the case of Spain, the price ratio for all categories (lower estimate) is 1.01 using this exchange rate period compared with 0.96 using the exchange rate for June 2000.

Classification of molecules

The Commission sought the assistance of DHAC to classify the 150 molecules included in the price comparisons. The molecules were classified according to their status as at 30 June 2000. Their status since June 2000 may have changed as new molecules may have been listed or as patents have expired.

The price comparisons for all categories would not be altered if molecules were transferred between the three sub-categories. However, given that the price ratios within each country differed across the sub-categories, the results obtained for each country could be sensitive to the classification of individual molecules at the sub-category level.

Several participants at the round-table disagreed with the categorisation of some molecules used in the preliminary price comparisons. According to one participant, many patented molecules in the me-too category could have been included in the new innovative category. Conversely, another participant argued that a molecule in the new innovative category should have been classified as a me-too pharmaceutical.

It should be noted that the terms of reference set out the definitions of pharmaceuticals to be used in this study. DHAC categorised the 150 molecules according to these definitions which are consistent with those used under PBS pricing arrangements; that is, the categories (new innovative, me-too and generic) also are used for price-setting purposes.

In response to specific comments and as part of the data validation process, the classification of the 150 molecules was re-examined by the Commission with the assistance of DHAC. This resulted in four molecules being reclassified (table 3.15). The final classification is contained in appendix D.

Table 3.15 **Reclassified molecules**

Molecule	*Preliminary category*	*Final category*
Calcitriol	New innovative	Generic
Interferon beta–1b	New innovative	Me-too
Leuprorelin acetate	New innovative	Me-too
Salmeterol xinafoate	New innovative	Me-too

Source: DHAC (pers. comm., 20 May 2001).

The price ratios were recalculated using the final classification. Compared to the preliminary results, the reclassification had no effect on the price ratios for all categories. There were only minor changes in the price ratios for the me-too and

generic categories. However, for some countries, the final results for new innovative pharmaceuticals (table 3.5) differed significantly from the preliminary results. While the final price ratios were lower for all comparison countries except NZ, the changes were substantial for the US and Canada in particular.

3.5 Conclusion

This chapter has reported the results of a comparison of manufacturer prices in Australia for 150 top-selling PBS-listed pharmaceuticals. The principal finding is that manufacturer prices in Australia for these top-selling products are low compared to those in the US, Canada, the UK and Sweden. Australian prices are close to those in France, Spain and NZ.

Accounting for discounts has a significant impact on the size of the observed price difference between Australia and the US. However, prices in Australia are still well below those in the US when discounts are taken into account. Significant discounts also may be available in the UK for generic items but there is insufficient information to enable an assessment of the effect of discounts on the price comparisons. There is no evidence of significant discounts being offered in Canada and Sweden. Information on discounts in NZ, Spain and France is unavailable.

Prices in Australia for new innovative pharmaceuticals are much closer to those in other countries. Although there is still a significant gap in new innovative prices for the US and the UK, the gaps are less than for the other categories. Australian prices for new innovative pharmaceuticals are close to those in Canada and Sweden, the same as those in NZ, and above those in France and Spain.

The largest price differences were observed for me-too pharmaceuticals. Australian prices are below those in all comparator countries, except for NZ on the lower estimate of prices.

Significant price differences also were observed for generic pharmaceuticals. Generic prices were found to be much higher than Australia for the US, Canada, the UK and Sweden. Generic prices in Australia are close to those in France and slightly above those in Spain and NZ.

Finally, an analysis of the price comparisons by therapeutic group shows that four groups have a large influence on the overall results. These influential groups include pharmaceuticals acting on the cardiovascular system, alimentary tract and metabolism, the nervous system and the respiratory system. For these groups, me-too pharmaceuticals account for a significant share of the observed price differences between Australia and most comparison countries.

4 Reasons for price differences

The primary purpose of this study is to estimate, for selected countries, differences in the prices received by manufacturers for pharmaceuticals listed on the Pharmaceutical Benefits Scheme (PBS) (chapter 3). The terms of reference also require the Commission to identify, as far as possible, the reasons for any observed differences.

A number of potential reasons for the observed price differences were identified at a roundtable meeting of industry experts held to discuss the preliminary results. They included inter-country differences in:

- pharmaceutical subsidy arrangements;
- cost-containment policies (especially the effects of price reviews, economic evaluations and reference pricing); and
- the speed of introduction of new pharmaceuticals to the market.

In addition, roundtable participants identified particular factors that may have contributed to the results for the individual categories.

This chapter examines whether the factors identified by participants are likely to have contributed to the reported results.

4.1 Subsidy arrangements

Some roundtable participants considered that differences in the pharmaceutical subsidy arrangements prevailing in the comparison countries may have contributed to the observed price differences. It was also considered that price differences may depend on how subsidy arrangements are administered, including the willingness of governments to exploit any bargaining power they possess.

Systemic differences in subsidy arrangements

Chapter 2 noted that countries can be classified by aspects of their subsidy arrangements, including:

- whether public pharmaceutical subsidy or private insurance arrangements dominate; and
- whether governments have a positive or negative subsidy list.

Based on these characteristics, Australia's subsidy arrangements differ most from those applying in the United States (US), Canada, and the United Kingdom (UK). The results in chapter 3 showed that prices in these countries were significantly higher than those in Australia.

In the US and Canada, private insurers cover pharmaceutical costs for a significant proportion of the population. The coverage of government subsidy schemes is generally limited to specific groups in society, such as the aged, people with disabilities and the poor (appendix B). Reflecting this, the public sector share of total pharmaceutical expenditure in the US and Canada (around 15 and 32 per cent respectively) is the lowest amongst the comparison countries. In contrast, the public sector accounts for around 53 per cent of total pharmaceutical spending in Australia.[1]

The lower population coverage of the government subsidy schemes and the existence of multiple private insurers competing against each other may have diluted the buying power of government agencies and private sector insurers. However, many of the individual entities operating in the US and Canada are likely to spend more on pharmaceuticals each year than the Australian Government spends on the PBS. Also, competition among private insurers may strengthen incentives to reduce pharmaceutical prices.

Significant price differences also were observed between Australia and the UK, even though both provide universal subsidies. Whereas companies operating in Australia apply for a listing on the PBS (a positive subsidy list), the UK Government decides which products will not be eligible for subsidies (that is, placed on a negative list). A positive subsidy list may provide governments with somewhat more power in negotiating reimbursement prices, especially for me-too pharmaceuticals (chapter 2).

Of the remaining comparison countries, Sweden had significantly higher prices than Australia whereas prices in France, Spain and New Zealand (NZ) were broadly similar. All four of these countries are similar to Australia in that they offer universal subsidies covering a large number of products on positive subsidy lists.

The difficulties in finding associations between price differences and subsidy arrangements suggest that the price differences reflect additional factors such as

1 This figure includes expenditure on over-the-counter (OTC) products.

differences in demand conditions, the subsidy status of pharmaceuticals, volume restrictions, delays due to marketing approval requirements, patent arrangements, the level of competition amongst pharmaceuticals within therapeutic groups, and production and marketing costs.

One further possibility is that the results reflect differences in the contribution of the pharmaceutical industry to the economies of the comparison countries. For instance, a possible argument is that Governments may be more sensitive to using their negotiating power to lower prices for subsidised pharmaceuticals, when the pharmaceutical industry is a relatively large contributor to the economy.

The evidence for this hypothesis is mixed. Prices were higher than in Australia in four countries that are major producers and exporters of pharmaceuticals. In the US, the UK, Sweden and France the pharmaceutical industry accounts for between 1.1 and 1.7 per cent of gross domestic product (GDP). The UK, France and Sweden also are net exporters of pharmaceuticals (imports and exports are about equal in the US) (appendix B).

Comparatively low prices were observed in Australia and NZ, whose pharmaceutical industries are relatively small, accounting for around 0.6 per cent of GDP in Australia and 0.4 per cent of GDP in NZ. Like Australia, NZ also is a significant net importer (appendix B).

However, the high prices observed for Canada do not fit in with the view that the largest price differences are observed in countries with the largest pharmaceutical industries. Canada's industry accounts for around 0.8 per cent of GDP.

In addition, while prices in Spain were about the same as Australia's, it has a relatively significant industry (accounting for 1.4 per cent of GDP) (appendix B). However, the low prices in Spain may reflect the fact that it has only recognised pharmaceutical patents since 1992. According to Kanavos (1999b), this has meant that a large number of copy products exist on the Spanish pharmaceutical market, which are significantly cheaper than the originator products.

Overall, it is difficult to find a clear association between the broad features of the subsidy arrangements in the comparison countries and the price differences with Australia.

Differences in the administration of subsidy arrangements

Some of the overall results may be due to differences in the way that subsidy arrangements were applied to the pharmaceuticals in the sample. Specific factors affecting the price comparisons may include differences in:

- the level of subsidy; and
- volume controls (such as restrictions on the subsidised uses of pharmaceuticals).

The following discussion therefore focuses on how inter-country differences in the application of subsidy arrangements may influence the results.

Level of pharmaceutical subsidies

In principle, price differences for some matched pharmaceuticals may be due to differences in the effective rate of subsidy. Suppliers may be more willing to accept lower prices in exchange for obtaining subsidy status, depending upon the rate of subsidy (chapter 2).

As all comparison countries require consumers to make a contribution (copayment) towards the cost of subsidised pharmaceuticals, the effective subsidy rate depends, in part, on the level and type of copayment. There are significant differences across the comparison countries in the type of copayment system and levels of copayment for matched pharmaceuticals.[2] Some of the comparison countries have proportional copayment systems (France, Sweden and Spain), while others have a fixed copayment system (Australia, the UK and NZ).[3]

Statistics on the private contributions to expenditure on pharmaceuticals do not distinguish between private expenditure by patients or by third-parties (such as private insurers). Nevertheless, this information shows considerable variation across countries in the proportion of expenditure funded by governments (table 2.1).

Ideally, comparisons of effective subsidy rates would occur for individual pharmaceuticals. While subsidy information for all of the pharmaceuticals in the sample was unavailable, there is some evidence that subsidy levels do differ across the comparison countries. For example, in Australia, the Government pays around 75 per cent of the total cost of *ranitidine*.[4] In comparison, governments in France and Spain pay 65 and 60 per cent of the total cost respectively.

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2 Comparisons of subsidy levels are further complicated by the safety net arrangements that exist in most comparison countries. These may involve annual limits on the out of pocket expenditure on pharmaceuticals or provide for reduced copayments when a certain level of annual expenditure is exceeded.

3 A mixture of proportional and fixed copayment systems are used in the US and Canada.

4 The subsidy rate was calculated by dividing the total cost to the Government of subsidies for *ranitidine* (150 mg, 60 tablets) during 1999-2000 ($44.23 million) by total expenditure on the product ($58.68 million) (PBPA 2000, p. 26).

Due to the lack of information on subsidy rates for the pharmaceuticals in the sample, it is not possible to assess the contribution of this factor to the results.

Volume controls

Roundtable participants considered that Australia's use of volume controls for items listed on the PBS should be taken into account when interpreting the results. Volume controls include restrictions on indications (the circumstances in which subsidised pharmaceuticals may be used), requirements on physicians to seek authorisation prior to prescribing a medicine, and price-volume agreements).[5]

In principle, volume controls affect the level of sales and hence manufacturer revenues, giving rise to a trade-off between the prices and use of volume controls. If governments consider that the subsidy cost of a pharmaceutical is excessive, at the price offered by the supplier, they may attempt to reduce the budgetary cost by imposing volume restrictions (chapter 2).

However, it is difficult to predict how volume controls placed on pharmaceuticals will affect manufacturer prices, as this may depend on the characteristics of demand and supply. For example, imposing volume controls could cause manufacturer prices to rise if unit costs fall with the quantity produced. Also, imposing volume controls may not affect manufacturer prices if they are easily circumvented by doctors and/or patients.

Roundtable participants considered that volume controls are used more often in Australia than the comparison countries. It was considered that the results for new innovative pharmaceuticals could therefore mask differences in the way the matched pharmaceuticals are used.

While it was not possible to obtain information on volume controls for all countries, some information for Canada (Ontario) and NZ supports participants' views (box 4.1).

Overall, there is some evidence that volume restrictions are more likely to be used in Australia than in some comparison countries. However, it is not clear how the use of volume controls in Australia may have influenced the price differences.

5 The main types of volume controls are described in more detail in chapter 2.

Box 4.1 **Use of volume controls in Australia, NZ and Ontario**

The prevalence of volume controls for the new innovative and me-too pharmaceuticals in the sample was examined for Australia, NZ and Ontario.

In Australia, 20 out of the 21 new innovative molecules in the sample were subject to some form of restriction on their use (at 30 June 2000). Most of these molecules (17) were listed with the highest level of restriction (Authority Required). Of the 49 me-too molecules in the sample, 37 (or 76 per cent) were subject to some form of restriction on their use at 30 June 2000.

NZ also imposed volume controls on many of the new innovative and me-too molecules in the sample. Information was available for only 12 of the new innovative molecules in the sample. All of these items were covered by a restriction (that they could be prescribed by medical specialists only). For the 36 me-too molecules listed in the NZ schedule that were also available in Australia, it was found that 21 (or 58 per cent) had some form of restriction.

Slightly fewer molecules were subject to some form of restriction in the Canadian province of Ontario. Information was available for 11 new innovative molecules in the sample, nine (82 per cent) of which, required authorisation of some form and were reimbursed only if specified clinical conditions for use had been met. For me-too molecules, 14 out of the 35 me-too (40 per cent) molecules listed on the Ontario formulary required some form of authorisation.

Sources: DHAC (2000); Ministry of Health and Long–Term Care (2001) ; Pharmac (2000b).

4.2 Cost-containment mechanisms

Roundtable participants considered that the strong emphasis on cost-containment within Australia's subsidy arrangements had an important influence on the results. In particular, participants identified a number of influential elements of Australia's cost-containment systems, including:

- differences in cost-containment policies;
- the use of economic evaluations; and
- the use of reference pricing to establish reimbursement prices for specific groups of pharmaceuticals.

The influence of these elements is discussed separately and in the context of case studies for a small number of pharmaceuticals.

Cost-containment policies

Cost-containment policies include product-by-product price controls, reference pricing, economic evaluations and mandatory price cuts (chapter 2). The US, Canada and the UK are most different to Australia and the other comparison countries in their use of cost-containment policies because companies are relatively free to set prices for pharmaceuticals (box 4.2). Prices in these countries were considerably higher than in Australia, based on the overall results.

The other comparison countries, like Australia, employed more stringent cost-containment mechanisms, although there is considerable variation in the types of mechanisms that they use (box 4.2).

Within this sub-group, it was found that price differences with Australia were smallest for NZ and Spain even though these countries have very different cost-containment policies.

NZ may have the most stringent cost-containment measures of the comparison countries. Like Australia, it requires companies to submit economic evaluations with applications for listing new pharmaceuticals or for increasing the price or widening the clinical uses of pharmaceuticals already listed. It also has implemented a reference pricing system that covers sub-groups of therapeutically equivalent on- and off-patent pharmaceuticals, and sets benchmark reimbursement prices for these sub-groups at the level of the lowest-cost item. But it has gone further than Australia, by using competitive tendering and tender protection agreements to put additional downward pressure on prices (appendix B).

The cost-containment measures used in Spain may be less stringent. Companies are not required to submit economic evaluations. Also, while Spain has a reference pricing system, it extends to chemically equivalent (generic) pharmaceuticals only. Furthermore, benchmark reimbursement prices may be set above the level of the lowest-cost item within sub-groups.

The difficulty in finding a clear link between the price differences with Australia and the type of cost-containment policies may reflect differences in the way that cost-containment measures are applied. The results also may reflect particular factors in the comparison countries. Both Sweden and France are major producers and exporters of pharmaceuticals. And as noted above, Spain did not recognise pharmaceutical patents until relatively recently.

Overall, it is difficult to find a clear association between the price differences with Australia and the type of cost-containment policies employed by different countries.

Box 4.2 **Pharmaceutical cost-containment arrangements in comparison countries**

US: Companies are generally free to price pharmaceuticals. Managed care plans directly negotiate rebates from manufacturers based on their ability to steer members toward the cheapest pharmaceutical.

Canada: Companies are free to price new pharmaceuticals subject to Federal regulations which provide that launch prices of patented products should not be higher than the median price in seven other developed countries (including the UK and the US). Also, price rises cannot exceed the rate of change in the consumer price index.

UK: All new prescription products approved for marketing are automatically reimbursed. Companies are free to set prices for new products subject to an overall cap on their rate of return but must seek approval before they can increase the prices of existing products.

Sweden: Products are reimbursed once a price is agreed with the Government. Negotiations may have regard to international price comparisons — the aim is to award a 'European price'. Reference pricing is only applied to off-patent products. Pricing of new innovative pharmaceuticals are usually accompanied by a price-volume agreement.

France: Prices are negotiated via 'conventions' (five-year contracts). Reimbursed prices are based on several factors including: prices of local comparators; prices of the product in other European markets; and the degree of 'innovativeness' of the product (the therapeutic improvement over existing products).

NZ: Economic evaluations are mandatory for all new products. Reference pricing is widely used and groups may include patented and off-patent products. Additional cost-containment methods are used such as competitive tendering and tender protection agreements.

Spain: The Government controls prices of all prescribed pharmaceuticals. Factors considered in price negotiations include the prices of the product in other European markets, prices of therapeutically-equivalent products and the innovativeness of the product. Price-volume agreements are used frequently for more expensive products. Reference pricing is used for some generic products.

Source: Appendix B.

Role of economic evaluation

Roundtable participants considered that Australia's mandatory economic evaluation requirements, combined with the rigorous evidence-based approach to assessing reimbursement decisions, were major factors explaining the price differences, especially for me-too items.

Some participants considered that me-too products offer no measurable advantage over existing products. According to this view, a new me-too product is likely to receive the same price as comparable items (which may include another me-too or low-cost generic) under Australia's evidence-based system. It was therefore expected that prices for me-too products would be somewhat higher in countries that do not undertake evidence-based economic evaluations.[6]

Australia, NZ and the Canadian provinces of Ontario and British Columbia are the only jurisdictions to require companies to submit an economic evaluation with applications for listing new pharmaceuticals or for increasing the price or widening the clinical uses of pharmaceuticals already listed (chapter 2). Prices in Australia were close to those in NZ but not to Canada.

In Sweden, France and Spain, companies may elect to provide an economic evaluation of benefits over alternative treatments in arguing for higher reimbursement prices, but it is not compulsory to do so. Australian prices were closer to those in France and Spain but not to those in Sweden.

No information was available on the application of economic evaluations in the US managed care sector, but they are not used to determine reimbursement prices for items listed on the Federal Supply Schedule (FSS) (appendix B). In the US, large buyers also are able to obtain significant discounts off the list prices of me-too pharmaceuticals. The largest discounts were obtained on Australia's top-selling me-toos (ranging from 34 to 39 per cent). This could suggest that the ability to control admission to the list of subsidised products will be just as, if not more, important in influencing negotiated prices, as any requirement to undertake economic evaluations.

It is difficult to assess the impact of economic evaluations on price differences using the results of this study.

Role of reference pricing arrangements

Australia's reference pricing arrangements also were identified as a potential cause of the price differences. Roundtable participants suggested that price differences be computed for me-too pharmaceuticals subject to formal reference pricing, and the results compared with those for me-too products not covered by this policy.

6 In principle, competition should lead to some convergence of prices for therapeutically-equivalent me-too molecules. However, this assumes that physicians and patients are fully informed about the characteristics of pharmaceuticals and therefore able to determine the level of interchangeability.

Differences between the two results were expected to provide an indication of the extent to which Australia's reference pricing system has suppressed me-too prices.

The Commission identified 24 me-too pharmaceuticals within the sample of 49 that were covered at some point under reference pricing arrangements. These molecules accounted for approximately 76 per cent of the estimated revenue for all me-toos in the sample.[7]

These pharmaceuticals were chosen because their prices were reviewed by the Pharmaceutical Benefits Pricing Authority during 1999-2000 using the weighted average monthly treatment cost (WAMTC) methodology.[8] In essence, WAMTC is a mechanism used to price patented and off-patent (generic) pharmaceuticals that are considered by the Pharmaceutical Benefits Advisory Committee (PBAC) to be therapeutically-interchangeable. The method is used to compare the monthly treatment cost of pharmaceuticals which are available in different dosage types, strengths and pack sizes (box 4.3).

Price differences between Australia and the comparator countries were calculated for the WAMTC me-too pharmaceuticals. These results were then compared with those obtained for 25 me-too pharmaceuticals that were not under WAMTC pricing reviews at 30 June 2000 (table 4.1).

Table 4.1 **Price ratios for WAMTC and non-WAMTC me-too pharmaceuticals, list prices, as at 30 June 2000[a]**

		US	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
Higher								
	WAMTC	3.1	1.7	1.6	1.7	1.2	1.1	1.0
	Non-WAMTC	2.1	1.7	1.2	1.3	0.9	0.9	1.1
	Difference	1.0	0	0.4	0.4	0.3	0.2	-0.1
Lower								
	WAMTC	3.0	1.6	1.6	1.6	1.2	1.1	1.0
	Non-WAMTC	2.1	1.4	1.1	1.3	0.9	0.9	1.1
	Difference	0.9	0.2	0.5	0.3	0.3	0.2	-0.1

a As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, conclusions about relative price levels across countries cannot be drawn.

Source: PC estimates.

7 The individual molecules are identified in table D.2 in appendix D.

8 Recently, use of the methodology to review prices for these groups was suspended.

The results indicate that for all comparison countries except NZ, greater price differences were observed for those me-too items subject to reference pricing in Australia, than for products that were not.

Box 4.3 **Weighted average monthly treatment cost (WAMTC)**

WAMTC is a mechanism used to price patented and non-patented (generic) pharmaceuticals considered by the PBAC to be therapeutically-interchangeable.

The method involves estimating the annual cost of treatment using each pharmaceutical (based on daily dosage and script data):

$$WAMTC = \frac{\text{Total cost of the drug provided over a year}}{\text{Total number of months treatment provided}}$$

The WAMTC is calculated for all pharmaceuticals in a particular sub-group. The pharmaceutical with the lowest average monthly treatment cost is selected as the benchmark for the therapeutic group. The reimbursement price for other pharmaceuticals within the group are adjusted (lowered) to the point where their WAMTC is equal to the benchmark level. For those pharmaceuticals covered under the Therapeutic Group Premium policy, manufacturers may charge a premium above the reimbursement price which the patient (rather than the Government) must pay.

Five therapeutic sub-groups are currently subject to WAMTC pricing reviews. These are:

- H2 receptor antagonists (within the alimentary tract and metabolism ATC group);
- Proton pump inhibitors (alimentary tract and metabolism);
- ACE inhibitors (cardiovascular system);
- Calcium channel blockers (cardiovascular system); and
- HMG CoA reductase inhibitors (cardiovascular system).

Within these five sub-groups, a total of 20 me-too PBS molecules in 64 forms, were subject to price reviews using the WAMTC method as at 30 June 2000. A further five generic pharmaceuticals within the sample were subject to WAMTC pricing reviews.

A sixth sub-group (comprising four molecules), Selective Serotonin Re-uptake Inhibitors (SSRIs), was covered by the WAMTC arrangements prior to July 1999. At that time, price adjustments using the WAMTC mechanism were suspended, pending a review of the methodology. However, pharmaceuticals in this group have been included in the study of price differences for pharmaceuticals subject to WAMTC pricing reviews because the manufacturer price of these items at 30 June 2000 would have been influenced by the pricing reviews that occurred prior to mid-1999.

Sources: PBPA (2001; 2000).

However, these results should be interpreted with caution as the study was not designed to address this specific issue. Consequently, the sample of pharmaceuticals

in each group may not be representative of all me-too pharmaceuticals listed on the PBS. Differences in consumer preferences (relating to the form, dosage and strength of a medicine) may mean that the price ratios for the matched sub-samples are not representative of the true price ratios for all me-too WAMTC and non-WAMTC pharmaceuticals.

Another concern about the representativeness of this analysis relates to the group of non-WAMTC pharmaceuticals. Table 4.2 shows that the Commission was able to match many of the important me-too pharmaceuticals covered under WAMTC pricing arrangements. For instance, 50 per cent of the potential Australian revenue for WAMTC me-too pharmaceuticals in the sample was covered by matches for France and up to 99 per cent for the UK.

However, the Commission was unable to achieve a consistently high level of coverage for non-WAMTC me-too pharmaceuticals. Table 4.2 shows that only 34 per cent of the potential Australian revenue for non-WAMTC me-too pharmaceuticals was covered by matches for France and 38 per cent for Spain. Therefore, the price ratios for the non-WAMTC pharmaceuticals for France and Spain must be interpreted with caution.

Table 4.2 **WAMTC and non-WAMTC coverage of me-too pharmaceuticals, as at 30 June 2000**

	Unit	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
WAMTC								
Coverage[a]	%	66	57	99	55	50	72	78
No. of matches	no.	41	31	60	26	31	41	44
Non-WAMTC								
Coverage[b]	%	57	65	61	55	34	38	62
No. of matches	no.	38	42	47	36	33	34	34

a Coverage shows the percentage of total Australian manufacturer revenue for me-too WAMTC molecules accounted for by the matched forms. **b** Coverage shows the percentage of total Australian manufacturer revenue for me-too non-WAMTC molecules accounted for by the matched forms.

Source: PC estimates.

Overall, the results provide some support for the contention that Australia's reference pricing system has contributed to the reported price differences for me-too pharmaceuticals but due to the concerns about the representativeness of the sample, the extent of the contribution remains unclear.

Case studies of price differences over time

Roundtable participants considered that a better understanding of the reasons for price differences could be obtained by looking at price differences between Australia and the comparison countries over time. It was considered that a longitudinal study could be used to link changes in price differences to the application of particular cost-containment policies.

The principal purpose of this study was to obtain a snapshot of price differences between Australia and the comparison countries. Thus, prices over time were not obtained for the pharmaceuticals in the sample. However, additional pricing information was provided by GlaxoSmithKline Australia Limited (GSK) and the Department of Health and Aged Care (DHAC) for three pharmaceuticals *ranitidine* (Zantac), *paroxetine* (Aropax) and *salmeterol* (Serevent) (appendix F).

For all three products, the gap between prices in Australia and the comparison countries was larger at 30 June 2000 than at the earlier time periods. The increases in price gaps were due to a combination of nominal price reductions in Australia, price changes in the comparison countries, and changes in exchange rates.

The prices of all three products in Australia declined in nominal terms over the relevant periods. The price of *ranitidine* declined by 61 per cent (between May 1983 and June 2000), *paroxetine* declined by 45 per cent (between May 1993 and June 2000), and *salmeterol* declined by 36 per cent (between December 1994 and June 2000).

According to GSK, several factors contributed to the price reductions in Australia, including:

- competition from the entry of new producers (of generic equivalents and therapeutically-interchangeable products). For example, between May 1983 and June 2000 the patent on *ranitidine* in Australia expired and several competitors entered the market;
- price reductions at the time of listing (for two out of the three products, prices declined significantly in the period between the market launch and listing on the PBS). For *ranitidine*, the price reduction on listing occurred before the requirement for economic evaluations was introduced in Australia;
- reference pricing (two of the products are in therapeutic groups that were subject to WAMTC pricing reviews). For example, *paroxetine* is one of a number of Selective Serotonin Re-uptake Inhibitors (SSRIs) that were subject to reference pricing (until mid-1999); and

- changes in volume controls. According to GSK, a significant portion of the price reduction for *salmeterol* occurred when volume controls on the product were eased.

Movements in the price gaps for these products also were influenced by changes in nominal prices in the comparison countries. According to GSK, the price reductions that occurred in some countries were due to:

- competition from generics and therapeutically-interchangeable pharmaceuticals. For example, the price of *paroxetine* in the UK fell by 48 per cent due, in part, to the launch of new therapeutic competitors and price reductions by them; and
- government decisions such as mandatory price cuts. For example, the price of *salmeterol* in France fell due to several compulsory price cuts under a price-volume agreement with the Government.

Prices in the US for all three products increased significantly over the period (by between 19 and 45 per cent). However, there is considerable doubt about the prices and changes in them. While GSK provided list prices for the US, the comparable FSS prices for all three were consistently lower. For example, the FSS price for *salmeterol* was around 26 per cent below the list price reported by GSK.

Some of the change in the Australian dollar denominated prices of the products in the comparison countries were due to changes in exchange rates. The Australian dollar depreciated against most of the currencies over the different time periods examined.

In summary, for the three products examined, price differences with Australia generally increased over time due to a combination of factors influencing Australian prices and prices in comparison countries. The case studies suggest that price differences at a point in time are likely to be influenced by a combination of inter-country differences in competition and government regulation of prices and volumes.

4.3 Market launch of new pharmaceuticals

At the roundtable, it was suggested that pharmaceuticals available in Australia are 'older' than those in the comparison countries. It was considered that the price of a pharmaceutical is related to its global age (the time that has elapsed since the product was first launched anywhere in the world), such that older molecules obtain lower prices, possibly due to competition from 'new and improved' alternative therapies.

To examine this issue, the Commission used information from IMS Health on global and the local market launch dates, to estimate the average time between the global launch of a pharmaceutical and the launch of the product in each of the comparison countries.

The Commission focused on those molecules where it was possible to match at least one form (not necessarily the same one in all countries) with Australia across the seven countries. This yielded a sample of 39 molecules.[9] In order to undertake the comparison, the first date of marketing of any form of the molecule was used as the relevant basis for comparison.

Figure 4.1 shows the estimated median delay (measured in years) between the first launch of a sample of products anywhere in the world (the global launch date), and the local launch date, for Australia and six countries where data were available. This delay is likely to reflect many factors, including local demand conditions, marketing approval processes and the time taken to obtain a listing for reimbursement purposes.[10]

For most countries, there is no significant difference in the delay between the global launch and the local launch. For example, the delay between the global and Australian launch dates is an average of 2.6 years for all categories. This is similar to the results for France, the US, Spain, Canada and NZ.

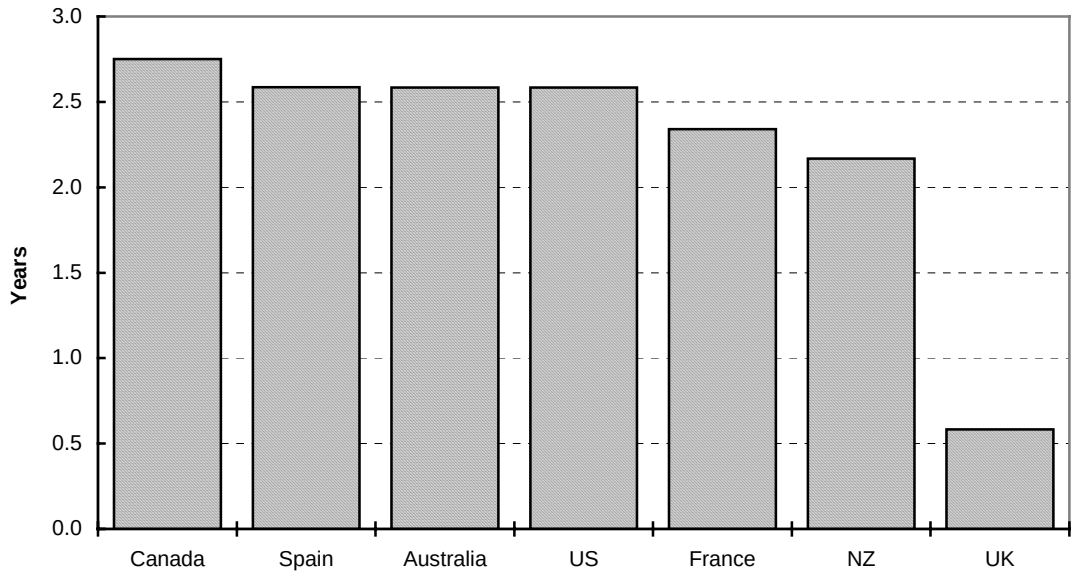
The exception is the UK, where the average delay between the global and local launch is just over 6 months. This could be due to the high number of new molecules launched in the UK (giving a delay of zero). Of the 39 molecules included in the sample, it was found that the global launch occurred in the UK in 12 cases. This compares with three molecules launched initially in the US, and none in Australia. The UK may be a relatively attractive market in which to launch new products because, once approved for marketing, new pharmaceuticals are automatically reimbursed under the UK's subsidy arrangements (appendix B).

The results suggest the ages of the molecules in the sample do not differ significantly. However, the results should be interpreted with caution. The major limitation is that the measured delay does not take into account the amount of time it takes to obtain a PBS listing. Another limitation is the small number of molecules (39) included in the sample.

9 The analysis was also undertaken for all 150 molecules (appendix E). The results did not differ significantly between the analyses.

10 According to Merck Sharp and Dohme (pers. comm., 22 June 2001), the time between seeking and obtaining reimbursement in Australia is considerably longer than in countries such as Sweden, France and Spain.

Figure 4.1 **Median launch delay for matched molecules (years)[a]**



a Comparisons are for 39 matched molecules (within the top 150 PBS molecules) with at least one form matched with Australia, excluding molecules with local launch dates prior to global launch dates. The molecule launch delay is calculated as the median value of the time difference between the global launch date and the date of launch of the first form in a country, for all molecules.

Data source: PC estimates.

4.4 Price differences for individual categories

A number of factors, apart from those already identified, may have had a specific influence upon the price differences for the separate categories of pharmaceuticals.

New innovative pharmaceuticals

For patented new innovative pharmaceuticals, it could be expected that manufacturers will be able to differentiate their prices across countries, reflecting differences in the price sensitivity of demand (chapter 2).

However, it was found that prices in Australia for the top-selling new innovative pharmaceuticals are close to those in most other comparison countries, except the US and the UK. International price benchmarking is employed to different extents in Canada, Sweden, France, Spain and NZ (chapter 2). The US and the UK do not use benchmarking. Prices in the US and the UK were higher than in Australia.

This finding may indicate that the use of international price benchmarking by governments may be discouraging manufacturers from differentiating their prices across countries according to market conditions.

Me-too pharmaceuticals

For me-too pharmaceuticals, there is some evidence that Australia's cost-containment arrangements may have contributed to the observed price differences. The finding, reported earlier in this chapter, that the size of the gaps between Australian and overseas prices was mostly larger for items under reference pricing, suggests that Australia's cost-containment systems explain some of the observed price differences for me-toos. Several other features of Australia's system may have been influential, including the requirement for economic evaluations and competition between therapeutic alternatives.

Generic pharmaceuticals

It is more difficult to determine the reasons for the finding that significant price differences exist for Australia's top-selling generic pharmaceuticals. Potential reasons include variations in:

- the costs of marketing and distributing generics;
- impediments to generic competition;
- the patent status of particular pharmaceuticals; and
- cost-containment policies affecting the pricing of generics (such as reference pricing and generic substitution).

In the absence of major barriers to international trade in generics, international price differences could be expected to reflect differences in transport, distribution and marketing costs in each country (arising, for example, from differences in product liability costs, labelling requirements and pharmaceutical registration and evaluation processes).

The results for generic pharmaceuticals may suggest that these costs differ across the comparison countries. For instance, previous studies have found that product liability and marketing costs are higher in the US compared to some other countries. Unlike most of the other comparison countries, direct to consumer advertising is permitted in the US and there is some evidence that advertising expenditure has been growing rapidly.[11]

11 For example, see Harris (2000).

Generic price differences also may be explained by the protection of some overseas markets through explicit or implicit trade barriers.

In most countries, national regulations permit new producers of a pharmaceutical to enter the market once the patent on a pharmaceutical has expired. Indeed, many countries such as Australia, the US and Canada, have adopted an abbreviated marketing approval procedure designed to facilitate the entry of generic producers.[12]

However, patent arrangements also can work to delay the entry of generic competitors. For example, in the US, under the Drug Price Competition and Patent Term Restoration Act 1984 (also known as Hatch-Waxman Act) the first generic producer to obtain a marketing approval receives a period of six months exclusivity from the date it commences marketing its pharmaceutical.

However, if the producer of the originator product seeks to challenge a prospective generic producer on the grounds that it has infringed a patent that is still in force, then, under the Hatch-Waxman Act, the US Federal Drug Administration automatically suspends the approval process for the new generic product for 30 months. There have been several cases where these US legal provisions have been used by pharmaceutical companies to deter or delay generic competition.[13] Indeed, the existence of these provisions may encourage pharmaceutical companies to obtain new patents on an existing product (by changing some aspects of the formulation or dispensing method) in order to deter generic competitors.

According to the OECD (2001), pharmaceutical companies in Europe also have attempted to deter generic entry through exploiting provisions of European Union (EU) law that allow producers of generics to obtain rapid approval for their products. Under EU law, generic producers need not conduct extensive clinical trials to demonstrate the efficacy, safety and quality of their products if it can be demonstrated that their products are bioequivalent with the reference product. However, the reference product must be 'marketed in the member state for which the application is made'. Some manufacturers of reference products have reputedly removed their product from the market shortly before patent expiration and replaced it with a slightly modified version. In this event, the generic producer faces the risk that its application for marketing approval will be rejected on the grounds that there is no longer a marketed reference product available (OECD 2001, p. 38).

12 Under pharmaceutical approval processes, companies seeking permission to market new pharmaceuticals usually must conduct trials to establish the safety, efficacy and quality of their products. Under an abbreviated marketing approval process, companies are usually only required to establish that their products are bio-equivalent to the originator pharmaceuticals.

13 See, for example, OECD (2001, p. 38) and The Economist (2001, p. 68).

Price differences for some of the generic molecules covered in this study also could exist because the relevant molecule is still covered by a patent in the comparison country (and therefore subject to little competition from chemically identical substitutes). For example, six different brands of the off-patent pharmaceutical *metformin hydrochloride* in 500 mg tablets (used to treat diabetes) are available in Australia. However, the Commission understands that in the US, it is covered by an extended patent and therefore the supplier may face less competition from alternative producers.

There is also evidence that pharmaceutical manufacturers of generics in some countries are able to obtain significantly higher prices compared to generic competitors. For instance, chapter 3 reported that US manufacturers of originator brands are able to sustain prices that are well above those of their generic competitors. The manufacturers of these high-priced originator brands may prefer to maintain higher prices at the cost of some reduction in market share, possibly in order to maintain perceptions of higher quality. This suggests some advantages exist in being the first to market.

In addition, companies in the US and NZ, and to some extent in Canada, are permitted to advertise products to consumers directly. The use of direct to consumer advertising may reinforce consumer perceptions of quality and enable manufacturers of the originators to maintain relatively high prices.[14]

Differences in cost-containment mechanisms also may explain some of the generic price differences. In Australia, the pricing arrangements for generics may limit the ability of suppliers of originator brands to charge higher prices than competing generic suppliers. Australia sets the reimbursement price for generics at the level of the lowest priced generic (chapter 2). Under the brand premium policy, suppliers may set a higher price but the patient pays the difference between the manufacturer's price and the reimbursement price. Other countries such as NZ, Sweden and Spain employ similar methods for setting generic reimbursement prices. However, Sweden and Spain do not set the benchmark price at the level of the lowest priced generic.

Another factor potentially contributing to price differences for generics is differences in the prescribing behaviour and price sensitivity of doctors. According to Jacobzone (2000, p. 16), there is some evidence that doctors in most countries are insensitive to prices, and that there is significant inertia in prescribing behaviour. This could reinforce any potential advantage to suppliers that are first to market a new pharmaceutical.

[14] In countries which do not permit direct to consumer advertising, marketing to prescribers (doctors) may serve a similar purpose.

Generic substitution policies are designed, in part, to overcome prescribing inertia (chapter 2). For example, in Australia, pharmacists are allowed to substitute a generic item for a more expensive branded product if the doctor has indicated that generic substitution is permitted and the patient agrees. The brand premium policy complements generic substitution by helping to heighten awareness of prices for generics. The policy allows suppliers of bioequivalent generics to set a price above that of the lowest-priced brand. The patient can then decide whether to buy the cheaper alternative or pay more for a particular brand.

In summary, a number of factors may have contributed towards the price differences for generics, including variations in:

- the costs of marketing and distributing generic pharmaceuticals;
- impediments to generic competition;
- the patent status of particular pharmaceuticals; and
- cost-containment policies affecting the pricing of generics (such as reference pricing and generic substitution).

4.5 Conclusions

The large number of factors potentially influencing pharmaceutical prices in Australia and the comparison countries, and the nature of the results, precludes definitive conclusions about the causes of the reported bilateral price differences.

The price differences are probably due to a combination of influences, including systematic differences in health systems, pharmaceutical subsidy and cost-containment systems, and production costs (including marketing and liability costs). They also may be due to a variety of factors affecting the prices of particular matched pharmaceuticals, such as inter-country differences in demand conditions, patent expiration and the level of competition from other me-too or generic products.

There is nevertheless some evidence to support the views of roundtable participants that Australia's subsidy and cost-containment arrangements have assisted in keeping prices relatively low. The size of the gaps between Australian and overseas prices were mostly larger for me-too items under reference pricing. Other features of Australia's cost-containment policies, such as the use of economic evaluations to assist in establishing and reviewing reimbursement prices, also may have contributed to the price differences. The case studies lend some support to the view that Australia has been successful in reducing the prices of products listed on the PBS over time through a combination of cost-containment measures.

A number of particular factors may have influenced the price differences for the separate categories of pharmaceuticals.

For new innovative pharmaceuticals, the use of international price benchmarking by governments may be reducing the scope for manufacturers to differentiate their prices across countries according to market conditions.

There is some evidence that cost-containment measures have contributed to the comparatively low prices for me-too pharmaceuticals in Australia. The size of the gaps between Australian and overseas prices was mostly larger for me-too items under reference pricing.

Price differences for generic pharmaceuticals may be due to a combination of differences in: cost-containment policies (such as reference pricing and generic substitution); the costs of producing, distributing and marketing generics; and competitive conditions.

A Consultation

A.1 List of visits

Alphapharm
Arrow Pharmaceuticals
AstraZeneca
Australian Pharmaceutical Manufacturers Association
Centre for Health Program Evaluation, Monash University
CSL Limited
Department of Health and Aged Care
Department of Industry, Science and Resources
Helen Lapsley, University of New South Wales
Merck Sharp and Dohme
Pfizer

A.2 Roundtable attendees

19 December 2000, Melbourne — 10.00am – 1.00pm

Alphapharm
AstraZeneca
Australian Pharmaceutical Manufacturers Association
Bristol Myers Squibb
CSL Limited
Department of Finance and Administration
Department of Health and Aged Care
Department of Industry, Science and Resources
Department of Prime Minister and Cabinet
Department of the Treasury
Janice Hirshorn
Merck Sharp and Dohme
Pharmacia Australia
Pharmacy Guild of Australia
Smith Kline Beecham

29 May 2001, Melbourne — 10.00am – 1.00pm

Alphapharm
AstraZeneca
Australian Pharmaceutical Manufacturers Association
Bristol Myers Squibb
Centre for Health Program Evaluation, Monash University
Department of Finance and Administration
Department of Health and Aged Care
Department of Industry, Science and Resources
Department of the Treasury
Eli Lilly Australia
Faulding Healthcare
GlaxoSmithKline
Merck Sharp and Dohme
Pharmacia Australia
Pharmacy Guild of Australia
University of Adelaide

A.3 Overseas consultation

Country	*Contributors*	*Organisation*
Canada	Don Willison Sc.D	Centre for Evaluation of Medicines, McMaster University
	Brad Buxton	Health Canada
	Linda Tennant; Chan Lam	Ontario Drug Programs Branch, Ministry of Health
	Wayne Critchley	Patented Medicines Prices Review Board
	Murray Elston	Canada's Research-Based Pharmaceutical Companies
France	Sandrine Chambaretaud	Ministry of Social Affairs
Netherlands	Margaret Ewen	World Health Organization
Norway	Kirsten Myhr	World Health Organization
New Zealand	Wayne McNee; Richard Braee	Pharmac
OECD	Stephane Jacobzone	OECD
Spain	Alejandra Montoro	Ministry of Health
	Carmen Perez Casas	Medicos sin Fronteras
Sweden	Anders Wessling; Charlotte Bunner	National Social Insurance Board
United Kingdom	Panos Kanavos	London School of Economics and Political Science
	Michael Brownlee; David Kullman; Jonathan Winawer	Pharmaceutical Price Regulation Scheme, Department of Health
United States	John Hansen	General Accounting Office

B International subsidy arrangements

This appendix summarises the subsidy and cost-containment arrangements employed in the following OECD countries:

- Canada;
- France;
- New Zealand (NZ);
- Spain;
- Sweden;
- United Kingdom (UK); and
- United States (US).

The discussion for each country is accompanied by a short description of the health care system in which the pharmaceutical subsidy arrangements are embedded.

Table B.1 summarises key socio-economic characteristics of the countries included in this appendix.

Table B.1 **Socio-economic factors[a]**

	Pop. ('000)	*Aged 65 & over[b] (per cent)*	*GDP per capita (US$)*	*Number of medicines per capita (containers)*	*Per capita health expenditure (US$)*	*Public share of health expenditure (per cent)*	*Per capita pharmaceutical expenditure[c] (US$)*	*Public share of pharmaceutical expenditure[c] (per cent)*	*Share of public pharmaceutical expenditure[c] in public health expenditure (per cent)*
	1999	**1997**	**1999**	**1997**	**1998**	**1998**	**1997**	**1997**	**1997**
Australia	18 967	12	21 248	9.9 ('98)	1 696	69.3	213	52.5	8.7
Canada	30 491	12	19 967	16.1 ('92)	1 893 ('99)	69.9	287 ('99)	31.9 ('99)	7.0 ('99)
France	59 099	16	24 292	51.0	2 358	76.4	506 ('98)	58.2 ('98)	16.4 ('98)
NZ	3 811	11	14 297	8.8 ('89)	1 127	77.1	188	70.8	13.1
Spain	39 418	16	15 126	26.5 ('96)	1 044	76.9	207	72.6	19.6
Sweden	8 868	17	25 753	6.4 ('96)	2 146	83.8	282	71.2	10.9
UK	59 333	16	23 908	9.8	1 685 ('99)	84.2 ('99)	244	64.2	12.5
US	272 878	13	31 935	6.5 ('84)	4 390 ('99)	44.2 ('99)	451 ('98)	15.4 ('98)	3.7 ('98)

a Figures in parentheses indicate the latest year available. **b** Percentage of the population aged 65 and over. **c** Pharmaceutical expenditure comprises prescription medicines, over-the-counter products and expenditure on other medical non-durables (such as bandages, elasticised stockings, incontinence articles, condoms and other mechanical contraceptive devices). Pharmaceuticals consumed in hospitals are excluded.

Source: OECD (2000).

B.1 Canada

Overview of Canada's health care system

Canada has a predominantly publicly financed and privately delivered health care system. The public system comprises an interlocking network of ten provincial and three territorial health insurance plans. Through adherence to principles set at the national level (under the Canada Health Act), the system is referred to as a 'national' health insurance system (Medicare). Medicare provides universal and comprehensive coverage for medically necessary hospital, in-patient and out-patient physician services but does not subsidise the cost of pharmaceuticals (HC 2000).

The Federal Government's role in the health system is to: develop and administer national standards or principles; assist in financing provincial health care services; and meet other constitutional requirements — such as direct health service delivery to specific groups, such as native Canadians.

Each province or territory is responsible for: managing and delivering health services; planning, financing and evaluating the provision of hospital care, physician and allied health care services; and some aspects of public health and prescription pharmaceutical care (HC 2000).

Main features of the pharmaceutical system

Like Australia, pharmaceutical expenditure in Canada has increased considerably since the 1980s. Health Canada (HC 1997) estimates that during the 1980s and 1990s, provincial pharmaceutical program expenditures increased at rates of between 11 to 20 per cent, per annum. In 1999, pharmaceutical expenditure was around 15 per cent of total health care expenditure, at US$287 per person (totalling around US$9 billion) (table B.1). According to the Patented Medicine Prices Review Board (PMPRB 2001), total sales of pharmaceuticals in 2000 was around US$10 billion.

Canada is a small producer of pharmaceuticals, with production of only US$4.6 billion in 1996 (or around 0.8 per cent of gross domestic product (GDP)), compared with the US of US$82.5 billion (or around 1.1 per cent of GDP) (OECD 2000). Like Australia, Canada is a net importer[1] of pharmaceuticals (in 1996 imports exceeded exports by US$1.3 billion) (OECD 2000).

[1] Pharmaceutical imports in Canada are ordinarily by manufacturers for purposes of repackaging and resale (PMPRB, Canada, pers. comm., 2 May 2001).

Per capita expenditure on pharmaceuticals and other medical non-durables is higher in Canada compared with all other comparison countries except France and the US. However, the percentage of public expenditure on pharmaceuticals and other medical non-durables is lower in Canada than all other countries except the US (OECD 2000).

Subsidy arrangements

Canada's pharmaceutical subsidy arrangements differ considerably from Australia's. Unlike Australia, which offers universal coverage, pharmaceuticals in Canada are subsidised for specific segments of the population. For example, the Federal Government is responsible for subsidising the cost of pharmaceuticals to a small segment of the population, including the 'First Nations' and Inuit living on reserves, war veterans, the Royal Canadian Mounted Police, military personnel and inmates of federal penitentiaries. Further, each Canadian province or territory administers its own publicly-funded prescription pharmaceutical program, with varying coverage and administrative arrangements (PMPRB, Canada, pers. comm., 2 May 2001). The provinces and territories account for approximately 80 per cent of public expenditures on pharmaceuticals (Willison, D., Canada, pers. comm., 16 May 2001).

Multiple payers finance prescription medicine expenditure in Canada. The provinces subsidise the costs for some sectors — for instance, seniors and social welfare recipients. Those pharmaceutical costs not covered by the public sector are paid for by the private sector — and mostly by insurance companies and by employers as employee benefits. It is estimated that around 22 per cent of elderly Canadians have some form of private pharmaceutical insurance, usually as retiree benefits from their former employers (Freund et al. 2000). In 1995, it was estimated that 62 per cent of prescription medicines were paid for by private plans, 19 per cent by provincial plans, seven per cent by both, while 12 per cent of Canadians were not covered (HC 2000). The elderly and social welfare recipients are estimated to account for approximately 33 per cent of total spending on pharmaceuticals in Canada (PMPRB, Canada, pers. comm., 2 May 2001).

A variety of different subsidy arrangements exist in the provinces. All elderly citizens in Canada with financial need have some form of insurance coverage for out-patient prescription pharmaceuticals — two provinces restrict pharmaceutical coverage to low income elderly; three other provinces provide the same levels of coverage to all elderly residents; and the remainder have coverage for all elderly but means-based variation in cost sharing (Freund et al. 2000). Rather than outline each scheme, those for Ontario and British Columbia are outlined below. These two provinces account for over 50 per cent of the Canadian population

(Statistics Canada 2000) and they have had a significant influence upon the development of reimbursement schemes in the other provinces.

Ontario

The Ontario Drug Benefit (ODB) program covered approximately 3100 pharmaceuticals in 1999. The ODB covers approximately 45 per cent of all claims (Ontario Drug Programs Branch, Canada, pers. comm., 23 May 2001). From 1990 to 1996, 38 per cent of new innovative pharmaceuticals approved by HC and introduced in Ontario were fully covered by the ODB program (Rx&D 1999). The ODB accounts for 40 per cent of all prescription spending in Ontario (Brogan Inc 2001).

Manufacturers seeking to have a product included on the ODB formulary must complete a submission to the Ontario Ministry of Health and Long–Term Care's Drug Programs Branch — the Drug Quality and Therapeutics Committee (DQTC) reviews the submissions. DQTC bases its recommendation on various criteria including evidence on safety and efficacy, and the availability of suitable alternative agents.

Eligibility for reimbursement under the ODB is limited to:

- persons aged 65 years or over;
- persons receiving professional services under the Home Care Program; and
- residents of long-term care facilities or homes for special care (and who are eligible for welfare assistance).

Pharmaceuticals listed on the ODB formulary are reimbursed at the listed drug benefit price (DBP).[2] Most products listed on the formulary are reimbursed at the DBP, plus a ten per cent mark-up and applicable fees (dispensing and compounding). The mark-up is intended to cover distribution costs. Often the acquisition charges are the same as the ODB cost (Ontario Drug Programs Branch, Canada, pers. comm., 23 May 2001).

Copayments were introduced under the ODB program in July 1996. As at 1999, those eligible for coverage under the ODB pay a maximum of Can$2 per prescription, provided they meet certain criteria (for instance, a senior single person with an annual net income of less than Can$16 018). Otherwise, patients pay for pharmaceuticals up to an adjustable threshold (for example, $100

2 The DBP is the reimbursement price, to manufacturers, for each form of the pharmaceutical.

deductible)[3] and then a maximum of Can$6.11 per prescription (Ministry of Health and Long-Term Care 2001).

British Columbia

British Columbia's (BC) pharmaceutical insurance program is called Pharmacare (BCP). The program began in January 1974. Every BC resident is eligible for coverage under one of seven benefit plans (Ministry of Health and Ministry responsible for Seniors 2001a).

Residents aged 65 and over pay the first Can$200 in dispensing fees. All other eligible drug costs for these people are fully reimbursed. The drug costs for persons residing in long-term care facilities and people receiving social income assistance are reimbursed at 100 per cent.

Three plans also provide specific coverage for cystic fibrosis and some mental health drugs, as well as families qualifying for at home assistance for special needs children.

All residents not covered by one of the other plans belong to BCP's universal plan. Under this plan, residents must pay for pharmaceuticals up to an annual deductible of between Can$600 or Can$800, depending on their income. Families qualifying for a Can$600 deductible receive 100 per cent of BCP reimbursement on expenditure exceeding the deductible. Families qualifying for a Can$800 deductible must pay a 30 per cent copayment of eligible drug and dispensing costs up to Can$2000 per year, past which BCP pays 100 per cent of eligible costs.

Pricing of pharmaceuticals

The pricing arrangements in Canada vary according to the province and the type of pharmaceutical. Each provincial pharmaceutical plan establishes its own reimbursement price and a variety of pricing mechanisms are used. However, according to the PMPRB (Canada, pers. comm., 2 May 2001), there is little variation in pharmaceutical prices across Canada.

Patented pharmaceuticals

All patented prescription and non-prescription pharmaceuticals sold in Canada, including those reimbursed by provinces, must comply with a set of pricing

[3] The yearly out-of-pocket amount paid by an enrollee before a health plan will make any payment.

guidelines set out in the Patent Act 1985 and administered by the PMPRB. These arrangements apply to a large portion of the market in Canada. In 2000, 63 per cent of the US$10 billion in pharmaceutical sales were accounted for by patented medicines (PMPRB 2001).

The PMPRB is responsible for ensuring patented pharmaceutical prices in Canada are not excessive. To ensure this, patentees are required to file comprehensive price and sales information on a regular basis (PMPRB, Canada, pers. comm., 2 May 2001). The PMPRB can investigate allegations of excessive pricing and order patentees to reduce the price and take measures to offset any excess revenues they may have received (PMPRB 1999).

The guiding principles behind the PMPRB's pricing guidelines are:

- the prices of most new patented pharmaceuticals cannot exceed the price of the most expensive pharmaceuticals in a therapeutic class;
- for breakthrough pharmaceuticals, the prices cannot exceed the median of the price of the same pharmaceuticals in seven specified countries (France, Germany, Italy, Sweden, Switzerland, the UK, and the US);
- the prices of existing patented pharmaceuticals cannot increase by more than annual changes in the Consumer Price Index (CPI); and
- the price of a patented pharmaceutical in Canada can, at no time, exceed the highest price for the same pharmaceutical in the comparator countries (PMPRB, Canada, pers. comm., 2 May 2001).

Although the PMPRB monitors pharmaceutical industry research and development (R&D), it does not take industry development considerations (such as levels of local investment and R&D expenditure) into account in determining whether a price is excessive (PMPRB, Canada, pers. comm., 2 May 2001).

Provincial schemes

In the province of Ontario, economic evaluation plays a critical role in decisions on whether to include a pharmaceutical on the ODB formulary. The Ministry of Health and Long-Term Care (2000b, pp. IIIA–14) will only list a pharmaceutical that is priced higher than the alternative, if an economic evaluation has been conducted on the pharmaceutical and it is shown to offer a significant therapeutic advantage. Consequently, the Ministry has published broad guidelines for economic analysis of pharmaceuticals (Ministry of Health and Long-Term Care 1994).

The independent review committee responsible for evaluating pharmaceuticals (the DQTC) continually monitors and revises the list of pharmaceuticals available on the ODB.

Economic evaluation also plays a critical role in decisions on whether to include new pharmaceuticals on the BCP formulary. According to the Ministry of Health (pers. comm., 7 June 2001), decisions to include a new pharmaceutical on Pharmacare take into account:

- an evidence-based assessment of the therapeutic advantage of the pharmaceutical;
- economic evaluation;
- the financial impact on Pharmacare; and
- other relevant information as specified by experts.

In seeking to have a new pharmaceutical listed on the BCP formulary, companies must submit an economic evaluation that, among other things, identifies appropriate comparators and provides quantitative evidence of claimed improvements or greater efficacy relative to these comparators.

The province of BC uses a low cost alternative (LCA) system and a reference pricing system to determine reimbursement prices for items already listed on the BCP formulary. The LCA program pays the lowest price for pharmaceuticals that contain the same active ingredient(s). Patients eligible for Pharmacare benefits will receive full coverage for the preferred 'reference' pharmaceutical. They may choose a more expensive pharmaceutical and pay only the difference in price.

BCP also uses a reference pricing system called the Reference Drug Program (RDP), that appears to be similar to Australia's Therapeutic Group Premium Policy, to determine reimbursement prices for certain items.

The RDP was introduced in October 1995 and now covers several categories of drugs, including: H2 antagonists (used to treat certain stomach complaints); nitrates for treating angina; NSAIDs (anti-inflammatory drugs for treating arthritis); drugs used to treat high blood pressure (excluding diuretics and beta blockers); ACE Inhibitors and some calcium channel blockers (Ministry of Health and Ministry responsible for Seniors 2001c).

Under RDP, Pharmacare designates a reference pharmaceutical — defined as the most cost-effective pharmaceutical within a therapeutic category (which can be a combination of therapeutic categories). Patients who are eligible for Pharmacare have the option of being fully covered for the reference pharmaceutical or, as in Australia, paying the difference between it and the more expensive pharmaceutical.

According to the Ministry of Health (pers. comm., 7 June 2001), the RDP seeks to promote the coverage of pharmaceuticals based on the best scientific evidence and economic information available. For specific therapeutic categories of drugs, BCP limits the maximum level of coverage, consistent with each of its benefit plans, to the cost of a product or products within that category. BCP recognises other drugs in the category up to the level of the 'reference product(s)'.

For products not subject to RDP or LCA, or for which special exemptions to RDP or LCA have been granted, BCP pays a maximum price no greater than the manufacturer's price plus seven per cent.

Discounts

Pharmaceutical discounts may be offered in Canada. However, the PMPRB argues there is 'no extensive discounting' on patented pharmaceuticals in Canada:

> It is the PMPRB's experience that the selling price of a patented [pharmaceutical] to all classes of customers across the country is close to the price listed in the Ontario Drug Benefit Formulary. That conclusion suggests that there is no extensive discounting on these products.

The PMPRB also stated that:

> Analysis … of provincial [pharmaceutical] expenditures in six provinces has also found no considerable differences in the prices charged to the provincial [pharmaceutical] plans. This result would be predicted given that provincial formulary prices are public and at least one province, Quebec, has a policy that it will not list a [pharmaceutical] at a price higher than the best price available to another publicly-funded [pharmaceutical] program. (pers. comm., 2 May 2001)

Other cost-containment mechanisms

Prescribing guidelines, limitations and budgets

Attempts are made in Canada to influence prescribing behaviour via prescribing guidelines. Even though there are no Federal prescribing guidelines, most provinces and territories have clinical practice guidelines. There appear to be no sanctions for doctors who fail to follow them (Kanavos 1999b).

Policies to encourage generic substitution

The price mechanisms used by the provinces in Canada tend to favour, when available, generic substitution (HC 2000). For example, the province of Ontario

encourages generic pharmaceuticals by only reimbursing pharmacists for the lowest cost interchangeable generic pharmaceutical product on the ODB formulary. The interchangeability between two pharmaceuticals is met when both products have the same active ingredient(s) in the same strength and dosage form (Ministry of Health and Long-Term Care 1999). Pharmacists usually dispense the lowest priced interchangeable product unless 'no substitution' is written on the prescription and the no substitute order meets prescribed conditions (Ministry of Health and Long-Term Care 2000a).

These policies may have contributed to the relatively large share of the Canadian pharmaceutical market which is accounted for by generics. According to HC (1997), in 1996-97, 40 per cent of prescriptions written in Canada were for generics (representing 12 per cent of total pharmaceutical sales). As noted above, the PMPRB estimated that patented items accounted for 67 per cent of the Canadian market, implying that the market share of generics (including originator brands) is around 23 per cent of total sales.

B.2 France

Overview of the French health care system

Table B.1 shows that, after the US, France spends the most per capita on health (US$2358 per person). Public expenditure on health as a proportion of total expenditure is around 76 per cent — which is greater than Australia, Canada and the US.

The French health care system covers virtually the entire population (99 per cent) (Kanavos 1999b). The system is funded by an employee/employer contribution, patient copayments and taxes. According to the French Ministry of Social Affairs, in 1999, taxes represented nearly 40 per cent of health insurance resources (France, pers. comm., 16 May 2001).

There are different health care schemes available, determined by the individual's social and/or professional category. The main scheme covers employees and pensioners (and their families), and covers 80 per cent of the population. It is funded mainly by employer contributions (a levy of 12.8 per cent of gross salaries) and employee contributions (a levy of 6.8 per cent of gross salaries). In addition, 87 per cent of the population also are members of voluntary, supplementary sickness funds, or private health insurance, which cover out-of-pocket expenses on health services (including pharmaceuticals).

Main features of the pharmaceutical system

Pharmaceutical production in France increased from around US$1.4 billion in 1970 to over US$21 billion in 1995, in nominal terms, or around 1.4 per cent of GDP (OECD 2000). In 1996, France was a net exporter of pharmaceutical products (exports were approximately US$7.2 billion and imports US$5.7 billion) (Jacobzone 2000, pp. 67–68).

Per capita expenditure on pharmaceuticals and other medical non-durables is higher in France (US$506) than in many other developed countries (table B.1). The public share of total expenditure per capita is also relatively high at US$295 per person. Reimbursed pharmaceuticals account for around 90 per cent of the French market (Levy 1997).

Pharmaceutical consumption per capita in France is the highest within the OECD countries, reaching 51 medicines per person in 1997 (OECD 2000). According to Kanavos (1999b, p. 68) a major contributor to France's high per capita consumption of medicines is the fact that patients can either see a general practitioner (GP) or have direct access to specialists (without first seeing a GP). Kanavos considers that the prescribing levels of specialists are usually higher than those of GPs and, in addition, a GP may not know which pharmaceuticals a specialist has prescribed for the same patient, and vice versa. However, according to the French Ministry of Social Affairs, in 1999, 84 per cent of pharmaceuticals in ambulatory care were prescribed by GPs (who represent around 50 per cent of physicians in ambulatory care) (France, pers. comm., 16 May 2001).

Between 1990 and 1997, the average annual rate of growth of total pharmaceutical expenditure[4] was 4.3 per cent, while public expenditure grew on average at around 4.5 per cent a year (OECD 2000).

Subsidy arrangements

The national health insurance fund (*Caisse Nationale d'Assurance Maladie* (CNAM)) subsidises prices of pharmaceuticals to all citizens.

The Transparency Committee grants reimbursement status for subsidised pharmaceuticals where medical efficacy has been proven. The decision to grant a product reimbursement status is based on an assessment of the product's medical

4 Total pharmaceutical expenditure includes expenditure on other medical non-durables (such as bandages, elasticised stockings, incontinence articles, condoms and other mechanical contraceptive devices). It also includes spending on prescription medicines and over-the-counter (OTC) products, but excludes pharmaceuticals consumed in hospitals (OECD 2000).

benefit or therapeutic value and is determined by evaluating the risk/benefit ratio of the product, taking into account the current treatment alternatives and their characteristics (Friedeberg-Steward 2000, p. 1203). Although it is not mandatory, a company can present an economic evaluation of its product when seeking a listing with the national health insurance fund (Ministry of Social Affairs, France, pers. comm., 16 May 2001).

Comparisons between new products and currently available treatment alternatives are determined by the *Amelioration du Service Medical Rendu* (ASMR). Unless the product is the first in a new class, the evaluation is done in comparison with products of the same pharmaco-therapeutic class.

Pharmaceuticals granted reimbursement status are placed in one of three classes on a 'positive list', which determines the level of reimbursement. These are:

- 100 per cent reimbursement for life-saving medicines. Products in this category include agents against diabetes, AIDS, cancer and chronic diseases;
- 65 per cent for reimbursed pharmaceuticals not included in one of the other two groups (for example, pharmaceuticals for certain infectious diseases); and
- 35 per cent for pharmaceuticals mainly used for non-serious conditions and disorders.

The majority of reimbursable products (72 per cent) lie in the 65 per cent category (Ministry of Social Affairs, France, pers. comm., 16 May 2001).

Reimbursement rates also depend on the type of beneficiary. For example, patients suffering from a specified long-term illness are exempt from copayments for all medicines relevant to that condition (Kanavos 1999b, p. 70).

Pricing of pharmaceuticals

Once a pharmaceutical has been approved on the grounds of its safety, efficacy and quality, manufacturers are free to set the price of their pharmaceuticals in the market. However, if they want their pharmaceuticals to be subsidised by the national health insurance fund, reimbursement status firstly has to be granted by the Transparency Committee. Once reimbursement status is granted, through negotiations, the Pricing Committee (*Comite Economique*) sets the actual price. Manufacturers cannot price reimbursable pharmaceuticals above the price set by the Pricing Committee (Ministry of Social Affairs, France, pers. comm., 16 May 2001).

In January 1999, the Government approved two new methods by which prices for reimbursed pharmaceutical products will be set:

- a company can subscribe to a five-year contract ('convention') in which prices of products are agreed upon. The convention is the main method by which prices of reimbursed pharmaceuticals are set. Negotiations are based on sales forecasts, made at the therapeutic class level. If actual sales exceed the targets, firms are required to pay rebates. Companies also may reduce prices for older products in order to receive higher prices on new products (Ministry of Social Affairs, France, pers. comm., 16 May 2001); or
- a company can agree to negotiate prices on a 'product-by-product' basis. According to the Ministry of Social Affairs (France, pers. comm., 16 May 2001) only one per cent of firms have opted for the 'product-by-product' pricing.

The reimbursement price of a pharmaceutical is based on discussions surrounding the pricing rationale of companies[5] and the degree of innovativeness of the product as indicated by the ASMR level (table B.2) granted by the Transparency Committee (Friedeberg-Steward 2000, p. 1204).

Table B.2 **ASMR levels**

Level I	A major therapeutic improvement over existing therapy
Level II	An important improvement over existing products
Level III	A moderate improvement over existing products
Level IV	A minor improvement over existing products
Level V	No improvement over existing products, only economic benefits
Level VI	Rejection

Source: Friedeberg-Steward (2000).

A 'convention' is negotiated between the company and the Pricing Committee which links a certain price to a fixed volume of sales, by therapeutic classes. The price for a new product is usually highest for ASMR Levels I and II. For products that exhibit no improvement over existing products, prices usually will be set at the level of (or lower than) those of existing pharmaceuticals.

The convention is valid for five years, after which, pharmaceuticals are again subjected to the Transparency Committee and the Pricing Committee for evaluation of their therapeutic value and price. The prices may change before the convention expires if the company exceeds the agreed maximum sales volume.

For innovative products, pricing is based on evidence that the products have clear clinical improvements over existing similar products which, according to Willison,

5 Discussions include: the size of the target population; the prevalence of the condition to be treated and the number of diagnoses per year; the current number of prescriptions for the condition; prices of local comparators and prices of the product in other European markets; and sales forecasts for the next three years.

(Canada, pers. comm., 16 May 2001) may include patent and off-patent products. Pricing of innovative products also may take into account the prices of similar products in other European countries.

In the past, the French Government also has implemented across-the-board price reductions for certain items. For example, in July 1998, companies marketing generics had to reduce prices to 30 per cent below those of the originator brands. However, many companies failed to do so. Therefore, in November 1998, the Government issued a ruling reducing prices of 37 generic products by up to 50 per cent on some products (Kanavos 1999b).

Other cost-containment mechanisms

Prescribing guidelines, limitations and budgets

Until relatively recently, the French Government had a system of prescribing guidelines, mainly in the form of negative recommendations for doctors (Kanavos 1999b). Under this system, random checks on doctors occurred and financial penalties could be imposed if the guidelines were breached. However, no penalties have been imposed from 1999 onwards because the *Conceils d'Etat* rejected the way these penalties were calculated (Ministry of Social Affairs, France, pers. comm., 16 May 2001). According to Willison, (Canada, pers. comm., 16 May 2001), these guidelines have recently been abolished.

Policies encouraging generic substitution

Compared to many other countries, the generic pharmaceutical market in France is relatively small.

Originator off-patent pharmaceuticals and generic copies account for around 16 per cent of total prescriptions in France — as of January 2000, generic copies accounted for 5.6 per cent of all pharmaceutical packs prescribed. The volume of generic dispensing is growing, although at a slow rate (EGA France 2001).

There have been recent attempts to encourage the generic market. For instance, in 1998, pharmacists signed an agreement with the Government allowing generic substitution where the product shares the same active ingredient, dosage and pharmaceutical form. Companies marketing generics also have launched campaigns aimed at increasing doctors' awareness of how prescribing generics can help reduce costs.

B.3 New Zealand

Overview of New Zealand's health care system

NZ has a comprehensive, publicly-funded health care system supplemented by private health insurance. The National Advisory Committee on Health and Disabilities advises the Government on which services should be publicly funded, and on funding priorities. The Government, through the Ministry for Health, allocates money to the District Health Boards (DHBs) to purchase health services and issues broad guidelines on what services must be provided. The DHBs run public hospitals and provide other services (for example, public health nursing services).

Health services are provided in both public and private settings. Primary care (first contact, self-referral health care) is mostly provided by publicly-subsidised, privately-owned general practices. Secondary medical care is mostly provided in publicly-owned hospitals (MOH 2000).

The NZ health system is in a process of reform. For example, beginning in 2000-01, increasing responsibility for funding health care has been transferred from the federal level (Ministry of Health) to the regional level DHBs. Further, the Ministry for Health has initiated a strategy document to provide a unified nationwide framework for the development of the NZ health sector (MOH 2000).

Main features of the pharmaceutical system

Since 1998, pharmaceutical expenditure growth in NZ has been relatively low. For example, between April 1998 and July 1999, total expenditure declined and, since July 1999, it has remained relatively stable (Pharmac 2000a).

According to the Pharmaceutical Management Agency Limited (Pharmac), pharmaceutical prices are the main factor explaining the recent decline and stability of pharmaceutical expenditure. This is due to a strong downward trend in prices over the past decade. For example, prices declined 35 per cent between April 1993 and April 2000 (Pharmac 2000a).

Consequently, per capita expenditure on pharmaceuticals and other medical non-durables is low in NZ (US$188) compared to many other countries. Like a number of these countries, the public sector accounts for a large share of total expenditure (US$133 per person). Further, NZ spends less per capita on health expenditure than Australia (OECD 2000).

NZ has a small pharmaceutical industry. In 1987, pharmaceutical production was US$150 million which represented about 0.4 per cent of GDP. NZ is a net importer of pharmaceuticals, importing US$312 million net in 1996 (OECD 2000).

Subsidy arrangements

The pharmaceutical subsidy arrangements in NZ provide universal coverage for the cost of many pharmaceuticals. Like Australia, the resident's level of subsidy depends upon his or her economic and health status. Residents holding a Community Service Card (based on family income and size) or High Use Health Card (based on 12 or more visits to a doctor in a year) obtain a larger subsidy. There are currently around 3000 pharmaceuticals subsidised by the NZ Government.

Pharmaceuticals granted reimbursement status are placed on a 'positive list'. Pharmac advises the Government on which pharmaceuticals to include on the schedule and the ex-manufacturer reimbursement level. The schedule is published three times a year and updated monthly (Pharmac 2000b).

Decisions on listing, subsidy levels, and prescribing guidelines and conditions, are made by the Pharmac Board with input from independent medical experts on the Pharmacology and Therapeutics Advisory Committee (PTAC) and its specialist sub-committees, and Pharmac's managers and analysts (Pharmac 2000c).

The Government also seeks to influence patients' demand for pharmaceuticals through a system of copayments. The amount of copayment depends upon the economic and health status of the patient. Residents with a Community Services Card or High Use Health Card pay NZ$3 per item for medicines. Adult patients, without the above cards, pay NZ$15 (children NZ$10) for subsidised medicines up to 20 items per year. Brand premiums also may be paid. Children under six are generally free (Pharmac 2000b).

NZ also has safety net arrangements. After 20 prescriptions in a year, family members' charges are NZ$2 per item for the rest of the year or free for concessional cardholders (Pharmac 2000b).

Pricing of pharmaceuticals

Like Australia and the Canadian provinces of Ontario and British Columbia, submissions from companies for the listing of new pharmaceuticals must identify

comparator products that are already listed on the schedule and be accompanied by evidence of any claimed benefits compared to these comparators (Pharmac 2001).[6]

In deciding whether to list a new pharmaceutical, resource allocation and budgetary constraints are two major issues influencing Pharmac's deliberations (Phamac 1999b, p. 1). Consequently, economic evaluations (specifically, cost–utility analysis (CUA)) play an important role in listing and pricing decisions.

Using CUA, Pharmac compares the cost-effectiveness of introducing different pharmaceuticals, in different therapeutic groups. This means, for example, that Pharmac attempts to compare the cost-effectiveness of a new pharmaceutical to prevent heart attack with another that cures gastric ulcers (Pharmac 1999b, p. 3). To do this, Pharmac ranks each new pharmaceutical according to value for money in terms of Quality-Adjusted Life Years (QALY) saved (Pharmac 1999b, p. 4).[7] Pharmac then uses other criteria when making its listing and pricing decisions, including:

- the community's health needs;
- the availability and suitability of existing medicines;
- the clinical benefits, costs and risks of a product;
- the direct cost to health service users; and
- other criteria as Pharmac sees fit (Pharmac 2000b).

Reference pricing is widely employed by Pharmac in setting reimbursement prices. Pharmac classifies all pharmaceuticals into therapeutic groups and further into sub-groups. Reimbursement prices are then set with reference to the lowest-priced pharmaceutical in the relevant sub-group — which may include both generic and patented pharmaceuticals. This system is similar to that applied for certain groups of pharmaceuticals in Australia and British Columbia.

Since 1997, Pharmac has introduced several additional measures designed to reduce the prices of off-patent pharmaceuticals. These are:

6 Companies also have to provide price information which includes: their selling price (GST exclusive); their selling prices to wholesalers in other countries where the pharmaceutical is marketed (in local currencies (excluding taxes), NZ dollar equivalents and exchange rates used); and alternative pricing proposals (for example, price-volume trade-offs) (Pharmac 2001, p. 16).

7 QALY measures the years gained through premature death prevention; quality-adjusted years gained; non-fatal events and illness prevented; quality-adjusted years lost; and pharmaceutical side effects (Pharmac 1999b).

- sole supply tenders (whereby pharmaceutical manufacturers compete against one another for the sole right to supply a pharmaceutical in a therapeutic sub-group);
- tender protection contracts (suppliers on the schedule agree to reduce the price of certain products, in exchange for a commitment from Pharmac not to tender the products); and
- cross-subsidisation of products.

Other cost-containment mechanisms

Prescribing guidelines, limitations and budgets

The Government seeks to influence the behaviour of prescribers through a number of strategies, including:

- budget-holding. Most GPs have entered into budget-holding arrangements to encourage cost-effective use of medicines;
- treatment restrictions. For some pharmaceuticals, patients need to meet specified criteria in order to be eligible for subsidy;
- prescriber guidelines. Physicians use these guidelines for more appropriately targeting pharmaceutical use. However, no sanctions are in place if physicians do not adhere to the guidelines (Jacobzone 2000, p. 75); and
- restricted prescribing rights. Pharmac's Pharmaceutical Schedule has restrictions that also extend to the type of prescriber, which aim to improve targeting. Examples include:
  - hospital pharmacy-specialist prescription. Prescriptions may only be written by a medical practitioner in the specialist category defined by the Schedule, and only hospital pharmacies may dispense; and
  - specialist authority. These are only subsidised after approval is obtained from Health Benefits Limited (patient must meet the specific criteria) (OECD 2001, p. 271).

Policies to encourage generic substitution

The Commission was unable to find any information on the size of generic markets in NZ.

Under a preferred brand arrangement, pharmacists are required to dispense only the preferred pharmaceutical where a prescription is written generically, or to seek the

doctor's approval to substitute the preferred pharmaceutical (if the prescription specifies a non-preferred brand).

B.4 Spain

Overview of the Spanish health care system

Health services in Spain are provided predominantly by the public sector, with approximately 77 per cent of total health expenditure funded by the public sector (table B.1). A mix of central and regional health authorities provide public health care services. Health services in ten regions are administered by the central Government through the *Instituto Nacional de la Salud* (the National Health Institute). Services in a further seven autonomous regions are provided by regional health authorities. Private sector expenditure on health care is funded via direct patient payments and insurance schemes.

Under Spain's health care system, most forms of medical treatment are provided free of charge. However, the consumer's freedom to chose his or her doctor or hospital is limited and patients must make a contribution towards the cost of prescription pharmaceuticals.

Compared to many other European countries, the share of GDP devoted to health care spending in Spain is low. Total public health care expenditure in Spain was US$39.5 billion in 1997, representing approximately 7.4 per cent of GDP.

Main features of the pharmaceutical system

The proportion of total and public health care spending devoted to pharmaceuticals rose throughout the 1990s. In 1996, the Ministry of Health reported that pharmaceutical expenditure had risen by 130 per cent over the previous seven years. In 1997, total spending on pharmaceuticals accounted for around 20.7 per cent of total health care costs — which is high compared with many other European countries. A relatively large share of pharmaceutical expenditure is financed through the public sector (around 73 per cent in 1997) — higher than all other countries listed in table B.1.

Pharmaceutical production in Spain was around US$7.0 billion in 1994, representing about 1.4 per cent of GDP (OECD 2000). In 1996, Spain was a net importer of pharmaceuticals (exports were valued at US$1.4 billion and imports at US$2.4 billion) (Jacobzone 2000, p. 68).

Until 1992, Spain did not recognise the patent protection of pharmaceutical products, although process patents were recognised (Medicos sin Fronteras, pers. comm., 18 May 2001). Therefore, a large number of copy products exist on the Spanish pharmaceutical market, which are significantly cheaper than the originator product (Kanavos 1999b).

Subsidy arrangements

Like Australia, the pharmaceutical subsidy arrangements in Spain provide for universal coverage of the population and cover a wide range of prescription items.

Prescription pharmaceuticals in Spain are subsidised under a national scheme with universal coverage. The Spanish Agency of Medicines grants the marketing authorisation. All matters regarding pricing and reimbursement of pharmaceuticals are the responsibility of the central Government (Medicos sin Fronteras, pers. comm., 18 May 2001). The *Dirección General de Farmacia y Productos Sanitarios* (Directorate General of Pharmacy and Health Products (DGFPS)) within the Ministry of Health is responsible for pharmaceutical affairs.

According to Kanavos (1999b, pp. 154–155), Spain has both a negative and a positive list. Prior to 1993, all prescription pharmaceuticals were automatically granted reimbursement status. In 1993, approximately 800 products were excluded from reimbursement and placed on a negative list (Kanavos 1999b, p. 155). In 1998, more products were added to this negative list (OECD 2001, p. 291).

In deciding whether to list a product on the reimbursement formulary, the *Subdirección General de Planificación Farmacéutica* (Pharmaceutical Planning area) within the DGFPS takes into account a number of factors, such as:

- the severity of the medical condition that the pharmaceutical is designed to treat;
- the usefulness of the pharmaceutical; and
- the efficacy and cost of the pharmaceutical compared to products that are already listed.

A product may be refused listing if the Government considers that the price proposed by the company is too high.

Most patients must make a contribution (copayment) towards the cost of prescription pharmaceuticals, which is based on a proportion of the pharmaceutical price. The disabled, people over 65 years of age, hospital patients and people being treated for work-related injuries are exempt from paying copayments. The copayment for patients under the age of 65 is 40 per cent of the price of the

pharmaceutical (Medicos sin Fronteras, pers. comm., 18 May 2001).[8] A reduced copayment of ten per cent applies to those suffering from chronic or life-threatening illnesses (up to a maximum of Pst439, around A$4.20, per prescription).

Pricing of pharmaceuticals

The Government controls the prices of all pharmaceuticals launched in the Spanish market (Kanavos 1999b, p. 151). Spain uses a mix of measures to influence pharmaceutical prices. As well as direct price controls for prescription pharmaceuticals, the Spanish Government has negotiated a set of profit controls with the pharmaceutical industry.

The *Subdirección General de Estudios Económicos* (Economic Affairs area), within the DGFPS, is responsible for price setting and price reviews. Prices of pharmaceuticals are determined taking into account several factors including:

- European price comparisons;
- therapeutic equivalents available locally and their local prices;
- innovativeness;
- profits;
- R&D in Spain;
- volume and value of sales;
- manufacturing and marketing costs (including distribution and promotion/advertising costs); and
- general administrative expenses (Medicos sin Fronteras, pers. comm., 18 May 2001).

According to Medicos sin Fronteras (pers. comm., 18 May 2001), the main factors used when determining prices of pharmaceuticals subsidised by the national scheme are the first two factors listed above, and, if the product is not manufactured in Spain, the transfer price established by the company. Although economic evaluations are currently used for hospital negotiations, they are not generally used in price negotiations or in determining reimbursement conditions (Medicos sin Fronteras, pers. comm., 18 May 2001).

A reference pricing system was proposed in 1996, and approved in 1999. At the beginning of 1999, around 50 bioequivalent generic pharmaceuticals, already on the

8 If a physician prescribes a pharmaceutical that is more expensive than the reimbursed price, the patient decides whether to accept a cheaper alternative or pay the difference.

market, were to be included in the reference price list. It was expected that approximately 200 generic pharmaceuticals were to be included on the list by the end of 1999 (Kanavos 1999b, p. 152). However, the reference pricing system was only fully implemented at the end of 2000. Currently, it applies to 74 active ingredients available as generics, marketed in 753 different presentations (that is, different pharmaceutical forms, dosage, and pack sizes) (Medicos sin Fronteras, pers. comm., 18 May 2001).

The reference price is set in the range 10–50 per cent below the most expensive medicines in each group of products. During the first trimester of 2001, the introduction of this system, besides other mechanisms, resulted in the first decrease in nominal pharmaceutical expenditure in 12 years (a five per cent decrease) (Medicos sin Fronteras, pers. comm., 18 May 2001).

Other cost-containment mechanisms

Prescribing guidelines, limitations and budgets

In 1998 the National Health Institute started monitoring the prescribing behaviour of physicians. The objective of the Institute is to monitor pharmaceutical expenditure by the physician's patients, rewarding those physicians with patient spending below a certain level but who still meet a number of good clinical practice and patient satisfaction criteria. Physicians may be awarded roughly 20 per cent of the savings made.

The Institute offers financial incentives to physicians in primary care, by giving bonuses of up to Pst125 000 to each physician who prescribes generics for at least six per cent of all prescriptions. In December 1999, generic prescribing accounted for only 3.5 per cent of the total prescribing in primary care (EGA Spain 2001).[9]

Policies to encourage generic substitution

The Ministry of Health has conducted several information campaigns promoting the use of generics and emphasising their safety, efficacy, and quality to physicians and the public.

Generic substitution is compulsory for the pharmacist. Further, the Spanish Government recently announced that the mark-up to pharmacists on generic

9 This figure excludes any branded products (Medicos sin Fronteras, pers. comm., 18 May 2001).

products would increase to 33 per cent compared to 29 per cent for non-generic products (Medicos sin Fronteras, pers. comm., 18 May 2001).

B.5 Sweden

Overview of the Swedish health care system

Sweden has a decentralised health care system. The Minister for Health and Social Affairs is responsible for overall health policy and proposing legislation. The 23 County Councils are responsible for the overall planning and allocation of resources towards health services. County Councils also run and own hospitals, health centres and other institutions. Municipalities, the lowest tier of government, are responsible for long-term care, domiciliary care and nursing homes.

Main features of the pharmaceutical system

Sweden's expenditure on out-patient pharmaceuticals increased substantially in the 1990s, as it did in Australia. For example, between 1990 and 1998, expenditure on pharmaceuticals almost doubled, rising from approximately SKr7 billion to SKr13 billion (RFV 2000a). According to Willison (Canada, pers. comm., 16 May 2001), this increase in expenditure may be linked with Sweden joining the European Union (EU) in 1995 and the subsequent influx of many more pharmaceuticals into the Swedish market.

Sweden has higher per capita expenditure on pharmaceuticals and health care than Australia. Further, the public sector share of expenditure is also higher than Australia (OECD 2000).

Like the UK, pharmaceutical production in Sweden accounts for a large percentage of its GDP. For example, pharmaceutical production was US$4.4 billion or approximately 1.7 per cent of GDP in 1996 (OECD 2000).

Sweden, like France and the UK, is a net exporter of pharmaceuticals. Sweden's net exports totalled US$1.6 billion in 1996.

Subsidy arrangements

Like many European countries, Sweden has a universal social insurance scheme. The scheme is available to all residents, including emergency patients from the EU/EEA countries and seven other countries. The scheme is administered by the

National Social Insurance Board (the *Riksförsäkringsverket,* RFV) and the social insurance offices. The social insurance scheme is financed primarily through payroll taxes, with County Council grants and patient copayments providing the remainder of funding. Special County Council grants and patient copayments cover out-patient costs for pharmaceuticals (RFV, pers. comm., 23 May 2001).

All prescription pharmaceuticals are automatically placed on a positive subsidy list once approval for marketing and a retail price are obtained. The positive list is called the Drug Benefit Scheme (DBS) and covers most prescription pharmaceuticals plus some over-the-counter (OTC) products. Sweden also has a negative list for pharmaceuticals. The negative list includes cough remedies, nicotine substitutes and hair restorers. In 2001, pharmaceuticals for the treatment of obesity and erectile dysfunction were added to this negative list (RFV, pers. comm., 23 May 2001).

Before a pharmaceutical can be included on the DBS, companies must apply for a reimbursement price from the RFV. It typically takes between three and six weeks to obtain a reimbursement price, but price negotiations may begin prior to market authorisation (RFV 2000b).

In seeking a reimbursement price for a new product from the RFV, companies must provide information on:

- its safety and efficacy (as determined by the Medical Agency);
- the requested pharmacy purchase price of the product;
- prices of competing products in the domestic market and abroad;
- the health and economic value of the product; and
- projected sales volumes for the first three years (RFV, pers. comm., 23 May 2001).

There are no formal economic evaluation guidelines in Sweden, but if a manufacturer of a new innovative pharmaceutical seeks to obtain a premium price, some form of economic evaluation is always requested. The RFV (2000b) argues it prefers cost-benefit documentation on a macro level, though it does accept cost-minimisation, cost-effectiveness and cost-utility analysis, when they address a particular issue at hand. There are no immediate plans to introduce economic evaluation guidelines in Sweden (RFV 2000b).

Patient copayments were introduced in Sweden in 1990, with all patient groups, with the exception of insulin users, making copayments. In 1997, a new system for patient copayment was introduced (RFV, pers. comm., 23 May 2001). It also was decided that the responsibility for out-patient pharmaceutical costs should gradually

be transferred to the County Councils (RFV 2000a). However, currently (and probably for the next few years at least) it will be a shared responsibility between the Government and the County Councils.

Consumers bear the full cost of their pharmaceutical consumption expenditure up to the point where their total pharmaceutical purchases, over a twelve-month period, exceed SKr900 (A$173). When the total purchases exceed this amount, the cost of pharmaceuticals will be subsidised. The reimbursement rate progressively increases with consumer purchases, until the ceiling of SKr1800 (A$346) per annum is reached. Once pharmaceutical expenditure has reached this level, the reimbursement rate is 100 per cent (OECD 2001, p. 302; RFV, pers. comm., 23 May 2001).

Pricing of pharmaceuticals

The RFV uses a reference pricing system (introduced on 1 January 1993) to set the reimbursement price of multi-sourced off-patent pharmaceuticals and prescribed OTC pharmaceuticals — the system excludes patented pharmaceuticals. By definition, the system covers only about ten per cent of market volume and the RFV has no plans for its extension (RFV 2000b).

The reimbursement price is set by reference to the price of the cheapest product available with the same active ingredient, pack size, dosage and route of administration (Kanavos 1999b), plus a ten per cent margin above the price of the cheapest generic (Drummond et al. 1997). If a pharmaceutical on the list had a price above the reference price level, the patient would pay the difference (Nilsson et al. 2000).

The reimbursement price of pharmaceuticals on the DBS cannot increase within two years of the product's launch. Further, the RFV restricts price negotiations to once per year. Pharmaceutical companies are allowed, however, to reduce the price of their product at any time. The RFV regularly reviews the reimbursement prices (RFV, pers. comm., 23 May 2001).

The RFV often includes a price-volume agreement when setting the price of new innovative pharmaceuticals on the DBS. This enables the RFV to limit the expected costs to the DBS by lowering the pharmaceutical price if sale forecasts, submitted by the manufacturer to the RFV, are exceeded.

The RFV also uses cross-country price comparisons when fixing the price of a product. Pharmaceutical manufacturers must provide information on prices in other EU countries where the product is marketed. The RFV aims to award a 'European

price' (RFV, pers. comm., 23 May 2001). According to Kanavos (1999b, p. 246), the RFV seeks to ensure that the 'Swedish price should be similar to that in Finland and Norway, but lower than that in Denmark, the Netherlands, Germany and Switzerland'.

More recently, proposals were developed to create a new pricing authority and to change the method of setting prices for pharmacists (RFV, pers. comm., 23 May 2001).

Prescribing guidelines, limitations and budgets

There are no national prescribing guidelines in Sweden but regional pharmaceutical and therapeutic committees have been established to provide doctors with information on more cost-effective treatments. The guidelines suggested by these committees are not policed and no sanctions are imposed upon doctors breaking the suggested guidelines. However, the County Councils' increased economic responsibility will most probably lead to increased control of prescribing costs (RFV, pers. comm., 23 May 2001).

Policies to encourage generic substitution

In 1994, generic substitution and parallel imports were allowed (RFV, pers. comm., 23 May 2001). In 1999, sales of generics (excluding originators) accounted for little more than five per cent of the Swedish pharmaceutical market (Kanavos 1999b). Kanavos (1999b) also indicated that this percentage remained stable for the few years leading up to 1999.

A study by Nilsson et al. (2000) found that the share of generic pharmaceuticals (including originator brands) available as a proportion of the total number of pharmaceuticals available in Sweden decreased from 44 per cent in 1980 to 30 per cent in 1997.

Nilsson et al. (2000) also argued that a large share of generic pharmaceuticals fail on the market within a few years of their introduction. Examining individual products over time, the study found that between 1991 and 1996, of the group of generic pharmaceuticals approved by the Swedish Medical Products Agency, 30 out of the 32 originator pharmaceuticals were still in the market compared to 17 out of the 31 generic copies. The originator pharmaceuticals had 70 per cent of the sales volume and 88 per cent of the sales value.

Nilsson et al. (2000) speculate that the Swedish reference pricing system may be partly responsible for reducing the market opportunities for new generic products.

According to this study, the main advantage most generic copies have over the branded originator is the fact that the copies can compete on the basis of lowering their prices well below the originator's price to gain market share. With reference pricing, the prices of most pharmaceuticals (including high-priced branded generics) are lowered to the reference price level. This mechanism reduces the ability of generic producers to compete with the branded originator on the basis of price setting. Further, in Sweden, generics are advertised much less than the original products and there are no strong incentives for physicians to prescribe inexpensive medicines.

The low level of generic sales has persisted despite the 1994 reforms allowing pharmacists to substitute a generic pharmaceutical for a prescribed pharmaceutical, if they receive approval from the doctor. Like many other countries, approval is not required if the name of the manufacturer or importer is absent from the prescription and the product is available under the same name from different sources.

The 1994 reforms also required the Medical Products Agency to provide doctors with generic information and for doctors to pass this information on to patients.

B.6 United Kingdom

Overview of the UK health care system

Per capita health expenditure in the UK (at US$1685) is similar to that in Australia, while the proportion of public expenditure on health is around 84 per cent — the highest of all the other countries listed in table B.1. The UK also has a relatively older population, with 16 per cent aged 65 and over (table B.1).

The National Health Service (NHS) provides universal health care coverage. It is funded by general taxation (96 per cent) and patient copayments (four per cent) (Warner-Lambert 1999). Patients have to register with GPs, who control access to specialists.

In addition, approximately 11 per cent of the population are covered by private health insurance. Private health insurance is not an alternative to the NHS, nor does it complement the NHS. It only provides a superior level of comfort and quicker access to treatment. Of those within the private schemes, employers pay around 60 per cent of contributions (Kanavos 1999b).

Main features of the pharmaceutical system

Pharmaceutical production in the UK was US$16.2 billion in 1994 (accounting for 1.6 per cent of GDP), compared to US$1.3 billion in 1970 (OECD 2000). In 1996, pharmaceutical exports were valued at around US$7.8 billion and imports at US$4.5 billion (Jacobzone 2000, p. 68).

In 1997, public expenditure on pharmaceuticals and other medical non-durables accounted for 12.5 per cent of total public expenditure on health in the UK (table B.1). This was considerably higher than Australia (8.7 per cent), Canada (7.0 per cent), Sweden (10.9 per cent) and the US (3.7 per cent).

Between 1990 and 1997, the average rate of growth of pharmaceutical expenditure was 8.5 per cent per annum, while public expenditure on pharmaceuticals grew on average at around 8.0 per cent per annum (OECD 2000).[10]

Subsidy arrangements

The UK Government subsidises pharmaceuticals for the whole population, through the NHS. This scheme is similar to Australia — it is a national scheme with universal coverage.

All prescription pharmaceuticals approved for marketing in the UK, except for those included on the pharmaceutical negative list, are automatically reimbursed in full (Kanavos 1999b). There are approximately 10 000 products prescribed in the community (DoH, pers. comm., 22 May 2001). The NHS (General Medical Services) Regulations 1992 lists a large range of pharmaceuticals (known as Schedule ten or the 'Black List') which are not subsidised under the NHS. Approximately 3000 pharmaceuticals are listed in Schedule ten (Lockharts Solicitors 1999). The pharmaceuticals included in the Black List are mostly OTC pharmaceuticals, including analgesics for mild to moderate pain, indigestion remedies, laxatives, cough and cold remedies, vitamins, tonics, benzodiazepine, sedatives and tranquillisers, anti-diarrhoeals, drugs for allergic disorders, hypnotics and anxiolytics, appetite suppressants, drugs for vaginal and vulval conditions, contraceptives, drugs used in anaemia, topical anti-rheumatics, drugs acting on the ear and nose, and drugs acting on the skin (excluding the generic forms) (DoH, pers. comm., 22 May 2001).

10 Expenditure on pharmaceuticals includes spending on medicines plus other medical non-durables (such as bandages, elasticised stockings, incontinence articles, condoms and other mechanical contraceptive devices).

In addition, 11 pharmaceuticals (four relate to treatment of erectile dysfunction) are listed in a second schedule (Schedule 11) which may only be used for the treatment of certain specified conditions (DoH, pers. comm., 22 May 2001).

The Advisory Committee on NHS Drugs determines the Black List. In assessing whether a product is black-listed, the Committee determines whether the product is necessary to provide either therapeutic or preventative treatment within the general medical services of the NHS. If there is a clinical need for this product, the Committee will then consider if the need is being met by another product already available under the NHS. If a product meets the same clinical need effectively and is at a lower price than listed products, the Committee recommends that the product in question be available under the NHS. If not, the product will be black-listed. The Committee periodically updates the Black List (Stanbridge 1997).

The National Institute for Clinical Excellence (NICE) was set up on 1 April 1999 (as part of the NHS). The role of NICE is different to that of the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia.

The role of NICE is to offer guidance and advice rather than to recommend which products should be eligible for subsidy. NICE aims to provide patients, health professionals and the public with robust, reliable national guidance on current 'best practice'. The guidance will cover both individual health technologies (including pharmaceuticals, medical devices, diagnostic techniques, and procedures) and the clinical management of specific conditions (NICE 1999).

NICE will provide NHS health professionals with three types of guidance:

- the results of appraisals of new and existing health technologies. For new technologies, the focus will largely be on those expected to have significant clinical or resource impact on the NHS. Existing technologies will be those for which there are unexplained or unacceptable variations in use, or controversy about their clinical and/or cost-effectiveness. The results of the appraisal process will provide patients and health professionals with a single, authoritative source of advice;
- clinical guidelines developed to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances; and
- simple methods of clinical audit to monitor the use of particular interventions, or the care received by patients, against agreed standards (NICE 1999).

For subsidised pharmaceuticals, individuals pay a fixed amount per prescription. The standard prescription charge is currently £6.10, irrespective of the actual cost of the pharmaceutical. In practice, only a small percentage of prescriptions attract a copayment fee. For instance, in 1999, over 85 per cent of all prescriptions filled in

England did not incur a copayment fee (DoH, pers. comm., 22 May 2001). The elderly, pregnant women, students and people on low incomes are exempt from this copayment (Stanbridge 1997). Patients also can opt to purchase pre-payment certificates, which effectively cap total copayments (Jazobzone 2000).

Pricing of pharmaceuticals

The UK is one of the few countries in the OECD where the Government does not control the manufacturer prices of new subsidised pharmaceuticals directly. However, it does intervene in price setting indirectly through regulating the profitability of pharmaceutical companies supplying certain products to the NHS under the Pharmaceutical Price Regulation Scheme (PPRS).

The PPRS is a voluntary agreement made between the Department of Health (DoH) and the pharmaceutical industry represented by the Association of the British Pharmaceutical Industry (ABPI). It has operated in various forms since 1957. A new scheme commenced on 1 October 1999 and will apply until 2004. The scheme applies to branded pharmaceuticals (whether covered by a patent or not), but does not apply to non-branded generic pharmaceuticals, exports, medicines sold under private prescriptions, and non-subsidised OTC medicines sold to the public (Kanavos 1999b).

The objectives of the PPRS include:

- to secure the provision of safe and effective medicines for the NHS at reasonable prices;
- to promote a strong and profitable pharmaceutical industry capable of sustained R&D expenditure to ensure the future availability of new and improved medicines; and
- to encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in the UK and other countries (DoH 1999a, p. 4).

The PPRS provides a framework for determining reasonable limits to profits made from the supply of medicines to the NHS. Under the PPRS, all pharmaceutical companies must submit an annual financial return (AFR) presenting the sales, costs[11] and capital employed for sales to the NHS.

[11] Costs are disaggregated into: manufacturing costs of goods; costs of distribution; cost of promotion; costs of medical information other than promotional information; general administrative costs; and R&D expenditure.

There are two levels of return on capital (ROC) targets:[12]

- level 1, used to decide price increase applications, has a ROC target of 17 per cent per annum; and
- level 2, used to analyse companies' AFRs, has a ROC target of 21 per cent per annum (DoH 1999a).

These allowable returns will be associated with an upper margin of tolerance (MOT). Companies will be able to retain profits of up to 140 per cent of the level two ROC target.[13] The MOT will not be available to a company for any year in which it has had a price increase agreed by the DoH.

If the DoH's assessment of an AFR shows profits in excess of the MOT, it will negotiate one or more of the following:

- price reductions, during the following year sufficient to bring prospective profits down to an acceptable level, on the basis of available forecasts;
- repayments of that amount of past profits which are agreed to exceed the MOT; and/or
- a delay and/or restriction of price increases agreed for the company.

New pharmaceuticals introduced following the granting of an EU or UK new active substance marketing authorisation may be priced at the discretion of the company, subject to its total profit constraint (DoH 1999a, p. 16).[14]

Firms in the PPRS wishing to raise the prices of existing pharmaceuticals must seek approval from the DoH. Price increases will only be approved if the DoH's assessment shows that the forecast profits in the current and following financial year of a company are below 50 per cent of their level one ROC target. No price increase is allowed within 12 months of a previous increase, and no price increase is allowed to compensate for loss of revenue as a result of other government initiatives (for example, price reductions under the Selected List Scheme) (DoH, pers. comm., 22 May 2001).

12 The allowable ROC which may be earned by companies from home sales of NHS medicines will be based on the historical value of average capital employed.

13 Taking the MOT into account, companies have an effective ROC of nearly 30 per cent.

14 The constraint is defined as a rate of return on manufacturers' total NHS capital stock (DoH, pers. comm., 22 May 2001). A company must provide costs and capital included in its AFR that are relevant to the supply of NHS medicines.

As part of the 1999 agreement between the Government and industry there was a 4.5 per cent decrease in prices of branded pharmaceuticals listed on the reimbursement list from 1 October 1999 (DoH, pers. comm., 22 May 2001).

In August 2000, a statutory maximum price scheme was put in place covering the main unbranded generic medicines supplied for NHS use in the community (DoH, pers. comm., 22 May 2001). Up to the end of 1998, competition in the market and incentives on community pharmacists to buy more cheaply than the headline price at which they were reimbursed had produced a gradual decline in the prices of generics over a period of years. In 1999, this trend was reversed and prices rose steeply. The maximum price scheme was introduced in response.

The scheme prohibits supply of certain generic medicines to community pharmacies and dispensing doctors, for NHS use, for more than a stated maximum price. The scheme applies mainly to 500 or so presentations of the preparations with the highest net ingredient cost. The maximum prices have been set primarily by reference to the historic prices that were reimbursed to community pharmacies and dispensing doctors, with some adjustment following consultation with interested parties.

Changes to the supply and reimbursement of generic medicines, including pricing arrangements, may result from a long-term review of the generics supply chain which is currently under way (DoH, pers. comm., 22 May 2001).

Other cost-containment mechanisms

Prescribing guidelines, limitations and budgets

Most doctors have access to a computerised prescribing advice system offering recommended treatment options on a range of clinical conditions (called PRODIGY). Under this system, a prescription also can be generated with the generic product as the default (Kanavos 1999b).

In the UK, from April 1999, all GPs have pharmaceutical budgets within Primary Care Groups (Kanavos 1999b). Spending by physicians is tracked monthly by the Prescription Analysis and Cost system (BCG 1999). The system is designed to provide an incentive for physicians to reduce the cost of their prescribing. According to the DoH (pers. comm., 22 May 2001) individual GP practices can earn incentive payments (modest sums to be spent for the benefit of patients) if they meet budgetary criteria and improve their prescribing to meet other specified conditions. The prescribing budget arrangements do not apply to the hospital sector.

Policies to encourage generic substitutions

For generic products, the main measures in place are the default prescription on the prescribing system and financial incentives available to doctors. At present over 65 per cent of all scripts are written generically, although these account for less than a quarter of total pharmaceutical expenditure (Kanavos 1999b). As well, pharmacists can substitute a generic product on a script where the product's patent has expired.

B.7 United States

Overview of the US health care system

The health care system in the US is mainly privately funded and provided. The public sector share of total expenditure on health is around 44 per cent in the US — the lowest compared to the seven other OECD countries listed in table B.1. Public health care is a shared federal and state government responsibility. Public health care arrangements are targeted at:

- the elderly (through Medicare), which reimburses many medical benefits but generally does not include coverage for out-patient pharmaceutical prescriptions;
- the poor (via the Medicaid program) which includes comprehensive pharmaceutical coverage; and
- veterans of military service (via the Veterans Administration), which includes comprehensive pharmaceutical coverage (GAO, pers. comm., 22 May 2001).

Within the private health insurance sector, there has been a shift to managed care plans[15] because they can generally charge lower prices than conventional insurance plans. The proportion of full-time workers with health insurance who were enrolled in such plans increased from around 26 per cent in 1988 to 61 per cent in 1995 (CBO 1998).

[15] Those with conventional health insurance plans (also known as fee-for-service plans) can receive care from any physician or hospital they choose. However, they usually have to pay for some initial amount of health care spending themselves (the deductible) and pay an additional amount (a copayment) on any costs beyond that. With managed care plans, however, beneficiaries are encouraged to use a limited network of health care providers, and usually pay lower amounts for the services (CBO 1998).

Managed care organisations are financed primarily through employer/employee and individual contributions, and beneficiaries are encouraged to use the services provided by health care providers who are part of the organisation.

Main features of the pharmaceutical system

The US is the main producer of pharmaceuticals, with its production increasing from US$6.6 billion in 1970 to US$82.5 billion in 1996 (OECD 2000). However, the US is not the largest exporter of pharmaceuticals amongst the OECD countries. The UK, for example, has higher exports. In 1996, the US exported US$6.84 billion and imported US$6.99 billion of pharmaceuticals (Jacobzone 2000, p. 68).

The majority of expenditure on pharmaceuticals and other medical non-durables is funded by the private sector. Most individuals have to obtain health benefits, including prescription pharmaceutical coverage, through employers who purchase health insurance or contract with a managed care plan (GAO, pers. comm., 23 May 2001). Table B.1 shows that although per capita total expenditure on pharmaceuticals and other medical non-durables is US$451 in the US (higher than all countries except France), public expenditure only accounts for a small part of this (US$70 per capita).

Between 1990 and 1997, the average rate of growth of total pharmaceutical expenditure[16] was 8.9 per cent per annum, while public expenditure grew on average at around 13.5 per cent per annum (OECD 2000).

Subsidy arrangements

The US Government generally subsidises the cost of a limited number of pharmaceuticals to particular segments of the population, namely the poor (through Medicaid), and defence personnel and veterans of military service (through the Department of Veterans Affairs).

Generally, the Medicare benefit package (covering people aged 65 and over, some disabled people under 65 years of age, and people with permanent kidney failure treated with dialysis or a transplant) does not provide subsidies for out-patient pharmaceuticals (GAO 2000a). However, Medicare beneficiaries can choose to have prescription pharmaceutical coverage by choosing to receive their Medicare

16 Total pharmaceutical expenditure includes expenditure on other medical non-durables (such as bandages, elasticised stockings, incontinence articles, condoms and other mechanical contraceptive devices). It also includes spending on prescription medicines and OTC products, but excludes pharmaceuticals consumed in hospitals (OECD 2000).

coverage from a Medicare+Choice plan that offers this benefit (GAO, pers. comm., 23 May 2001). Services provided to Medicare+Choice plans are through a managed care organisation (GAO 2000a).

Medicare beneficiaries also can purchase Medigap policies, or supplemental insurance, but only three of the policies offer pharmaceutical coverage (GAO, pers. comm., 23 May 2001). Eight per cent of Medicare beneficiaries have prescription pharmaceutical coverage through Medigap. However, these packages have a 50 per cent copayment, a US$250 deductible, and a cap at either US$1250 or US$3000 (Mathematica Policy Research 2000).

Medicaid is a jointly funded federal/state health insurance program.[17] Although federal government guidelines exist, each of the States is responsible for: establishing eligibility standards; determining the type, amount, duration, and scope of services; setting the rate of payment for services; and administering the program. Most state Medicaid programs pay for prescribed pharmaceuticals. States may impose nominal deductibles or copayments for Medicaid coverage, but in practice this is rare (Hood 1997, p. 6).[18]

The Veterans Administration is a separate government scheme that provides subsidised out-patient pharmaceutical services to veterans of military service. Veterans who receive medications for treatment of service-related conditions, or who have incomes that do not exceed the maximum Veterans Administration pension, receive free out-patient pharmaceutical services. Other veterans who have prescriptions filled by the Veterans Administration may be charged US$2 for each 30-day supply of medication (Department of Veterans Affairs 2001).

Most people in the US are either enrolled in private health insurance schemes — which provide subsidised pharmaceuticals to their enrollees — or are uninsured (18.4 per cent of the non-elderly population in the US had no health insurance in 1998 (The Economist 2000)), in which case pharmaceuticals are purchased at market (that is, unsubsidised) prices.

The private health insurance schemes are generally provided by managed care plans, and include Health Maintenance Organisations (HMOs), Preferred Provider

17 Medicaid is for certain low-income and needy people. It covers approximately 36 million individuals including children, the aged, blind, and/or disabled, and people who are eligible to receive federally assisted income maintenance payments (HCFA 2001).

18 According to the GAO (pers. comm., 23 May 2001), most State Medicaid programs require participants to pay nominal copayments, but allow pharmacies to waive the copayments if participants say they cannot afford the copayments.

Organisations (PPOs) and Point-of-Service (POS) plans.[19] Copayments are usually required for prescription pharmaceuticals. Most types of managed health care plans have moved to 'managing' their out-patient prescription pharmaceutical benefits through pharmaceutical benefit management (PBM) companies.

Within the privately-run managed health care sector, most schemes will have some form of pharmaceutical formulary (reimbursement list), which lists pharmaceuticals that are preferred for use and are subsidised by the plan. The lists are reviewed periodically and modified by the respective plans. The list may be:

- an 'open or voluntary' formulary, allowing coverage for both formulary and non-formulary medications, with beneficiaries paying no more for using non-formulary pharmaceuticals; or
- an 'incentive-based' formulary which offers enrollees lower copayments for the preferred product and generic pharmaceuticals, and partly subsidises non-formulary products, but the copayments are higher; or
- a 'closed, select or mandatory' formulary which limits coverage to selected pharmaceuticals and requires enrollees to pay the full cost of non-formulary pharmaceuticals (GAO 2000b).

PBM companies negotiate to pay lower prices for pharmaceuticals to both the manufacturers and the pharmacists. With a pharmacist, a PBM company channels their patients to use a particular pharmacy in return for lower retail prices. With manufacturers, the PBM companies negotiate lower prices based on their ability to influence their physicians and members to prescribe and consume particular brand-name products listed on their formulary. If there is a choice of pharmaceuticals, the least costly products are listed on the plan's formulary (Health Net 2001).

For private sector managed care plans (such as HMOs), fixed or variable copayments are required for prescriptions. Deductibles also usually apply (CBO 1998, p. 10). Currently, around 30 per cent of pharmaceutical costs are borne by cash paying patients (BCG 1999). However, this share is declining with the rise of HMOs and government programs.

[19] Enrollees in a HMO generally must seek services from those physicians and hospitals associated with the HMO. Those enrolled in PPOs can receive services from any provider, but pay higher deductibles and copayments if they choose service providers outside the PPO's network. POS plans (also known as open-ended HMOs) allow their enrollees to receive services from providers outside the plan's network. When enrollees use the network providers, a POS plan functions in a similar manner to HMOs. When other providers are used, the providers are paid on a fee-for-service basis and enrollees are responsible for deductibles and copayments.

Most private insurance plans have copayment requirements. For example, 60 per cent of retail sales are paid by a third party to some extent (BCG 1999). A 1993 survey by the Bureau of Labor Statistics found that HMOs generally charged US$3 to US$5 for a prescription pharmaceutical purchase (CBO 1998, p. 10). Under government plans, the copayments (if any) required for prescriptions are small.

Pricing of pharmaceuticals

In general, pharmaceutical companies and suppliers are free to price their products as they see fit for the majority of the US pharmaceutical market. However, depending on the subsidy program (private or government) various measures are used to contain the prices of subsidised pharmaceuticals.

Most government programs that cover prescription pharmaceuticals mandate some form of price control such as a mandatory rebate, discount, price cap or limit on price increases. The Medicaid Drug Rebate Program, in particular, requires that companies which sell to Medicaid provide rebates equal to the greater of 15.1 per cent of the average manufacturers price (AMP)[20] or the difference between the AMP and the manufacturers 'best price' to any other purchaser. Additional rebates are required for any products where price increases exceed the CPI (GAO 2000c).

In the private sector, managed care plans also adopt a variety of techniques to control manufacturer prices of pharmaceuticals on their reimbursement lists. Direct negotiations with pharmaceutical manufacturers often result in rebates (discounts) being offered by manufacturers to plans, thereby reducing the actual cost of pharmaceuticals. Cost-containment measures also extend to the distribution network, with plans negotiating reimbursement rates and dispensing fees with pharmacies (GAO 2000b).

Other cost-containment mechanisms

Prescribing guidelines, limitations and budgets

Prescribing guidelines for doctors are set by managed care organisations. The extent of recommendations and use of sanctions depends on the type of managed care

[20] AMP is the average price a wholesaler pays to a manufacturer for pharmaceuticals distributed to retail pharmacies. The Federal Supply Schedule prices and prices associated with direct sales to HMOs and hospitals are excluded.

setting involved (Jacobzone 2000). Formularies, usually listing generics where possible, also are used to encourage doctors to prescribe more cost-effectively.

Policies to encourage generic substitutions

Some government health programs, such as Medicaid, and many private health insurance plans have actively promoted generic substitution (CBO 1998). As well, by 1980, most States had passed laws allowing pharmacists to dispense a generic pharmaceutical even if the prescription called for a branded product.

The Drug Price Competition and Patent Term Restoration Act 1984 (also known as Hatch-Waxman Act) made it easier and less costly for generic pharmaceutical manufacturers to enter the market. Manufacturers needed only to demonstrate 'bioequivalence' to an already approved innovator pharmaceutical (that is, that the active ingredient is absorbed at the same rate and to the same extent in the generic as in the innovator pharmaceutical). Manufacturers are not required to prove independently the safety and efficacy of their products in the same way as new chemical entities.

There are, however, provisions in the Hatch-Waxman Act that also can work to delay the entry of generic competitors. For example, when the Hatch-Waxman Act reduced the testing requirements for generic pharmaceuticals, it also extended patent protection for new innovative pharmaceuticals (CBO 1998).

In addition, although the Hatch-Waxman Act provides the first generic producer (to obtain a marketing approval) a period of six months exclusivity from the date it commences marketing its pharmaceutical, it also allows for the US Federal Drug Administration to automatically suspend the approval process of this new generic product for 30 months if the producer of the originator product challenges the prospective generic producer on the grounds that it has infringed a patent that is still in force (OECD 2001).

C Methodology

This appendix describes in detail the methodology used to undertake the price comparison of Pharmaceutical Benefit Scheme (PBS)-listed molecules.

C.1 Introduction

Elements of the methodology that are explored in more detail in this appendix are:

- choosing the basket of molecules for comparison;
- choosing molecules within the basket;
- matching molecules;
- prices used;
- converting prices to a common currency; and
- weighting manufacturer prices.

C.2 Choosing the basket of molecules for comparison

The terms of reference for the study require the Commission to examine differences between the prices of PBS-listed molecules and the prices received overseas, and to explain, as far as possible, the reasons for any differences. In undertaking this task one issue to be addressed is whether molecules not subsidised under the PBS should be included as part of the price comparisons.

Defining the potential basket of molecules to include all prescription and over-the-counter molecules irrespective of whether they are listed on the PBS would provide the most comprehensive data set for this study. Also, including some non-PBS-listed molecules could provide a 'control group' that could provide information on the extent to which the PBS influences the prices of PBS-listed molecules. However, the list of PBS molecules is extensive and covers a large share of the Australian pharmaceutical market. Hence, there is likely to be a high degree

of substitutability between many PBS and non-PBS molecules, limiting the size and usefulness of a control group of non-PBS molecules.[1]

Cost and time constraints also precluded such a wide comparison of pharmaceutical prices. Therefore, the study focuses on PBS-listed molecules. In doing so, conclusions cannot be drawn about the impact of the PBS on overall pharmaceutical prices in Australia. Inferences can only be drawn about those molecules listed on the PBS.

C.3 Choosing molecules within the basket

There are approximately 820 molecules listed on the PBS. The practicalities of data availability preclude including all these molecules in the price comparison. Hence, it was necessary to identify a sample of PBS-listed molecules for comparison.

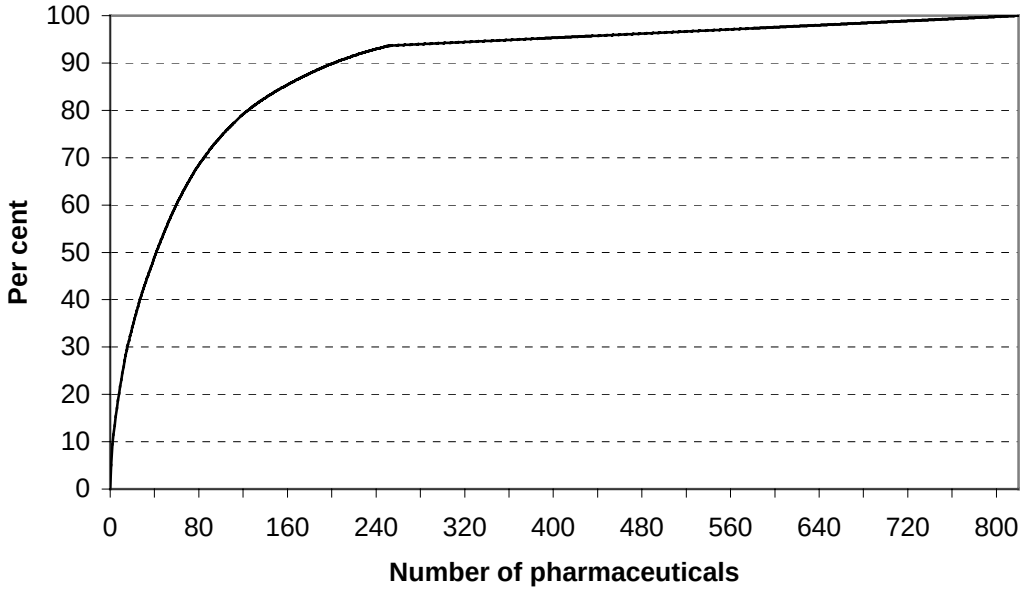
One possible approach is to select a pre-determined number of molecules from those listed on the PBS at random. The aim of random sampling is to ensure that the group of molecules chosen for the study is representative of all of those listed on the PBS. It also allows for conclusions to be drawn about the general level of pharmaceutical prices between Australia and overseas countries.

An alternative approach to choosing the sample of molecules is to select key molecules based on their share of total expenditure (defined as the sum of patient contribution and government subsidy), or the volume of consumption. Most previous studies have chosen the molecules for comparison on the basis of total expenditure (IC 1996).

Examination of PBS expenditure data shows that a small number of molecules accounts for a large share of total expenditure under the scheme (figure C.1). The top 250 pharmaceutical molecules account for over 90 per cent of total expenditure. The top 150 molecules account for over 80 per cent.

1 A high rate of substitutability between PBS and non-PBS pharmaceuticals implies that government interventions affecting the prices of PBS items also will affect the prices of non-PBS items.

Figure C.1 **Total annualised expenditure on PBS molecules, percentage, 1999-2000[a,b,c]**



a PBS expenditure data were adjusted using survey data collected by the Department of Health and Aged Care for non-subsidised PBS medicines for the year 1998. **b** Expenditure on molecules listed part-way during 1999-2000 was annualised (appendix D).**c** Pharmaceuticals are ranked by total annualised expenditure.

Data source: DHAC.

The characteristics of the PBS expenditure data indicate that choosing molecules based on total expenditure is the most appropriate approach for this study. The approach ensures that the prices of those molecules that have the most influence on pharmaceutical company revenues and Government subsidy payments are included in the study. The ability to match Australian molecules with those in overseas countries also is increased by focusing on those molecules that dominate expenditure in Australia.

However, in taking this approach to choosing the molecules for price comparisons, conclusions cannot be drawn about the general level of prices for PBS-listed molecules between Australia and overseas countries. The sample of molecules is not necessarily representative of the entire PBS market. Instead, inferences can only be drawn for those molecules selected.

Categorisation of molecules

The terms of reference require that the basket of PBS molecules examined includes three categories of molecules: new innovative; new chemical entities (me-too); and

molecules subject to generic competition (generics). The terms of reference also specified that there be at least ten forms in each of these groups.

The Commission sought the assistance of the Department of Health and Aged Care (DHAC) to categorise the top 150 molecules included in the price comparison. DHAC categorised the sample of 150 molecules into one of the three categories based on their status at (or as close as possible to) 30 June 2000. The number of new innovative, me-too and generic molecules in the sample is 21, 49 and 80, respectively (appendix D).

C.4 Matching molecules

Molecules are marketed to consumers in a wide variety of forms. A particular molecule can be marketed in forms that can differ by the dosage type (for example, tablets, syrups and injections), by strength (the amount of active ingredient) and by pack size. In Australia, 584 different forms for the top 150 PBS-listed molecules were identified for 1999-2000. It is important to note that the status of these molecules will change over time as patents expire and new items are listed.

The variety of ways in which molecules are sold complicates international price comparisons because the forms available for each molecule often differ between countries. Two approaches have been developed to account for different forms of molecules:

- aggregation across forms; and
- form matching.

Aggregation across forms

Aggregation across forms involves converting all dosage types, strengths and pack sizes to a standard unit for comparison.[2] One approach is to calculate a *price per gram of active ingredient*. This is done by weighting the price per gram of active ingredient for each form by its share of total sales revenue for all forms of the molecule. An alternative approach is to calculate a *price per standard dosage* for each molecule. This is done by converting different dosage types to a standard

2 This approach was used in the study by Danzon and Chao (2000).

dosage for comparison. A standard dosage can be defined as one tablet, capsule or a certain amount of liquid or cream.[3]

The aggregation across forms approach is comprehensive — it can include the price and quantity for all forms in each country in the price comparison. In doing so, it allows for global comparisons (all countries) to be undertaken because of the large sample sizes involved. It also allows for a more rapid calculation of price indexes compared to the form matching approach. This feature can be particularly important if the prices of many hundreds of molecules (with each available molecule in many different forms) are being compared across countries.

However, the approach also has some important disadvantages.

First, it is necessary to exclude molecules that contain multiple active ingredients from the sample. This is because of difficulties in determining the weight of each active ingredient in the molecule. For the top 150 molecules chosen for this study, 10 contain multiple ingredients.

Second, using this approach could show that a price differential exists even if the forms and prices of all molecules are identical across countries. This is because the price per gram of active ingredient or standard dosage may differ depending on the dosage type.[4] As the price of each form is weighted by its share in the total expenditure on the molecule, the resulting index can indicate a price differential if shares of the identical forms vary across countries.

Third, aggregation across forms is data intensive, as prices and quantities are required for each form and for each country under comparison. In countries such as the United States (US), there are many thousands of forms available (including different pack sizes) for Australia's top selling 150 PBS-listed molecules.

Form matching

The approach adopted by this study was to seek direct matches for each of the 584 forms of Australia's 150 top-selling molecules in each comparison country

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3 Another possible standard dosage is a defined daily dosage (DDD). DDDs are an international unit of pharmaceutical utilisation. They are established by the Nordic Council on Medicines and the World Health Organization Drug Utilisation Research Group. There is a level of subjectivity associated with the development of DDD. DHAC also has noted that on some occasions it is difficult to assign a DDD for a molecule with multiple active ingredients (DHAC 1999b).

4 The price per standard dosage, such as price per tablet, also usually differs across forms. For example, the price per tablet usually differs by the strength of the active ingredient.

(hereafter referred to as form matching).[5] The form matching approach is designed to achieve meaningful results through ensuring that, where possible, 'like with like' price comparisons are undertaken. Compared to alternative approaches used in some previous studies (section 1.3), under a form matching approach prices associated with injections and inhalers are not directly compared with those of tablets and syrups. Also, the relevant comparison is usually between a price per pack rather than per tablet or other measurement unit.

That said, the practicalities of matching many hundreds of forms necessitated making some assumptions. While an attempt was made to match identical dosage types, there often are many different forms within a particular dosage type. For example, many types of tablets and capsules may be available in slightly different forms, such as standard, slow-releasing or film-coated. In such cases, prices for slightly different forms within a given dosage type were considered comparable for this study.

Even by assuming comparability within a dosage type, in a number of instances a direct match on the form available in Australia still could not be obtained in the overseas country. Also, in some countries multiple prices exist for the same form of molecule. The approach adopted for these instances was as follows:

- if a match could not be obtained on dosage type or exact strength, the form was removed from the sample (coded as no match molecule (NMM), form (NMF) or strength (NMS));
- if Australia's pack size was unavailable in the overseas country, an estimate of the price of this pack size was created in some instances; and
- where multiple prices of the same form were encountered, a weighted average price was calculated if overseas volume data were available. Otherwise, the highest and lowest prices for the form were included in the price comparison.

In order to avoid making assumptions about the relationship between prices and pack sizes or the link between price per unit of active ingredient and different dosage types and strengths, *higher* and *lower* estimates of prices were reported for each comparison country.[6]

5 A direct match on form requires a match on dosage type, strength and pack size in the comparison country.

6 If a comparison country's pack size was within 20 per cent of the Australian pack size, a linear adjustment was made to the overseas price to calculate an equivalent Australian pack size price. The 20 per cent threshold was chosen in order to limit any bias arising from inter-country differences in the relationship between prices and pack sizes.

The procedure used to match pharmaceuticals is outlined in figure C.2 (the codes are explained in table C.1). The number of no-matches and matches obtained for the comparison countries using this procedure is examined in appendix E.

While form matching seeks to provide the most meaningful results, its use has some important implications for interpreting the price comparisons. In particular, the number of matches with the comparison countries is reduced (compared to the aggregation across forms approach). This is because the number and type of forms for which prices could be obtained differ across countries. Only 18 out of 584 forms were available in all of the comparison countries. As such, it was not possible to undertake a 'global' price comparison, with the prices of all forms compared across all comparison countries.[7] Instead, the study was restricted to bilateral price comparisons between Australia and each overseas country.

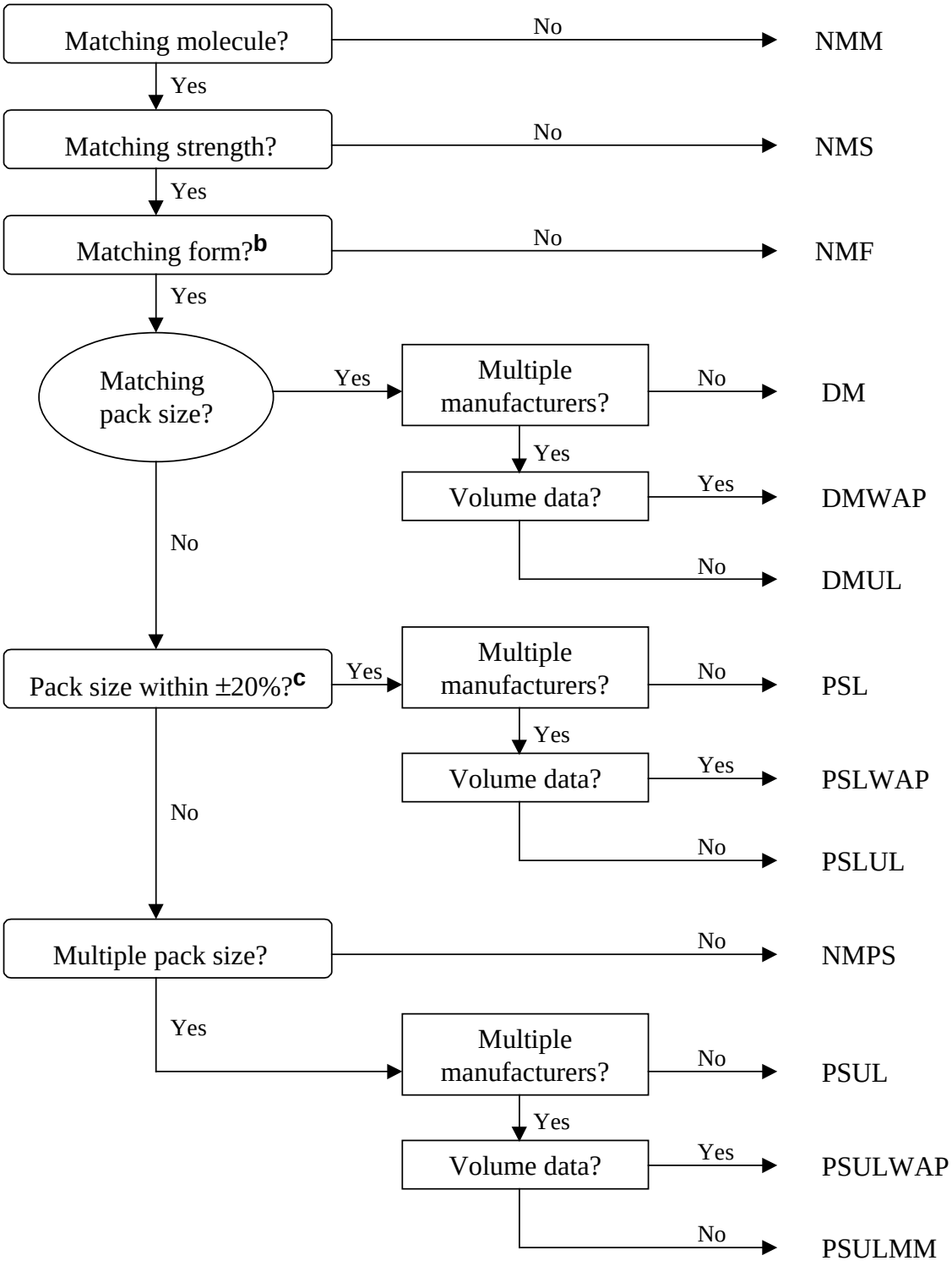
Importantly, using this approach, conclusions about the prices of the top selling PBS-listed molecules cannot be drawn across the comparison countries. For example, the price ratios produced for the US relative to Australia, and the United Kingdom (UK) relative to Australia cannot be used to draw inferences about the level of prices between the US and the UK. Such comparisons are problematic for two reasons:

- the price ratios are based on different samples of molecules; and
- simple comparisons between two foreign countries (by dividing one price ratio by another) alters the underlying price ratio formula creating interpretational difficulties.

Even if the sample of molecules were the same across all comparison countries, it still would not be valid to compare the price ratios. Dividing the price ratio for the US relative to Australia by that for the UK relative to Australia would produce a price ratio which weights US and UK prices by Australian quantities. Price ratios derived in this way are not relevant for the purpose of this study. They also are problematic as measures of relative prices between two foreign countries because the sample of molecules is drawn from the Australian PBS and Australian quantities are used as weights.

7 Another difficulty in comparing prices across countries based on top selling PBS-listed molecules is that the sample of molecules may be unrepresentative of the top selling molecules in each of the comparison countries. The results, therefore, cannot be used to draw inferences about whether manufacturer prices in the comparison country are, on average, higher or lower than Australia's.

Figure C.2 **Form matching procedure**[a]



[a] See table C.1 for a full explanation of the matching codes. [b] This refers to dosage type. [c] Pack sizes within or equal to ±20 per cent of the Australian pack size.

Table C.1 **Matching codes**

Code	*Short description*	*Full description*
NMM	No match molecule	No match was found for the molecule.
NMS	No match strength	For a matched molecule, no match was found for strength.
NMF	No match form	For a matched molecule and strength, no match was found for dosage type.
DM	Direct match	There is a direct match for molecule, strength, dosage type and pack size. As there is only one manufacturer, the price is used for both higher and lower estimates.
DMWAP	Direct match weighted average price	There is a direct match for molecule, strength, dosage type and pack size. As there are multiple manufacturers, volume data are used to calculate a weighted average price. This price is used for both higher and lower estimates.
DMUL	Direct match upper lower	There is a direct match for molecule, strength, dosage type and pack size. There are multiple manufacturers but, as there is no volume data, higher and lower prices are used.
PSL	Pack size linear	There are matches for molecule, strength, dosage type but not for pack size. For pack sizes within or equal to ±20% of the Australian pack size, the price is calculated using the linear method.[a] As there is only one manufacturer, the price is used for both higher and lower estimates.
PSLWAP	Pack size linear weighted average price	There are matches for molecule, strength, dosage type but not for pack size. Pack sizes are within or equal to ±20% of the Australian pack size. As there are multiple manufacturers, volume data are used to calculate a weighted average price. This price is then recalculated using the linear method and is used for both higher and lower estimates.
PSLUL	Pack size linear upper lower	There are matches for molecule, strength, dosage type but not for pack size. For pack sizes within or equal to ±20% of the Australian pack size, the price is calculated using the linear method. There are multiple manufacturers but, as there is no volume data, higher and lower prices are used.
NMPS	No match pack size	There are matches for molecule, strength, dosage type but not for pack size. Pack size exceeds ±20% of the Australian pack size. There is one or more manufacturers producing one different pack size.
PSUL	Pack size upper lower	There are matches for molecule, strength, dosage type but not for pack size. Pack sizes exceed ±20% of the Australian pack size. There is one manufacturer producing multiple pack sizes. If the Australian pack size lies between the overseas pack sizes, the closest pack size on each side of the Australian pack size are selected. If the Australian pack size is not in-between, the closest two pack sizes are selected. Prices are calculated using the linear method and are used as higher and lower estimates.

(Continued on next page)

Table C.1 (continued)

Code	*Short description*	*Full description*
PSULWAP	Pack size upper lower weighted average price	There are matches for molecule, strength, dosage type but not for pack size. Pack sizes exceed ±20% of the Australian pack size. If the Australian pack size lies between the overseas pack sizes, the closest pack size on either side of the Australian pack size are chosen. If the Australian pack size is not in-between, the closest two pack sizes are selected. As there are multiple manufacturers producing different pack sizes, volume data are used to calculate a weighted average price for each pack size. The prices are recalculated using the linear method and used as higher and lower estimates.
PSULMM	Pack size upper lower multiple manufacturer	There are matches for molecule, strength, dosage type but not for pack size. Pack sizes exceed ±20% of the Australian pack size. If the Australian pack size lies between the overseas pack sizes, the closest pack size on either side of the Australian pack size are selected. If the Australian pack size is not in-between, the closest two pack sizes are chosen. As there are multiple manufacturers producing different pack sizes but no volume data, the prices are calculated using the linear method and used as higher and lower estimates.

a The linear method calculates the price per pack by multiplying the price per tablet or capsule (based on the overseas pack size) by the Australian pack size.

C.5 Prices used

The terms of reference for the study specify that price comparisons should be made at the ex-factory (manufacturer) level. For all overseas countries except Sweden, manufacturer prices were obtained from IMS Health (chapter 3 and appendix D).

IMS Health prices can be considered the maximum prices received by manufacturers, referred to as the 'list' or published price. However, in some countries, the pharmaceutical market may be segmented into buyers of various sizes and influence. Some larger/institutional buyers within each country may be able to negotiate lower prices with manufacturers in the form of discounts off published list prices (chapter 3).

According to Danzon (1996), in the US, substantial discounts often are negotiated by the managed care plans and mail order sectors, while Medicaid and other Federal programs receive rebates and other forms of discount from manufacturers that are not reflected in list prices. There have been a number of attempts to quantify the discounts across the various segments of the US market (box C.1). The US may not be the only country that has substantial discounts available for large buyers. The list

prices in the UK also may overstate manufacturer prices because the data do not reflect discounts to pharmacists (Danzon and Chao 2000).

Box C.1 **Studies of discounting of pharmaceuticals in the United States**

Boston Consulting Group (BCG), 1993

The BCG study found that although 25 per cent of the market (the 'traditional retail pharmacy') was paying the list price for pharmaceuticals in 1992, an estimated 55 per cent of the market was receiving discounts of up to 30 per cent off the list price, comprising: 30 per cent off the list price for mail-order pharmacy (representing five per cent of the market); 30 per cent off the list price for managed hospital pharmacy (representing 15 per cent of the market); and 25 per cent off the list price for managed retail (representing 35 per cent of the market).

Congressional Budget Office (CBO), 1998

The CBO conducted an examination of pharmaceutical pricing and found that consumers without prescription drug insurance coverage pay higher prices for pharmaceuticals than those with insurance.

US House of Representatives, 1999

This study investigated the pricing of five brand-name prescription pharmaceuticals that accounted for the largest share of total sales to the elderly. The study attempted to estimate the differential between the prices charged to the pharmaceutical companies' most favoured customers (such as the Health Maintenance Organisations (HMOs) and the Federal Government) and the prices charged to seniors who lack prescription drug coverage. The study found that older Americans without insurance pay higher prices for commonly used pharmaceuticals (the average price differential was 134 per cent).

Federal Trade Commission (FTC), 1999

The FTC examined prescription pharmaceutical pricing practices and found that pharmaceutical companies practise differential pricing whereby companies set lower prices to large buyers like hospitals, HMOs and pharmaceutical benefit management companies (PBMs), and charge higher prices to other buyers that include the uninsured and independent and chain retail pharmacies.

Sources: The Pink Sheet April 5 (1993); US House of Representatives (1999).

Given the commercial nature of transactions between many buyers and sellers of pharmaceuticals, it is difficult to obtain information on the actual prices paid by some buyers in the comparison countries (chapter 3).

However, in some countries, government agencies publish the prices they pay for pharmaceuticals. As discussed in chapter 2, through deciding which pharmaceuticals are eligible for subsidies, governments often have considerable bargaining power with manufacturers. This manifests itself in cost-containment measures directed at both prices paid and total expenditure on pharmaceuticals. As

such, published prices by governments may be considered representative of the prices paid by larger/institutional buyers in each country.

An example of government published prices is the Federal Supply Schedule (FSS), which is administered by the Department of Veterans Affairs (VA) in the US. Pharmaceutical companies must make their brand-name pharmaceuticals available through the FSS in order to receive reimbursements for drugs covered by Medicaid. The prices negotiated under the FSS are intended to equal or better the prices manufacturers charge their 'most-favoured' non-federal customers under comparable terms and conditions (GAO 2000a). Danzon notes that 'manufacturers face a significant economic penalty for failure to participate in the FSS. This in turn gives the VA leverage in negotiating prices' (Danzon 1999, p. 11).

The FSS price may not be the lowest price available in the US market. First, price negotiations between VA and pharmaceutical suppliers involves both price and the terms and conditions of supply. Terms and conditions of supply include contract length and ordering and delivery practices. Because the terms and conditions can vary by pharmaceutical, the FSS may not be the lowest price in the market (GAO 1997; 2000a). Second, some buyers may be able to negotiate prices below those achieved under the FSS. For example, the VA has obtained some pharmaceutical prices lower than the FSS through the competitive tendering of national contracts. On average, these contracts have resulted in prices that are about one-third lower than corresponding FSS prices (GAO 2000a).

A further market segment, and hence a further set of pharmaceutical prices, that also could be included in the study are prices paid by hospitals. However, the hospital market appears to be different to the outpatient pharmaceutical market (which the PBS covers), because pharmaceutical companies adopt different pricing and marketing strategies. Hence, prices paid by hospitals may not provide useful information to help explain the influence of the PBS on listed pharmaceuticals. Also, information on the prices received by manufacturers on their sales to hospitals is not available for some of the comparison countries (Spain and Sweden).

C.6 Converting prices to a common currency

Manufacturer prices were calculated for each country in the local currency. In order to compare prices it was necessary to convert local currency prices into a common currency. The most commonly used approach is to use official exchange rates. An alternative approach is to use purchasing power parity (PPP) exchange rates.

The appropriate conversion factor depends on the purpose of the price comparison. The purpose of this study is to estimate, for selected countries, differences in the

prices received by manufacturers for pharmaceutical molecules listed on the PBS. Given this purpose, official exchange rates are the most appropriate conversion factor. This is because they provide the most relevant information on the revenue and cost implications of pricing PBS-listed molecules at international, rather than Australian, levels. Official exchange rates also are one factor taken into consideration by the Pharmaceutical Benefits Pricing Authority (PBPA) in reviewing the price of existing pharmaceuticals and those recommended for listing under the PBS.[8]

A limitation of using official exchange rates is that they can fluctuate over time, reflecting short-term factors. Hence, the results may be sensitive to the time period on which the exchange rate is based. This problem can be overcome by calculating 'average' exchange rates for the comparator countries over a specified time period.

For the results presented in chapter 3, the average exchange rate for the month of June 2000 was used to convert overseas currencies into Australian dollars. This was chosen as it is the closest average exchange rate to the time period over which the pharmaceutical prices were collected.

Recognising that exchange rates fluctuate over time, the sensitivity of the price comparisons to different exchange rates was tested. Prices were converted using average exchange rates for:

- 30 June 2000;
- the three months to June 2000;
- the 1999-2000 financial year; and
- the period 1 July 1998 to 30 June 2000 (1998-99 to 1999-2000).

The results for these different exchange rates are summarised in chapter 3 and presented in more detail in appendix E.

The alternative to using official exchange rates is PPPs, which are designed to reflect the real purchasing power of a national currency. Some researchers have suggested PPPs should be used to convert overseas prices on the basis that they better reflect the resources that a consumer must forgo in order to purchase a basket of pharmaceuticals. Hence, PPPs may be appropriate to assess whether consumers or governments are 'better-off' under foreign or Australian prices. PPPs also tend to be less sensitive to short-term speculative movements compared to official exchange rates.

8 Consideration of official exchange rates occurs under 'factor g' in reviewing prices for existing and new pharmaceuticals (PBPA 2000).

However, PPPs are less appropriate than official exchange rates given the purpose of this study. In particular, they do not accurately reflect the revenue and cost implications of pricing PBS-listed molecules at international rather than Australian levels. Official exchange rates, and not PPPs, are used in reviews of new and existing pharmaceutical prices by the PBPA. While the results reported in chapter 3 are based on official exchange rates, the results for prices converted by PPPs are included as part of the sensitivity analysis (appendix E).

C.7 Weighting manufacturer prices

The terms of reference require the Commission to calculate some form of weighted average price. This requirement reflects the fact that unweighted price comparisons are unduly influenced by higher-priced molecules, as no level of 'significance' is applied to each price.

The choice of an appropriate weight depends on the purpose of the study and the information sought from the resulting price comparison. Two issues in weighting prices were identified:

- the choice of countries from which weights are obtained; and
- the choice of weights from the countries chosen.

Choice of country

A range of values could be used to weight pharmaceutical prices for each of the countries included in the study.

If the weights applied are sourced from Australia (as suggested by the terms of reference), the resulting index is known as a *Laspeyres* index. Under this approach, the index can provide information on whether prices in Australia are higher or lower than those overseas. If weights are sourced from the comparison countries, the resulting index is known as a *Paasche* index. This index can provide information on the revenue and cost implications to a comparison country if it purchased its pharmaceutical requirements from Australia.

If pharmaceutical consumption patterns differ across countries, the Laspeyres and Paasche indexes will give different results when applied to the same price data. Often, a calculated relative price differential (based on the same molecule prices) will be greater for that of the Laspeyres index compared to that of the Paasche

index. This result is usually attributed to the assumption that consumers will buy relatively less of those molecules whose prices have become relatively dearer.[9]

Given the limitations of these two indexes, other indexes have been developed, such as the *Fisher's ideal* index, that represents a combination of home and overseas country weights.

Past studies have found that pharmaceutical consumption patterns differ considerably across countries, due to factors such as disease patterns, pharmaceutical availability and medical practices (see, for example, Danzon and Chao 2000). This means that different results are likely to be obtained depending on the country (or combination of countries) from which the price weights are obtained. As a consequence, some studies have recommended that a range of indexes be reported (Andersson 1993). In contrast, other studies have argued that it is probably most appropriate for each country to weight prices by its own consumption patterns (Danzon and Chao 2000).

The purposes of this study suggest that Australia is the most appropriate country from which to obtain the price weights (Laspeyres index). The resulting index provides information on the revenue and cost implications of pricing Australia's top selling PBS-listed molecules at international prices. Information on the cost and revenue implications for overseas countries of purchasing their pharmaceutical requirements at Australian prices (Paasche index) is of less relevance for this study.

Choice of weight

Having chosen to obtain the price weights from Australia, it is then necessary to decide what weights will be applied.

From the perspective of pharmaceutical companies, it may be that weighting pharmaceutical prices by the volume of sales is appropriate. This is because the resulting index provides an indication of the revenue that pharmaceutical companies could have received if they obtained the comparison country's prices on their Australian sales. The robustness of this interpretation depends on the extent to which Australian consumption and supply patterns would change in response to the new (overseas) set of prices.

From the Government's perspective, it also may be considered useful that the study provides information on the effect of the PBS on aggregate subsidy payments. In

9 For further discussion on index numbers see Karmel and Polasek (1978).

this case, the relevant quantity weight is the volume of sales that attracted a subsidy payment from the Government. This is estimated by the number of PBS scripts.

Prices were weighted by both the volume of sales and the number of PBS scripts. However, the results differed little between the two different weights. The results in chapter 3 are presented weighted by the volume of Australian sales. Results with prices weighted by the number of PBS scripts can be found in appendix E.

D Data sources

This appendix describes the data sources used in the international price comparisons.

D.1 Summary of sources

A number of data sources were used to undertake the international price comparisons (table D.1).

Table D.1 **Sources of data**

Country	*Data sources*
Australia	IMS Health, Department of Health and Aged Care
United States	IMS Health, Federal Supply Schedule
United Kingdom	IMS Health, Chemist and Druggist Monthly Price List, Prescription Cost Analysis
Canada	IMS Health, Ontario Drug Benefit Formulary and Pharmacare Low Cost Alternative Reference Drug Program Booklet (British Columbia)
New Zealand	IMS Health, Pharmac Pharmaceutical Schedule
France	IMS Health, National Health Insurance Fund
Spain	IMS Health
Sweden	Riksförsäkringsverket (RFV; National Social Insurance Board)

In the following section, data obtained from IMS Health are first described. Additional data sources obtained from individual countries are then described.

D.2 IMS Health data

IMS Health data for the 150 molecules included in the study was obtained for Australia, the United States (US), Canada, the United Kingdom (UK), France, Spain and New Zealand (NZ). The data provided by IMS Health included:

- the form names and new form codes (NFC) for each molecule;[1]

[1] NFCs for pharmaceuticals are developed by the European Pharmaceutical Marketing Research Association. They were first developed in the mid 1960s and are an internationally recognised system of classifying pharmaceuticals (EPHMRA 2001). They were used to assist in matching pharmaceuticals.

- local currency manufacturer prices;
- volume data for 30 identified molecules in each comparison country and the top 150 molecules in Australia;
- the global launch date for each molecule;
- the manufacturer and launch date for each form in the respective country; and
- reimbursement status.

Discussion on the collection, interpretation, and limitations of IMS Health data can be found in chapter 3 of the report.

D.3 Australia

Manufacturer prices and expenditure data were obtained from the Department of Health and Aged Care (DHAC) for 1999-2000. This data included the number of scripts, Commonwealth Government subsidy payments and total expenditure (sum of patient contribution and government subsidy) for pharmaceuticals subsidised under the PBS.

The DHAC data included expenditure on highly specialised (section 100) pharmaceuticals. The Commonwealth Government negotiates the price and provides funding to the States and Territories for these pharmaceuticals, which are medicines for chronic conditions that because of their clinical use or other special features, are restricted to supply through hospitals (DHAC 2000).

For the purpose of ranking molecules by total expenditure, two adjustments were made to the DHAC data, namely:

- an estimate of the volume of PBS pharmaceuticals that did not attract a PBS subsidy was added. This estimate was obtained from the 1998 *Australian Statistics on Medicines* (DHAC 1999b); and
- for pharmaceuticals that were listed part-way during 1999-2000, total expenditure was annualised on the basis of average monthly expenditure.[2]

Brand and therapeutic group premiums

In Australia, government policies permit manufacturers to add either a brand premium (BP) or a therapeutic group premium (TGP) to the negotiated or subsidised price of some products. For those products for which a BP or TGP

[2] Expenditure was annualised for part-way listed forms to ensure that important new pharmaceuticals, as measured by the level of expenditure, were included in the study.

applied, a weighted average price was calculated between the premium and non-premium form based on their volume of sales.

Weighted average monthly treatment cost

The Pharmaceutical Benefits Pricing Authority uses the weighted average monthly treatment cost (WAMTC) method to determine the reimbursement price for pharmaceuticals in a number of therapeutic groups. Table D.2 lists those pharmaceuticals within the sample that have been subject to WAMTC pricing reviews, classified by their category (me-too or generic).

Table D.2 **Pharmaceuticals covered under TGP/WAMTC arrangements at 30 June 2000[a]**

Me-too	*Generic*
TGP and WAMTC molecules	
Amlodipine Besylate	Captopril
Atorvastatin Calcium	Nifedipine
Enalapril Maleate	Ranitidine Hydrochloride
Famotidine	
Felodipine	
Fosinopril Sodium	
Lisinopril	
Nizatidine	
Perindopril Erbumine	
Pravastatin Sodium	
Quinapril Hydrochloride	
Ramipril	
Simvastatin	
Trandolapril	
Additional WAMTC molecules	
Candesartan Cilexetil[b]	Diltiazem Hydrochloride
Citalopram Hydrobromide	Fluoxetine Hydrochloride
Fluvastatin Sodium[c]	Moclobemide
Irbesartan[b]	Omeprazole
Lansoprazole	
Omeprazole Magnesium	
Pantoprazole Sodium Sesquithydrate	
Paroxetine Hydrochloride	
Sertraline Hydrochloride	
Venlafaxine Hydrochloride	

a Selective Serotonin Reuptake Inhibitors (SSRIs) molecules (*citalopram hydrochloride, fluoxetine hydrochloride, paroxetine hydrochloride, and sertratine hydrochloride*) are included within the WAMTC group because earlier price reviews could have affected their price. **b** Prices are not directly subject to WAMTC reviews but are affected indirectly through price links to *enalapril maleate*. **c** Price is not directly subject to WAMTC reviews but is indirectly through price links to *simvastatin*.

Source: DHAC.

Classification of molecules

The top 150 molecules included in the price comparison were categorised by DHAC, and are presented in table D.3.

Table D.3 **Molecule classification**

New innovative	*Me-too*	*Generic*
Alendronate Sodium	Amlodipine Besylate	Aciclovir
Alprostadil	Atorvastatin Calcium	Allopurinol
Carvedilol	Budesonide	Amiodarone Hydrochloride
Ciprofloxacin	Candesartan Cilexetil	Amoxycillin
Cisapride	Ceftriaxone	Amoxycillin with Clavulanic Acid
Clopidogrel Hydrogen Sulfate	Citalopram Hydrobromide	Aspirin
Clozapine	Docetaxel	Atenolol
Cyclosporin	Eformoterol Fumarate Dihydrate	Azathioprine
Disodium Pamidronate	Enalapril Maleate	Beclomethasone Dipropionate
Epoetin Alfa	Famciclovir	Betamethasone Dipropionate
Filgrastim	Famotidine	Betamethasone Valerate
Insulin Lispro	Felodipine	Calcitriol
Interferon Alfa-2b	Fluticasone	Calcium
Latanoprost	Fluticasone Propionate	Captopril
Leflunomide	Fluvastatin Sodium	Carbamazepine
Mycophenolate Mofetil	Follitropin Alfa	Cefaclor
Olanzapine	Follitropin Beta	Cephalexin
Ribavirin And Interferon Alfa-2b	Fosinopril Sodium	Chloramphenicol
Risperidone	Gabapentin	Codeine Phosphate with Paracetamol
Rituximab	Goserelin Acetate	Cyproterone Acetate
Terbinafine Hydrochloride	Interferon Beta-1a	Desferrioxamine Mesylate
	Interferon Beta-1b	Diazepam
	Irbesartan	Diclofenac Sodium
	Ketoprofen	Diltiazem Hydrochloride
	Lamivudine	Dothiepin Hydrochloride
	Lamivudine With Zidovudine	Doxycycline
	Lamotrigine	Erythromycin Ethyl Succinate
	Lansoprazole	Flucloxacillin
	Leuprorelin Acetate	Fluoxetine Hydrochloride
	Lisinopril	Frusemide
	Mesalazine	Gemfibrozil
	Mometasone Furoate	Gliclazide
	Nizatidine	Glucose Indicator-Blood
	Oestrogens-Conjugated	Glyceryl Trinitrate
	Omeprazole Magnesium	Hypromellose with Dextran
	Pantoprazole Sodium Sesquihydrate	Indapamide Hemihydrate
	Paroxetine Hydrochloride	Influenza Vaccine
	Perindopril Erbumine	Insulin Isophane (N.P.H.)
	Pravastatin Sodium	Insulin Neutral
	Quinapril Hydrochloride	Insulin Neutral-Insulin Isophane (N.P.H.), (Mixed) (Biphasic Isophane)
	Ramipril	Ipratropium Bromide
	Roxithromycin	Isosorbide Mononitrate
	Salmeterol Xinafoate	Isotretinoin
	Sertraline Hydrochloride	Levodopa with Carbidopa
	Simvastatin	Levonorgestrel with Ethinyloestradiol
	Stavudine	Medroxyprogesterone Acetate
	Trandolapril	Metformin Hydrochloride
	Valaciclovir Hydrochloride	Metoprolol Tartrate
	Venlafaxine Hydrochloride	Minocycline

(Continued on next page)

Table D.3 (continued)

New innovative	*Me-too*	*Generic*
		Moclobemide
		Morphine Sulfate
		Naproxen
		Nifedipine
		Norethisterone
		Oestradiol
		Oestrogens-Conjugated And
		Medroxyprogesterone Acetate
		Omeprazole
		Oxazepam
		Paclitaxel
		Paracetamol
		Phenoxymethylpenicillin
		Piroxicam
		Pneumococcal Vaccine, Polyvalent
		Prazosin Hydrochloride
		Prednisolone
		Prochlorperazine
		Ranitidine Hydrochloride
		Salbutamol Sulfate
		Sodium Cromoglycate
		Sodium Valproate
		Somatropin (Recombinant Human Growth Hormone)
		Sotalol Hydrochloride
		Sulfasalazine
		Tamoxifen Citrate
		Temazepam
		Terbutaline Sulfate
		Timolol Maleate
		Trimethoprim with Sulfamethoxazole
		Verapamil Hydrochloride
		Warfarin Sodium

Source: DHAC.

D.4 United States

Pharmaceutical prices were obtained from the publicly available Federal Supply Schedule (FSS) in the US. The FSS is a catalogue of manufacturer prices containing over 17 000 pharmaceutical products available to federal agencies and institutions. The FSS is administered by the Department of Veterans Affairs. Prices were obtained from the FSS in November 2000.

D.5 United Kingdom

Pharmaceutical prices were obtained from the *Chemist and Druggist Monthly Price List*. Prices are reported at the manufacturer level. Prices reported are the maximum (list) price received by manufacturers. Prices obtained are at July 2000 (CD 2000a; 2000b).

Pharmaceutical prices also were obtained from the *Prescription Cost Analysis.* Prices are reported at the wholesale level. Prices are reported before any discounts and, therefore, can be considered list or the maximum prices received by manufacturers. Prices are at September 1999 (DoH 2001).

D.6 Canada

Pharmaceutical prices for Ontario were obtained from the *Ontario Drug Benefit Formulary/Comparative Drug Index* (no. 36) supplemented with relevant updates (Ministry of Health and Long–Term Care 1998). Prices are at the manufacturer level for April 2000.

Prices for British Columbia were obtained from the *Pharmacare Low Cost Alternative Reference Drug Program Booklet*. These prices are for March 2001 (Pharmacare 2001b).

D.7 New Zealand

Pharmaceutical prices were obtained from the publicly available *New Zealand Pharmaceutical Schedule*, published by Pharmac. Prices are reported at the manufacturer level, and represent the price negotiated between Pharmac and pharmaceutical companies. Prices are those effective from April to June 2000 (Pharmac 2000a).

D.8 France

Pharmaceutical prices were obtained from the National Health Insurance Fund (Caisse Nationale d'Assurance Maladie (CNAM)). Prices are at the manufacturer level for September 2000.

D.9 Sweden

Pharmaceutical prices were obtained from the Riksförsäkringsverket (RFV; National Social Insurance Board). The RFV sets a reimbursement price for each pharmaceutical (based on information supplied by the companies). Prices obtained were at the wholesale (pharmacy buying) level. A wholesaler margin was deducted to obtain an estimate of manufacturer prices. Prices are for November 2000.

D.10 Case study

Pricing information was provided by GlaxoSmithKline Australia Limited (GSK) for three particular brands of the following pharmaceuticals: *ranitidine* (Zantac); *paroxetine* (Aropax); and *salmeterol* (Serevent). The information provided by GSK is summarised in the following tables.

Table D.4 **Ranitidine hydrochloride (Zantac) 150mg tablets, pack of 60[a,b]**

	Australia	*US*	*Canada*	*Sweden*	*Spain*
Launch date	Apr '82	na	Nov '82	Aug '83	Oct '82
Launch price	42.60	na	37.40	46.01	44.37
Launch ER[c]	1.00	na	1.25	6.91	111.43
May 1983 price	41.93	75.57[d]	52.74	49.87	44.37
1982-83 ER	1.00	1.01	1.25	6.37	111.43
June 2000 price	16.42	144.97[e]	71.35	35.75	35.30

a Prices reported in this table are expressed in Australian Dollars. **b** The FSS price of *rantidine* was A$115.25 at November 2000, representing a 21 per cent discount. In contrast, the cheapest generic price for *rantidine* in the US was A$3.02. *Ranitidine* was reimbursed on the PBS in August 1984 at a price of $34. **c** The market launch exchange rate (ER) is the average exchange rate for the financial year (ending 30 June) within which the pharmaceutical was launched. **d** The January 1993 price was used. **e** The November 2000 price was used. **na** Not available.

Data sources: ABS (2000b); DHAC (pers. comm., 25 June 2001); EconData (1999); GSK (pers. comm., 20 June 2001).

Table D.5 **Paroxetine hydrochloride (Aropax) 20mg tablets, pack of 30[a,b]**

	Australia	*US*	*Canada*	*UK*	*Sweden*	*NZ*
Launch date	Nov '93	Jan '93	May '93	Feb '91	May '93	Aug '92
Launch price	50.03[f]	59.54	53.73	77.11	63.43	41.91
Launch ER[c]	1.00	0.73	0.89	0.44	4.28	1.37
May 1993 price	50.03	59.54[d]	53.73	81.01	63.43	41.91
1992-93 ER	1.00	0.73	0.89	0.42	4.28	1.37
June 2000 price	27.58	100.48[e]	51.57	45.03	50.69	28.07

a Prices reported in this table are expressed in Australian Dollars. **b** The FSS price of *paroxetine* was A$54 at November 2000, representing a 46 per cent discount. *Paroxetine* was reimbursed on the PBS in August 1994 at a price of $49.93. **c** The market launch exchange rate (ER) is the average exchange rate for the financial year (ending 30 June) within which the pharmaceutical was launched. **d** The May 1993 US price was unavailable but has been estimated using the launch price. **e** The November 2000 price was used. **f** The launch price at November 1993 was used as the price as for May 1993.

Data sources: ABS (2000b); DHAC (pers. comm., 25 June 2001); EconData (1999); GSK (pers. comm., 20 June 2001).

Table D.6 **Salmeterol Xinafoate (Serevent) oral pressurised inhaler, 25 mic/dose, 120 doses[a,b]**

	Australia	*US*	*France*	*Spain*
Launch date	Jun '93	Mar '94	Aug '94	Sep '92
Launch price	41.90	58.76	42.88	49.97
Launch ER[c]	1.00	0.68	4.06	75.19
Dec 1994 price	41.90	57.34	42.88	36.75
1994-95 ER	1.00	0.73	4.06	97.94
June 2000 price	26.94	92.01	36.11	38.47

a Prices reported in this table are expressed in Australian Dollars. **b** The FSS price of *salmeterol* was A$68 at November 2000, representing a 26 per cent discount. *Salmeterol* was reimbursed on the PBS in February 1995 at a price of $37. **c** The market launch exchange rate (ER) is the average exchange rate for the financial year (ending 30 June) within which the pharmaceutical was launched.

Data sources: ABS (2000b); DHAC (pers. comm., 25 June 2001); EconData (1999); GSK (pers. comm., 20 June 2001).

E Results in detail

This appendix provides further detail on the results presented in chapter 3 of the report. It includes:

- an analysis of matching results;
- list price comparisons;
- diagnostic tests;
- price comparisons with the Federal Supply Schedule (FSS);
- information on the difference between higher and lower estimates;
- price comparisons by therapeutic group; and
- data on molecule age and launch delay.

E.1 Analysis of matching results

Table E.1 shows the numbers of no-matches, direct matches and adjusted matches achieved for each comparison country using the form matching procedure (outlined in appendix C).

The number of no-matches exceeded the combined number of direct and adjusted matches for all the comparison countries except the United Kingdom (UK). For most countries, the form matching approach resulted in a relatively high number of no-matches for dosage type (NMF). Three Anatomical Therapeutic Chemical (ATC) groups were responsible, on average, for around half of the no-matches for dosage type. The largest single contributor was pharmaceuticals acting on the respiratory system. The other leading groups included the genito urinary system and sex hormones, and antineoplastic and immunomodulating agents.

Some countries scored a relatively high number of no-matches for pack size (NMPS) and strength (NMS). The ATC groups relating to the nervous system, the cardiovascular system, and general anti-infectives for systemic use, on average, accounted for about half of the no-matches on pack size. The same three groups accounted for approximately 45 per cent of the no-matches for strength. All countries scored a relatively low number of no-matches for molecule (NMM) except for Sweden.

Table E.1 **Matching results, all categories**

Code[a]	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
No matches							
NMM	21	30	22	172	58	55	42
NMS	56	64	103	28	113	96	45
NMF	179	161	86	134	124	115	156
NMPS	55	87	47	63	113	114	75
Total	311	342	258	397	408	380	318
Direct matches							
DM	99	107	116	71	70	70	216
DMWAP	11	8	17	0	3	6	1
DMUL	54	49	64	51	35	49	23
Total	164	164	197	122	108	125	240
Adjusted matches							
PSL	14	7	45	19	29	23	12
PSLWAP	0	0	6	0	8	16	0
PSLUL	7	8	34	8	10	36	3
PSUL	53	16	20	32	16	1	4
PSULWAP	3	7	5	0	1	1	2
PSULMM	32	40	19	6	4	2	5
Total	109	78	129	65	68	79	26
Total matches[b]	273	242	326	187	176	204	266

[a] Table E.2 contains abbreviated descriptions for these codes. [b] Sum of direct and adjusted matches.

Source: PC estimates.

The level of matching varied between the comparison countries, with the UK achieving the highest number of matches (326) whereas France achieved the lowest (176). For all countries, the number of direct matches exceeded the number of adjusted matches. Direct matches using the same price (DM) and direct matches using two prices for upper and lower estimates (DMUL) accounted for most of the direct matches. There were relatively few direct matches using a weighted average price (DMWAP) as cost considerations limited the amount of volume data that could be obtained for the comparison countries.

PSL and PSUL matches, on average, accounted for about half of the total number of adjusted matches. These two types of matches relate to pharmaceuticals produced by one manufacturer. There was only a small number of adjusted matches using weighted average prices (PSLWAP and PSULWAP) for the reason mentioned above. The relatively high number of PSULMM matches obtained for the United States (US), Canada and the UK indicates a stronger presence of multiple manufacturers producing various pack sizes than in the other countries.

Table E.2 **Matching codes**[a]

Code	*Short description*
NMM	No match molecule
NMS	No match strength
NMF	No match form (dosage type)
NMPS	No match pack size
DM	Direct match
DMWAP	Direct match weighted average price
DMUL	Direct match upper lower
PSL	Pack size linear
PSLWAP	Pack size linear weighted average price
PSLUL	Pack size linear upper lower
PSUL	Pack size upper lower
PSULWAP	Pack size upper lower weighted average price
PSULMM	Pack size upper lower multiple manufacturer

[a] See table C.1 (appendix C) for a full explanation of these codes.

E.2 List price comparisons

This section reports the results of price comparisons under different exchange rates and price weights. The same qualifications applying to the results, as described in chapter 3 of the report, also apply to these price comparisons.

Exchange rates used in the price comparisons

A number of different average exchange rate periods were used to test the sensitivity of the results to fluctuations in official exchange rates during the 24 months to June 2000 (table E.3). In addition, price comparisons also were undertaken using purchasing power parity exchange rates.

Table E.3 **Average exchange rates and purchasing power parities**[a]

$1A=	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
June 2000	0.5941	0.8756	0.3929	5.1985	4.1062	104.0875	1.2615
30 June 2000	0.6023	0.8907	0.3961	5.3195	4.1515	105.3050	1.2817
Three months to June 2000	0.5907	0.8716	0.3844	5.2216	4.1452	105.1221	1.2300
1999-2000	0.6296	0.9250	0.3944	5.3516	4.1214	104.5377	1.2474
1998-99 to 1999-2000	0.6273	0.9338	0.3876	5.2074	3.9020	98.9498	1.2143
PPP[b]	0.7634	0.8969	0.5031	7.3855	5.0382	100.0000	1.1221

[a] Each exchange rate is calculated as the average of the buying and selling rate for that period. Each rate has been rounded to four decimal places. [b] Represents the average PPP for GDP for the calendar years 1999 and 2000.

Sources: ABS (2000b); The Age (2000); OECD (2001).

The sensitivity analysis reported in this appendix (summarised in chapter 3) shows that the results of the price comparison are not sensitive to the different official exchange rates. However, purchasing power parity exchange rates for the seven countries differ significantly from their official exchange rates in the US, the UK, Sweden, France and NZ. This reflects different relative price levels for non-traded goods and services in these countries compared to Australia.

List price comparisons

Tables E.4 to E.23 provide the list price comparisons, with prices weighted by Australian sales volumes and the number of PBS scripts for the five different exchange rates.

Average exchange rate for June 2000

The price comparisons weighted by the volume of Australian sales differed little from those weighted by the number of PBS scripts. For some countries, the price ratios are slightly higher for certain categories while in other instances they are lower. The small differences in the price comparisons in part reflects the high level of correlation (0.90) between the volume of Australian sales and number of PBS scripts for each form.

Table E.4 **Price ratios for all categories, list prices**
Average exchange rate for June 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	3.48	1.81	1.64	1.57	1.17	1.02	0.98
lower est.	1.00	2.62	1.51	1.48	1.48	1.12	0.96	0.92
PBS volumes								
higher est.	1.00	3.44	1.82	1.64	1.56	1.17	1.04	0.97
lower est.	1.00	2.61	1.54	1.50	1.47	1.12	0.98	0.92

Source: PC estimates.

Table E.5 **Price ratios for new innovative, list prices**

Average exchange rate for June 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	2.17	1.09	1.26	1.17	0.92	0.85	1.00
lower est.	1.00	2.04	1.09	1.25	1.10	0.92	0.85	1.00
PBS volumes								
higher est.	1.00	2.17	1.09	1.27	1.17	0.92	0.85	1.00
lower est.	1.00	2.07	1.08	1.27	1.10	0.92	0.85	1.00

Source: PC estimates.

Table E.6 **Price ratios for me-too, list prices**

Average exchange rate for June 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	2.99	1.71	1.64	1.65	1.18	1.08	1.01
lower est.	1.00	2.85	1.59	1.57	1.58	1.18	1.02	0.97
PBS volumes								
higher est.	1.00	2.94	1.70	1.64	1.64	1.17	1.08	1.02
lower est.	1.00	2.80	1.61	1.58	1.58	1.17	1.03	0.98

Source: PC estimates.

Table E.7 **Price ratios for generics, list prices**

Average exchange rate for June 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	4.63	2.15	1.77	1.65	1.28	0.97	0.92
lower est.	1.00	2.53	1.51	1.41	1.49	1.10	0.89	0.83
PBS volumes								
higher est.	1.00	4.65	2.24	1.79	1.63	1.27	1.00	0.89
lower est.	1.00	2.52	1.58	1.44	1.48	1.10	0.92	0.81

Source: PC estimates.

Average exchange rate for 30 June 2000

Compared to using the average exchange rate for June 2000, the price ratios decrease for all countries using the average exchange rate for 30 June 2000. For all countries except Sweden, the extent of the decrease is less than two per cent.

Table E.8 **Price ratios for all categories, list prices**

Average exchange rate for 30 June 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	3.43	1.78	1.62	1.54	1.16	1.01	0.96
lower est.	1.00	2.59	1.48	1.47	1.44	1.11	0.95	0.91
PBS volumes								
higher est.	1.00	3.39	1.79	1.63	1.53	1.15	1.02	0.96
lower est.	1.00	2.58	1.51	1.49	1.44	1.11	0.97	0.91

Source: PC estimates.

Table E.9 **Price ratios for new innovative, list prices**

Average exchange rate for 30 June 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	2.14	1.08	1.25	1.14	0.91	0.84	0.98
lower est.	1.00	2.01	1.07	1.24	1.07	0.91	0.84	0.98
PBS volumes								
higher est.	1.00	2.14	1.07	1.26	1.14	0.91	0.84	0.99
lower est.	1.00	2.04	1.06	1.26	1.08	0.91	0.84	0.99

Source: PC estimates.

Table E.10 **Price ratios for me-too, list prices**

Average exchange rate for 30 June 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	2.95	1.68	1.63	1.61	1.17	1.07	0.99
lower est.	1.00	2.82	1.57	1.56	1.55	1.17	1.01	0.96
PBS volumes								
higher est.	1.00	2.90	1.67	1.63	1.61	1.16	1.07	1.00
lower est.	1.00	2.77	1.58	1.57	1.54	1.16	1.02	0.97

Source: PC estimates.

Table E.11 **Price ratios for generics, list prices**

Average exchange rate for 30 June 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	4.57	2.12	1.76	1.61	1.27	0.95	0.90
lower est.	1.00	2.49	1.49	1.40	1.46	1.08	0.88	0.81
PBS volumes								
higher est.	1.00	4.59	2.20	1.78	1.60	1.26	0.99	0.88
lower est.	1.00	2.49	1.55	1.43	1.45	1.09	0.91	0.79

Source: PC estimates.

Average exchange rate for three months to June 2000

Compared to using the average exchange rate for June 2000, the price ratios increase for all countries except Sweden, France and Spain using the average exchange rate for the three months to June 2000. The price ratios increase by 2.6 per cent for NZ and by less than one per cent for the US and Canada, while they decrease by around one per cent or less for Spain, France and Sweden.

Table E.12 **Price ratios for all categories, list prices**

Average exchange rate for three months to June 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
Higher est.	1.00	3.50	1.82	1.67	1.57	1.16	1.01	1.00
Lower est.	1.00	2.64	1.51	1.51	1.47	1.11	0.95	0.95
PBS volumes								
higher est.	1.00	3.46	1.83	1.68	1.56	1.15	1.03	1.00
lower est.	1.00	2.63	1.54	1.54	1.46	1.11	0.97	0.95

Source: PC estimates.

Table E.13 **Price ratios for new innovative, list prices**

Average exchange rate for three months to June 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	2.18	1.10	1.28	1.16	0.91	0.84	1.02
lower est.	1.00	2.05	1.09	1.28	1.09	0.91	0.84	1.02
PBS volumes								
higher est.	1.00	2.19	1.09	1.30	1.16	0.91	0.85	1.03
lower est.	1.00	2.08	1.08	1.30	1.10	0.91	0.85	1.03

Source: PC estimates.

Table E.14 **Price ratios for me-too, list prices**

Average exchange rate for three months to June 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	3.01	1.72	1.67	1.64	1.17	1.07	1.04
lower est.	1.00	2.87	1.60	1.60	1.57	1.17	1.01	1.00
PBS volumes								
higher est.	1.00	2.95	1.71	1.68	1.64	1.16	1.07	1.04
lower est.	1.00	2.82	1.61	1.61	1.57	1.16	1.02	1.01

Source: PC estimates.

Table E.15 **Price ratios for generics, list prices**

Average exchange rate for three months to June 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	4.66	2.16	1.81	1.64	1.27	0.96	0.94
lower est.	1.00	2.54	1.52	1.44	1.48	1.09	0.88	0.85
PBS volumes								
higher est.	1.00	4.68	2.25	1.83	1.62	1.26	0.99	0.91
lower est.	1.00	2.54	1.58	1.47	1.47	1.09	0.91	0.83

Source: PC estimates.

Average exchange rate for financial year 1999-2000

Compared to using the average exchange rate for June 2000, the price ratios decrease for all countries except NZ using the average exchange rate for the financial year 1999-2000. The price ratios decrease by around five to six per cent

for the US and Canada, while they change by less than three per cent for the other countries.

Table E.16 **Price ratios for all categories, list prices**

Average exchange rate for 1999-2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	3.28	1.71	1.63	1.53	1.17	1.02	0.99
lower est.	1.00	2.48	1.43	1.48	1.43	1.12	0.96	0.93
PBS volumes								
higher est.	1.00	3.24	1.72	1.64	1.52	1.16	1.03	0.98
lower est.	1.00	2.46	1.45	1.50	1.43	1.12	0.98	0.93

Source: PC estimates.

Table E.17 **Price ratios for new innovative, list prices**

Average exchange rate for 1999-2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	2.04	1.04	1.25	1.13	0.92	0.85	1.01
lower est.	1.00	1.93	1.03	1.25	1.07	0.92	0.85	1.01
PBS volumes								
higher est.	1.00	2.05	1.03	1.27	1.14	0.92	0.85	1.02
lower est.	1.00	1.95	1.02	1.26	1.07	0.92	0.85	1.02

Source: PC estimates.

Table E.18 **Price ratios for me-too, list prices**

Average exchange rate for 1999-2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	2.83	1.62	1.63	1.60	1.18	1.08	1.02
lower est.	1.00	2.70	1.51	1.56	1.54	1.17	1.02	0.98
PBS volumes								
higher est.	1.00	2.77	1.61	1.64	1.60	1.17	1.08	1.03
lower est.	1.00	2.65	1.52	1.57	1.53	1.17	1.02	0.99

Source: PC estimates.

Table E.19 **Price ratios for generics, list prices**

Average exchange rate for 1999-2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	4.37	2.04	1.76	1.60	1.28	0.96	0.93
lower est.	1.00	2.39	1.43	1.40	1.45	1.09	0.88	0.84
PBS volumes								
higher est.	1.00	4.40	2.12	1.78	1.59	1.27	0.99	0.90
lower est.	1.00	2.39	1.50	1.44	1.44	1.09	0.92	0.81

Source: PC estimates.

Average exchange rate for financial years 1998-99 and 1999-2000

Compared to using the average exchange rate for June 2000, the price ratios increase for four countries and decrease for the remaining countries. Price ratios increase by about five per cent for France and Spain whereas prices decrease by around five to six per cent in Canada and the US.

Table E.20 **Price ratios for all categories, list prices**

Average exchange rate for 1998-99 and 1999-2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	3.30	1.70	1.66	1.57	1.23	1.08	1.01
lower est.	1.00	2.48	1.41	1.50	1.47	1.18	1.01	0.96
PBS volumes								
higher est.	1.00	3.26	1.71	1.67	1.56	1.23	1.09	1.01
lower est.	1.00	2.47	1.44	1.52	1.47	1.18	1.03	0.96

Source: PC estimates.

Table E.21 **Price ratios for new innovative, list prices**

Average exchange rate for 1998-99 and 1999-2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	2.05	1.03	1.27	1.17	0.97	0.90	1.04
lower est.	1.00	1.93	1.02	1.27	1.10	0.97	0.90	1.04
PBS volumes								
higher est.	1.00	2.06	1.02	1.29	1.17	0.97	0.90	1.04
lower est.	1.00	1.96	1.01	1.29	1.10	0.97	0.90	1.04

Source: PC estimates.

Table E.22 **Price ratios for me-too, list prices**

Average exchange rate for 1998-99 and 1999-2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	2.84	1.61	1.66	1.64	1.24	1.14	1.05
lower est.	1.00	2.71	1.50	1.59	1.58	1.24	1.08	1.01
PBS volumes								
higher est.	1.00	2.78	1.60	1.66	1.64	1.23	1.14	1.06
lower est.	1.00	2.66	1.51	1.60	1.57	1.23	1.08	1.02

Source: PC estimates.

Table E.23 **Price ratios for generics, list prices**

Average exchange rate for 1998-99 and 1999-2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	4.39	2.02	1.79	1.65	1.35	1.02	0.95
lower est.	1.00	2.40	1.42	1.43	1.49	1.15	0.93	0.86
PBS volumes								
higher est.	1.00	4.41	2.10	1.82	1.63	1.34	1.05	0.92
lower est.	1.00	2.40	1.48	1.46	1.48	1.16	0.97	0.84

Source: PC estimates.

Purchasing power parity for GDP, average for 1999 and 2000

Compared to using the average exchange rate for June 2000, the price ratios change significantly for most countries using the purchasing power parity exchange rate. The price ratios decrease for the US, Canada, the UK, Sweden and France. For the US, the UK and Sweden, the price ratios fall by around 22 to 30 per cent. The price ratios rise for NZ (12 per cent) and Spain (four per cent).

Table E.24 **Price ratios for all categories, list prices**

Average purchasing power parity for GDP, 1999 and 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	2.71	1.77	1.28	1.11	0.95	1.07	1.10
lower est.	1.00	2.04	1.47	1.16	1.04	0.91	1.00	1.04
PBS volumes								
higher est.	1.00	2.68	1.78	1.28	1.10	0.95	1.08	1.09
lower est.	1.00	2.03	1.50	1.17	1.03	0.91	1.02	1.04

Source: PC estimates.

Table E.25 **Price ratios for new innovative, list prices**

Average purchasing power parity for GDP, 1999 and 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	1.69	1.07	0.98	0.82	0.75	0.89	1.12
lower est.	1.00	1.59	1.06	0.98	0.77	0.75	0.89	1.12
PBS volumes								
higher est.	1.00	1.69	1.06	0.99	0.82	0.75	0.89	1.13
lower est.	1.00	1.61	1.05	0.99	0.78	0.75	0.89	1.13

Source: PC estimates.

Table E.26 **Price ratios for me-too, list prices**

Average purchasing power parity for GDP, 1999 and 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	2.35	1.67	1.30	1.18	0.97	1.13	1.13
lower est.	1.00	2.24	1.56	1.24	1.13	0.97	1.06	1.09
PBS volumes								
higher est.	1.00	2.30	1.66	1.30	1.18	0.96	1.13	1.14
lower est.	1.00	2.20	1.57	1.25	1.13	0.96	1.07	1.10

Source: PC estimates.

Table E.27 **Price ratios for generics, list prices**

Average purchasing power parity for GDP, 1999 and 2000

	Aust	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
IMS volumes								
higher est.	1.00	3.63	2.10	1.39	1.18	1.05	1.00	1.03
lower est.	1.00	1.99	1.48	1.11	1.07	0.89	0.92	0.93
PBS volumes								
higher est.	1.00	3.65	2.19	1.41	1.17	1.04	1.04	1.00
lower est.	1.00	1.99	1.54	1.13	1.06	0.89	0.96	0.90

Source: PC estimates.

E.3 Diagnostic tests

The price comparisons reported in chapter 3 have been examined on an unweighted basis using a number of diagnostic tests.

Z-statistics have been computed in order to test whether price differences between Australia and each of the comparison countries are statistically significant. Critical values for the z-statistic are ±1.96 and ±2.58 at the five and one per cent levels of significance respectively. If a computed z-statistic lies in the chosen critical region, this provides grounds for rejecting the null hypothesis that prices for the selected PBS-listed items are generally the same in Australia and a given comparison country. In such a case, the alternative hypothesis that price levels are different between the two countries is accepted and, therefore, it can be concluded that the price differences are statistically significant.

The z-statistic used for testing the null hypothesis requires that the 'populations' of prices from which the samples are drawn follow a normal distribution (or that the sample sizes are at least 30) and that the samples are randomly and independently drawn. These requirements are meant to ensure that the samples also are approximately normally distributed. As outlined in appendix C, the Australian sample of pharmaceuticals was chosen according to specific criteria (that is, PBS-listing and PBS expenditure ranking) which, together with the form matching procedure, determined the samples for the comparison countries. This means that the samples were neither randomly or independently selected and, in some cases, sample sizes were less than 30.

The Shapiro-Wilk test (also known as the w-statistic) has been used to assess whether the price ratios derived from the samples are normally distributed. For ease of interpretation, the following tables present the probability associated with the

w-statistic (rather than the statistic itself). This probability is compared against the chosen level of significance. If the probability is less than the level of significance, the null hypothesis of normality is rejected and it can be concluded that the price ratios do not come from a normal distribution.

Kurtosis and skewness indexes also have been computed to examine the characteristics of the price ratio distributions relative to those of a normal distribution. (A normal distribution is symmetric about its mean value with a bell-shaped frequency curve or distribution of values.)

The kurtosis index measures the peakedness or flatness of a distribution compared to that of a normal distribution. A positive value for this index indicates a peaked distribution relative to the normal distribution whereas a negative value indicates a flatter distribution. The skewness index measures the degree of asymmetry of a distribution. A positive value for this index indicates a distribution with a longer tail extending to the right whereas a negative value indicates a distribution with a longer tail extending to the left. The closer the kurtosis and skewness indexes are to zero, the closer a given distribution of price ratios approximates those of a normal distribution.

For these diagnostic tests, unweighted price ratios were calculated for each comparison country relative to Australia. That is, prices were not weighted by their Australian expenditure. For each pharmaceutical category, the number of price ratios for each comparison country was equivalent to the number of bilateral matches achieved with Australia. Price ratios were computed for both higher and lower estimates of prices. The diagnostic tests were then applied to each price ratio series.

All categories

For all categories, the computed z-statistics indicate that the price differences with Australia are statistically significant for all comparison countries except NZ (table E.28). In the case of NZ, at the five per cent level of significance, the null hypothesis is rejected for the price ratios based on the higher estimate of prices and accepted for the price ratios based on the lower estimate of prices. The null hypothesis is accepted at the one per cent level for the price ratio series based on the higher and lower estimates of prices.

Table E.28 **Diagnostic tests, all categories of pharmaceuticals**

Diagnostic	*Estimate*	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
Z-statistic	Higher	13.00	11.64	11.30	7.92	4.08	-3.31	2.13
	Lower	10.43	8.12	10.39	7.94	2.86	-5.46	0.27
P(w)[a]	Higher	0.01	0.01	0.01	0.01	0.01	0.01	0.01
	Lower	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Kurtosis	Higher	10.87	5.36	19.47	33.16	10.75	0.28	12.46
	Lower	9.12	10.70	8.19	17.18	3.95	0.53	14.33
Skewness	Higher	2.77	2.06	3.52	4.72	2.68	0.60	2.51
	Lower	2.53	2.79	2.25	3.12	1.60	0.71	2.45

a Probability of the w-statistic in percentage terms.

Source: PC estimates.

Based on the probability of the w-statistic, the null hypothesis of normality is rejected for all comparison countries using the five or one per cent level of significance. The price ratio distributions exhibit a very high degree of positive kurtosis and skewness for all the comparison countries except Spain. Using the lower estimate of prices, the price ratio distributions for Spain are nearest to those of a normal distribution whereas those for Sweden exhibit the highest positive kurtosis and skewness.

New innovative pharmaceuticals

For new innovative pharmaceuticals, the test statistics indicate that price differences with Australia are statistically significant for the US, the UK and Spain (table E.29). In the case of Sweden, the null hypothesis is rejected for higher and lower estimates at the five cent level of significance but is accepted for the lower estimate at the one per cent level. For NZ and Canada, the null hypothesis that prices for the selected PBS items are generally the same as in Australia is accepted at both levels of significance. In the case of France, the null hypothesis is rejected at the five per cent level but accepted at the one per cent level.

Table E.29 **Diagnostic tests, new innovative pharmaceuticals**

Diagnostic	*Estimate*	*US*	*Canada*[a]	*UK*	*Sweden*	*France*[a]	*Spain*[a]	*NZ*[a]
Z-statistic	Higher	7.59	1.94	2.97	3.43	-2.10	-4.94	-0.55
	Lower	6.72	1.85	2.86	2.47	-2.29	-4.88	-0.55
P(w)[b]	Higher	1.69	0.01	0.34	50.42	27.34	1.68	1.12
	Lower	0.88	0.01	0.61	7.16	25.13	3.14	1.12
Kurtosis	Higher	0.14	4.71	3.42	0.84	0.83	-1.13	1.89
	Lower	0.55	4.65	3.28	1.66	1.10	-1.11	1.89
Skewness	Higher	0.86	1.93	1.36	0.02	-0.44	-0.18	-0.71
	Lower	1.01	1.93	1.32	0.39	-0.49	-0.23	-0.71

a Because the sample was less than 30, the t-statistic was computed and compared to the relevant critical values based on the t-distribution. **b** Probability of the w-statistic in percentage terms.

Source: PC estimates.

The results of the normality test are sensitive to the level of significance chosen. The null hypothesis of normality is rejected for most comparison countries using the five per cent level but is accepted in most cases using the one per cent level. Compared to all categories, the price ratio distributions for most countries exhibit a much lower degree of kurtosis and skewness. The price ratios for Spain exhibit some negative kurtosis and those for NZ, France and Spain exhibit slight negative skewness. That said, the price ratio distributions for new innovative items are generally more normal that those for the other categories.

Me-too pharmaceuticals

For me-too pharmaceuticals, price differences with Australia are not statistically significant for NZ and Spain (table E.30). For these two countries, the null hypothesis is accepted at both levels of significance.

Table E.30 **Diagnostic tests, me-too pharmaceuticals**

Diagnostic	*Estimate*	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
Z-statistic	Higher	9.29	7.64	8.45	7.33	4.23	1.11	0.63
	Lower	9.15	9.01	9.30	6.55	4.21	0.00	-0.25
P(w)[a]	Higher	0.01	0.01	0.01	0.01	0.19	14.53	0.01
	Lower	0.01	12.12	0.01	0.01	0.15	30.49	0.01
Kurtosis	Higher	1.23	7.70	9.90	0.35	1.78	-0.27	3.90
	Lower	1.37	0.80	11.52	0.58	1.81	-0.27	3.42
Skewness	Higher	1.34	2.17	2.60	0.99	1.03	0.07	1.33
	Lower	1.37	0.63	2.24	1.00	1.04	0.12	1.13

a Probability of the w-statistic in percentage terms.

Source: PC estimates.

The null hypothesis of normality is rejected for most comparison countries using the five and one per cent levels of significance. However, the null hypothesis is accepted for Spain and the lower estimate for Canada at both levels of significance. The price ratio distributions generally exhibit positive kurtosis (except for Spain) and positive skewness. Based on the lower estimate of prices, the price ratios for Spain are closest to those of a normal distribution whereas those for the UK exhibit the highest degree of positive kurtosis and skewness for this category.

Generic pharmaceuticals

For generic pharmaceuticals, the computed z-statistics indicate that price differences with Australia are statistically significant for most comparison countries (table E.31). However, based on the lower estimate of prices for NZ and France, the null hypothesis is accepted at both levels of significance. Based on the higher estimate of prices for NZ, the null hypothesis is rejected at the five per cent level but accepted at the one per cent level.

The null hypothesis of normality is clearly rejected for all comparison countries using both levels of significance. Compared to the new innovative and me-too categories, the price ratio distributions generally exhibit higher positive kurtosis and skewness. Based on the lower estimate of prices, the price ratios for Spain are closest to those of a normal distribution whereas those for Sweden exhibit the highest positive kurtosis and skewness.

Table E.31 **Diagnostic tests, generic pharmaceuticals**

Diagnostic	*Estimate*	*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
Z-statistic	Higher	10.91	10.06	8.11	5.17	2.77	-4.93	2.14
	Lower	6.43	5.78	6.18	5.19	1.05	-7.03	0.49
P(w)[a]	Higher	0.01	0.01	0.01	0.01	0.01	0.01	0.01
	Lower	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Kurtosis	Higher	6.43	2.98	16.67	22.06	7.45	1.36	9.35
	Lower	7.61	6.39	6.47	15.00	4.00	2.35	12.09
Skewness	Higher	2.16	1.59	3.35	4.17	2.46	0.90	2.28
	Lower	2.48	2.33	2.21	3.19	1.77	1.17	2.40

[a] Probability of the w-statistic in percentage terms.

Source: PC estimates.

As most of the price ratio series were found to be non-normally distributed, the results of hypothesis tests using z-statistics need to be interpreted with caution. Apart from the sampling approach adopted in this study, the use of simple ratios

(derived from those samples) may have contributed to the positive skewness and kurtosis detected above.

E.4 Price comparisons with Federal Supply Schedule

To examine the issue of prices paid by larger/institutional buyers in the US, prices contained in the FSS were compared to those obtained from IMS Health.

The approach adopted involved attempting to match forms from both the FSS and IMS Health sources, focusing on the top-selling molecules in each category (42 molecules and 101 forms in total), accounting for around 45 per cent of Australian manufacturer revenue. The molecules included in the comparison are listed in table E.32.

Table E.32 **Molecules included in price comparisons with FSS**

New innovative	*Me-too*	*Generic*
Alendronate Sodium	Amlodipine Besylate	Amoxycillin
Alprostadil	Atorvastatin Calcium	Atenolol
Ciprofloxacin	Enalapril Maleate	Calcitriol
Clozapine	Famotidine	Captopril
Epoetin Alfa	Felodipine	Cefaclor
Latanoprost	Fosinopril Sodium	Cephalexin
Leflunomide	Goserelin Acetate	Diclofenac Sodium
Mycophenolate Mofetil	Irbesartan	Diltiazem Hydrochloride
Olanzapine	Lansoprazole	Fluoxetine Hydrochloride
Risperidone	Lisinopril	Gemfibrozil
Rituximab	Paroxetine Hydrochloride	Isosorbide Mononitrate
Terbinafine Hydrochloride	Pravastatin Sodium	Medroxyprogesterone Acetate
	Quinapril Hydrochloride	Metformin Hydrochloride
	Sertraline Hydrochloride	Omeprazole
	Simvastatin	Ranitidine Hydrochloride
		Verapamil Hydrochloride

Source: PC.

From this sample, price comparisons with Australia were undertaken using FSS and IMS Health prices (tables E.33 to E.36). The percentage difference between the two sets of price ratios was then used to estimate discounts that larger/institutional buyers in the US can obtain off list prices. Note that the price ratios in tables E.33 to E.36 differ from those contained in E.4 to E.7. This occurs because they use different samples. That is, more forms are covered in tables E.4 to E.7 compared to E.33 to E.36.

Table E.33 **Price ratios, IMS Health and FSS prices, all categories**

Average exchange rate for June 2000

	Unit	*Aust. sales volumes*	*PBS scripts*
IMS Health prices			
higher estimate	ratio	3.27	3.22
lower estimate	ratio	2.66	2.68
FSS prices			
higher estimate	ratio	2.49	2.48
lower estimate	ratio	1.84	1.78
Estimated discount[a]			
higher estimate	%	24	23
lower estimate	%	31	33
No. of matches	no.	101	101
Coverage[b]	%	44	47

[a] The estimated discount represents the difference between IMS Health and FSS price ratios expressed as a percentage of the IMS Health price ratio. [b] Coverage shows the percentage of total Australian manufacturer revenue for the 150 molecules accounted for by the matched forms.

Source: PC estimates.

Table E.34 **Price ratios, IMS Health and FSS prices, new innovative**

Average exchange rate for June 2000

	Unit	*Aust. sales volumes*	*PBS scripts*
IMS Health prices			
higher estimate	ratio	2.07	2.04
lower estimate	ratio	1.91	1.92
FSS prices			
higher estimate	ratio	1.94	1.90
lower estimate	ratio	1.86	1.82
Estimated discount[a]			
higher estimate	%	6	7
lower estimate	%	3	5
No. of matches	no.	26	26
Coverage[b]	%	54	52

[a] The estimated discount represents the difference between IMS Health and FSS price ratios expressed as a percentage of the IMS Health price ratio. [b] Coverage shows the percentage of total Australian manufacturer revenue for new innovative molecules accounted for by the matched forms.

Source: PC estimates.

Table E.35 **Price ratios, IMS Health and FSS prices, me-too**

Average exchange rate for June 2000

	Unit	*Aust. sales volumes*	*PBS scripts*
IMS Health prices			
higher estimate	ratio	2.95	2.94
lower estimate	ratio	2.80	2.80
FSS prices			
higher estimate	ratio	1.94	1.94
lower estimate	ratio	1.70	1.71
Estimated discount[a]			
higher estimate	%	34	34
lower estimate	%	39	39
No. of matches	no.	33	33
Coverage[b]	%	52	54

a The estimated discount represents the difference between IMS Health and FSS price ratios expressed as a percentage of the IMS Health price ratio. **b** Coverage shows the percentage of total Australian manufacturer revenue for me-too molecules accounted for by the matched forms.

Source: PC estimates.

Table E.36 **Price ratios, IMS Health and FSS prices, generics**

Average exchange rate for June 2000

	Unit	*Aust. sales volumes*	*PBS scripts*
IMS Health prices			
higher estimate	ratio	4.62	4.37
lower estimate	ratio	2.73	2.75
FSS prices			
higher estimate	ratio	4.00	3.93
lower estimate	ratio	2.08	1.88
Estimated discount[a]			
higher estimate	%	14	10
lower estimate	%	24	32
No. of matches	no.	42	42
Coverage[b]	%	30	36

a The estimated discount represents the difference between IMS Health and FSS price ratios expressed as a percentage of the IMS Health price ratio. **b** Coverage shows the percentage of total Australian manufacturer revenue for generic molecules accounted for by the matched forms.

Source: PC estimates.

E.5 Difference between higher and lower estimates of prices

As discussed in chapter 3, higher and lower estimates of prices were reported in instances where there were multiple manufacturers of the same pharmaceutical, pack size differences with Australia or a combination of the two.

Table E.37 provides summary statistics on the percentage contribution each issue makes to the price range across countries for all categories.

Table E.37 **Contribution to price range, all categories**

Contributor	*No. of forms*	*Contribution to price range*[a]
	no.	%
United States		
Pack size	56	15
Multiple manufacturers	61	57
Pack size and multiple manufacturers	32	29
Canada		
Pack size	23	7
Multiple manufacturers	57	39
Pack size and multiple manufacturers	40	54
United Kingdom		
Pack size	25	2
Multiple manufacturers	98	83
Pack size and multiple manufacturers	19	15
Sweden		
Pack size	32	16
Multiple manufacturers	59	70
Pack size and multiple manufacturers	6	14
France		
Pack size	27	17
Multiple manufacturers	35	45
Pack size and multiple manufacturers	4	38
Spain		
Pack size	2	1
Multiple manufacturers	85	81
Pack size and multiple manufacturers	2	18
New Zealand		
Pack size	9	20
Multiple manufacturers	23	72
Pack size and multiple manufacturers	5	8

[a] Totals may not sum to 100 due to rounding.

Source: PC estimates.

E.6 Therapeutic groups

Table E.38 presents the detailed results of the international price comparisons using ATC groups.

Table E.38 **Price comparisons for ATC groups, list prices**

ATC group		*US*	*Canada*	*UK*	*Sweden*	*France*	*Spain*	*NZ*
Key results, all categories	Upper	3.48	1.81	1.64	1.57	1.17	1.02	0.98
	Lower	2.62	1.51	1.48	1.48	1.12	0.96	0.92
Alimentary tract and metabolism	Upper	3.98	1.86	1.76	1.98	1.47	1.25	0.82
	Lower	3.75	1.58	1.72	1.89	1.32	1.10	0.71
Antineoplastic and immunomodulating agents	Upper	1.56	0.99	1.07	1.09	0.78	0.46	0.67
	Lower	1.53	0.98	1.04	1.03	0.76	0.45	0.67
Blood and blood forming organs	Upper	4.69	1.41	1.14	1.23	1.17	0.97	1.43
	Lower	1.77	1.39	1.07	1.22	1.17	0.97	1.43
Cardiovascular system	Upper	3.38	1.86	1.62	1.44	1.23	1.02	0.91
	Lower	2.49	1.62	1.48	1.34	1.18	0.97	0.90
Dermatologicals	Upper	4.35	1.54	1.05	1.20	0.87	0.71	0.70
	Lower	4.03	1.45	1.03	1.01	0.87	0.71	0.70
General anti-infectives for systemic use	Upper	3.49	1.06	1.60	1.45	1.05	0.79	0.91
	Lower	1.97	0.86	1.40	1.32	1.02	0.77	0.89
Genito urinary system and sex organs	Upper	5.46	3.07	1.55	1.53	0.94	1.04	1.36
	Lower	4.19	1.26	1.45	1.37	0.89	1.02	1.36
Musculo-skeletal system	Upper	5.77	3.00	2.49	1.87	1.02	0.97	0.96
	Lower	2.14	1.63	1.62	1.85	1.01	0.83	0.81
Nervous system	Upper	3.03	1.79	1.58	1.57	0.97	1.12	1.31
	Lower	2.33	1.31	1.41	1.43	0.97	1.07	1.19
Respiratory system	Upper	4.15	2.07	1.75	2.96	1.46	1.17	1.24
	Lower	4.11	2.01	1.70	2.83	1.43	1.11	1.20
Sensory organs	Upper	2.39	1.33	1.31	1.14	0.94	0.74	0.89
	Lower	1.82	1.07	1.17	1.14	0.84	0.74	0.86
Systemic hormonal preparations, excluding sex hormones	Upper	2.64	0.81	0.98	1.41	0.81	0.49	0.74
	Lower	2.44	0.53	0.96	0.98	0.81	0.49	0.74
Various	Upper	2.23	2.10	4.70	nm	1.18	0.40	1.30
	Lower	1.36	1.38	2.24	nm	1.18	0.40	1.28

nm No matches were found for this category.

Source: PC estimates.

Table E.39 identifies, for each ATC group, the share of new innovative, me-too and generic pharmaceuticals in total Australian expenditure on the top-selling molecules. The number of pharmaceuticals in these four ATC groups account for over half of the available forms in the sample (302 out of 584 forms). The table shows that expenditure on cardiovascular system pharmaceuticals, especially those in the me-too category, accounts for a large share of total Australian expenditure on the 150 top-selling molecules. For the other three influential ATC groups, me-too and generic pharmaceuticals accounted for the largest share of Australian expenditure.

Table E.39 **Influential ATC groups, number of forms and share of Australian pharmaceutical expenditure**

ATC group	*Category*	*Number of forms in the sample*	*Share of total Aust. expenditure (per cent)*[a]
Cardiovascular system	Generics	48	6.8
	Me-too	47	26.9
	New	4	0.3
	All	99	34.0
Nervous system	Generics	53	5.0
	Me-too	16	5.7
	New	11	4.0
	All	80	14.7
Alimentary tract and metabolism	Generics	32	7.7
	Me-too	11	5.8
	New	7	0.9
	All	50	14.4
Respiratory system	Generics	50	5.5
	Me-too	22	3.7
	New	0	0.0
	All	72	9.2

[a] Shows the share of each category in total expenditure in Australia on the top 150 molecules.

Source: PC estimates.

E.7 Molecule age and launch delay

Table E.40 **Molecule launch delay, median value, multilateral comparison (years)[a]**

	Unit	*US*	*Aust*	*France*	*Spain*	*Canada*	*NZ*	*UK*
All	no.	3.5	3.4	3.3	3.3	3.0	2.8	0.9
Generic	no.	7.6	6.3	3.7	4.4	4.4	6.1	2.0
Me-too	no.	2.7	3.0	2.1	2.3	2.8	1.8	0.7
New	no.	1.9	2.2	3.3	1.8	2.2	2.2	0.4

a Comparisons are for the 100 molecules (within the top 150 PBS molecules) available across all countries, excluding molecules with form launch dates prior to global launch dates (for example, *fluvastatin* in the UK and *clopidogrel* in the US), and molecules without information on their form launch date. The molecule launch delay is calculated as the time from global launch date to the first form launch date. Information on form launch date in Sweden was unavailable.

Source: PC estimates.

Table E.41 **Molecule age, median value, multilateral comparison (years)[a]**

	Unit	*Aust*	*NZ*	*France*	*US*	*Canada*	*Spain*	*UK*
All	no.	14.3	15.8	15.9	17.0	17.1	17.6	18.8
Generic	no.	22.5	22.8	25.6	23.1	24.9	26.1	26.4
Me-too	no.	7.4	7.9	7.8	8.4	8.3	8.1	9.6
New	no.	5.1	6.0	4.4	6.5	7.2	6.1	6.3

a Comparisons are for the 100 molecules (within the top 150 PBS molecules) available across all countries, excluding molecules with form launch dates prior to global launch dates (for example, *fluvastatin* in the UK and *clopidogrel* in the US), and molecules without information on their form launch date. The molecule launch age is calculated as the time between first form launch date and 30 June 2000. Information on form launch date in Sweden was unavailable.

Source: PC estimates.

F Case studies of price differences

Additional pricing information was provided by GlaxoSmithKline Australia Limited (GSK) and the Department of Health and Aged Care (DHAC) for three particular pharmaceuticals, namely *ranitidine hydrochloride* (Zantac), *paroxetine hydrochloride* (Aropax) and *salmeterol xinafoate* (Serevent) (box F.1). Even though they are not necessarily representative of the sample of pharmaceuticals covered in this study, they assist in identifying factors that may have influenced price differences over time.

F.1 Ranitidine

Ranitidine was launched in Australia on the private prescription market in April 1982. While the launch price at this time is unknown, in May 1983, the manufacturer price of the product was $41.93. It was listed on the PBS 16 months later, in August 1984 with a manufacturer price of $34 per pack.

Figure F.1 shows the Australian price as a proportion of the overseas price for *ranitidine* at May 1983, and at 30 June 2000 respectively, for the United States (US), Canada, Sweden and Spain. It shows that the price differences between Australia and the comparison countries have increased significantly over the period.

Based on information provided by GSK, it appears that the changes in the price differences were due to a combination of price reductions in Australia, price changes in the comparison countries, and a depreciation in the Australian dollar.

Between May 1983 and June 2000, the price of *ranitidine* in Australia (including any brand premiums) fell by around 61 per cent (from $41.93 to $16.42). Some of this decline may be due to:

- negotiations over the listing price: around one-third (19 percentage points) occurred in the period between May 1983 and the listing of the product on the PBS (in August 1994);
- generic competition: between May 1983 and June 2000 the patent on *ranitidine* in Australia expired and several competitors entered the market;

- reference pricing: *ranitidine* is included in the H2 receptor antagonist group and therefore its price has been subject to reference pricing reviews under the weighted average monthly treatment cost (WAMTC) methodology; and
- volume controls: initially *ranitidine* was listed as an Authority Required item. Later this was changed to a restricted benefit.[1]

Box F.1 **Price differences over time**

Additional pricing information was obtained for three products.

- *Ranitidine* (marketed in Australia as Zantac) available in 150mg tablets in a packet of 60 tablets. It is used to treat a variety of stomach disorders (and belongs to the alimentary tract and metabolism group). Prices were obtained for the US, Canada, Sweden and Spain. It is classified as a generic molecule.
- *Paroxetine* (marketed in Australia as Aropax) available in 20mg tablets, with 30 tablets per packet. It is used to treat mental disorders such as depression (and belongs to the nervous system group). Prices were obtained for the US, Canada, the United Kingdom (UK), Sweden and New Zealand (NZ). It is classified as a me-too molecule.
- *Salmeterol* (marketed in Australia as Serevent) available in a pressurised inhaler dispensing 25 micrograms per dose, with 120 doses. It is used to treat asthma (and is classified under the respiratory system group). Prices were obtained for the US, France and Spain. It is classified as a me-too molecule.

These particular items were chosen by the Commission because they were available in a number of the comparison countries.

The Commission sought prices for each of the products for four different points in time. GSK provided prices at (or as close as possible to) the date on which the product was first marketed (market launch), an intermediate date chosen by the Commission (which was chosen to maximise the number of countries included in the comparisons), and at 30 June 2000. DHAC provided information on the price at which the three products were listed on the Pharmaceutical Benefits Scheme (PBS) (in all cases this was after market launch).

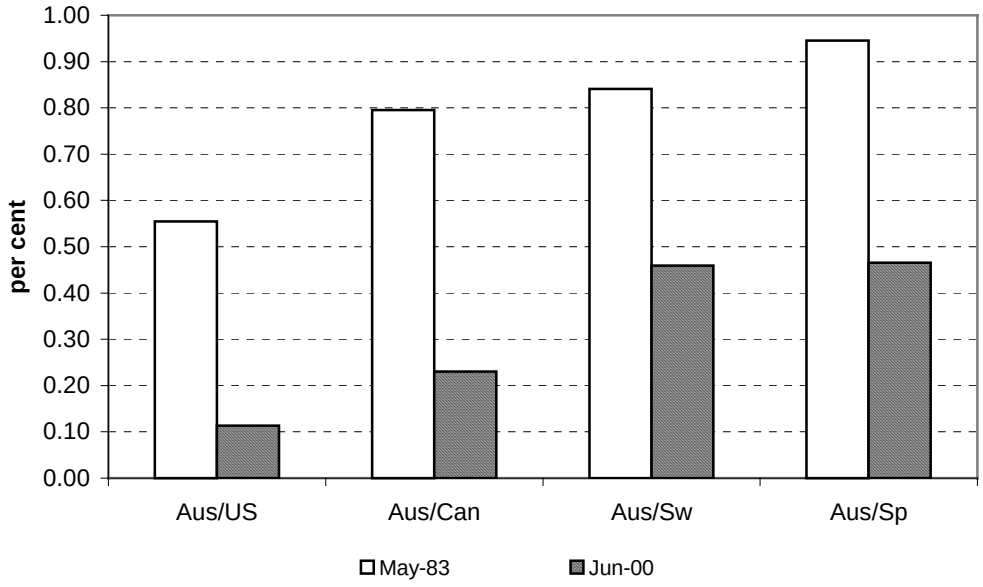
As the products were launched at different times, the time periods covered by the case studies vary. Hence the results cannot be compared.

The information used in these case studies is summarised in appendix D.

Source: GSK (pers. comm., 20 June 2000).

1 According to DHAC (pers. comm., 29 June 2001) at 30 June 2000 the restricted uses were substantially the same as those when first listed.

Figure F.1 **Relative Australian price of Ranitidine (Zantac) May 1983 and 30 June 2000**



Data sources: ABS (2000b); DHAC (pers. comm., 25 June 2001); EconData (1999); GSK (pers. comm., 20 June 2001).

According to GSK, some of the widening of the price differences between Australia and the comparison countries was due to changes in the foreign prices. Between May 1983 and June 2000, nominal prices in:

- the US increased by 19 per cent (in US dollar terms). This change should be viewed with caution because no allowance is made for discounts. The list price for *ranitidine* in the US was US$91.27 at June 2000 but the Federal Supply Schedule (FSS) price (at November 2000) was around 21 per cent lower (US$72.48);
- Canada were unchanged (in Canadian dollars) due to a price freeze implemented in 1993 by provincial drug plans, and competition from generics;
- Sweden fell by 40 per cent, also due primarily to competition from generics; and
- Spain fell by 2.5 per cent due to compulsory price cuts imposed by the Government.

The Australian dollar denominated prices of *ranitidine* in the comparison countries were also influenced by changes in exchange rates. Between 1982-83 and 1999-2000, the value of the Australian dollar fell against all of the foreign currencies thereby pushing up the Australian dollar denominated overseas prices. The Australian dollar depreciated by 38 per cent against the US dollar; 26 per cent

against the Canadian dollar; 16 per cent against the Swedish kroner; and 6 per cent against the Spanish pesetas.

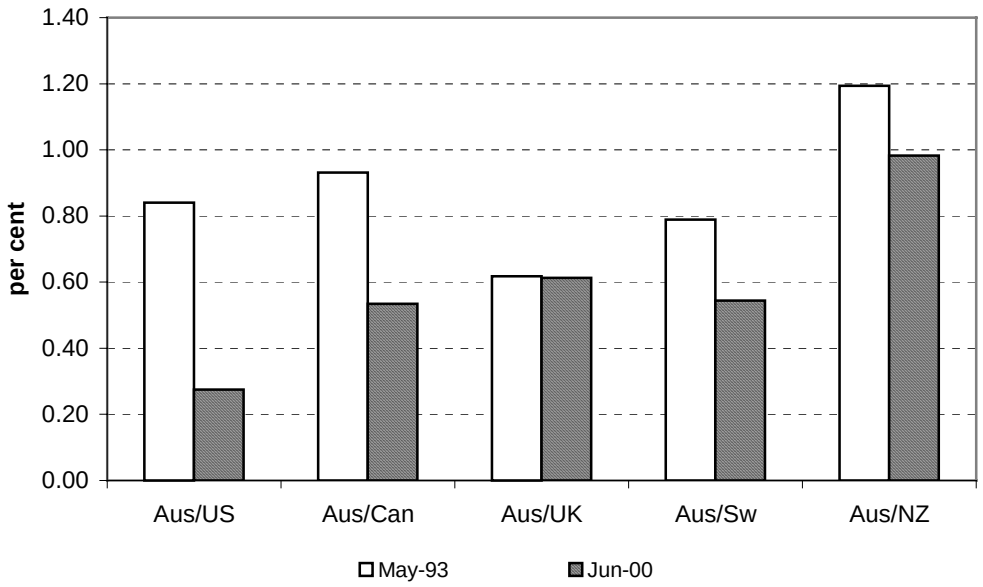
F.2 Paroxetine

Paroxetine was launched in Australia on the private prescription market in November 1993 (at a launch price of $50.03). It was listed on the PBS approximately nine months later, in August 1994 at $49.93.

Price differences between Australia and several countries were also estimated for *paroxetine*. Figure F.2 shows how prices in Australia compared with those in the US, Canada, the UK, Sweden and NZ at May 1993, and at 30 June 2000 respectively. At the market launch, the price of the product in Australia was relatively close to the prices in all comparison countries, except the UK. Over the period, price differences increased significantly for all countries except the UK.

The fall in the relative price of *paroxetine* in Australia was due to a combination of price reductions in Australia, price changes overseas, and a depreciation in the Australian dollar.

Figure F.2 **Relative Australian price of Paroxetine (Aropax), May 1993 and 30 June 2000**



Data sources: ABS (2000b); DHAC (pers. comm., 25 June 2001); EconData (1999); GSK (pers. comm., 20 June 2001).

Over the period, the price of *paroxetine* in Australia fell in nominal terms by around 45 per cent (from $50.03 to $27.58). Unlike the case for *ranitidine*, almost all of this occurred after it was listed on the PBS. The product is under a patent in Australia and the other comparison countries. Although this means that there is no direct competition from generic producers, the product faces competition from a range of therapeutic alternatives. *Paroxetine* is one of a number of Selective Serotonin Re-uptake Inhibitors (SSRIs) that were subject to reference pricing. This means that the price of *paroxetine* has been influenced by the changes in prices of other SSRIs.

There is some evidence that the local price also may have been affected by changes in the restrictions on the use of the product. According to DHAC (pers. comm., 29 June 2001), *paroxetine* (and its therapeutic competitors *fluoxetine* and *sertraline*) were initially listed as Authority Required items for 'major depression where other anti-depressants were not appropriate.' This means they were to be used as second-line therapy after less expensive agents. They were transferred off authority after convincing the Pharmaceutical Benefits Advisory Committee (PBAC) that they were of acceptable cost-effectiveness at appreciably reduced prices.

According to GSK, some of the change in the price differences for *paroxetine* were also due to changes in the overseas prices. Between May 1993 and June 2000, the nominal price in:

- the US increased by 45 per cent. This change also should be viewed with caution as the US price does not account for any discounts. It was found that the FSS price of US$34.37 (at November 2000) was 46 per cent lower than the list price of US$63.26 (at June 2000);
- Canada was unchanged due to a price freeze implemented by provincial plans. Some provinces in Canada also compared the price of *paroxetine* to those of generic SSRIs (such as *sertraline* and *citalopram*);
- the UK fell by 48 per cent. Some of the price reduction was caused by competition from therapeutic substitutes;
- Sweden was unchanged (no reasons were given); and
- NZ fell by 39 per cent due to the increased availability of a low-priced comparator (*fluoxetine*).

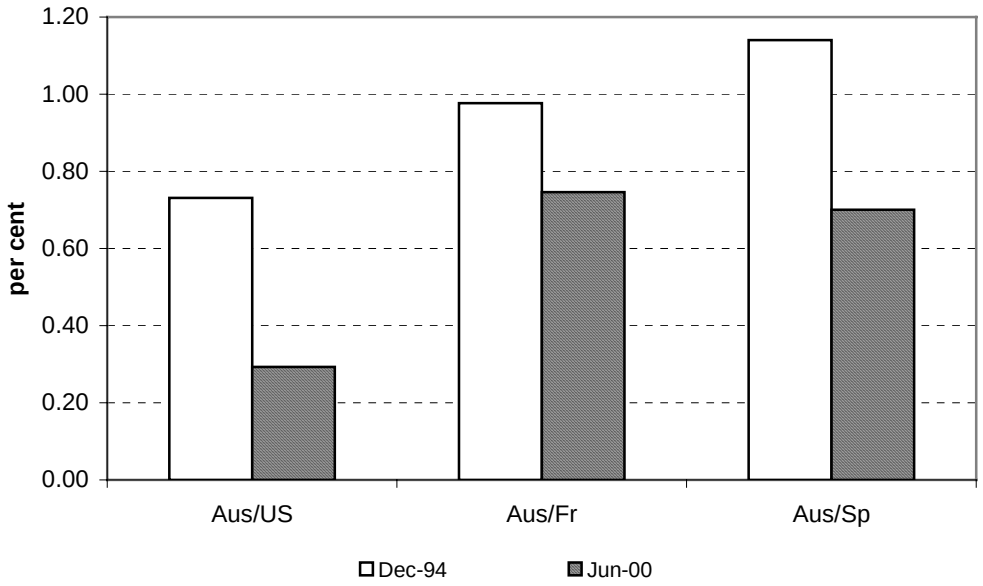
The Australian dollar denominated prices of *paroxetine* in the comparison countries were also influenced by changes in exchange rates. In the period between June 1993 and June 2000, the value of the Australian dollar rose against two of the five currencies (by 4 per cent against the Canadian dollar and 25 per cent against the Swedish kroner). The dollar depreciated against the US dollar (14 per cent), the UK pound (six per cent), and NZ dollar (by nine per cent).

F.3 Salmeterol

Salmeterol was launched in Australia on the private prescription market in June 1993 (at a price of $41.90). It was then listed on the PBS in February 1995 (at a price of $37.00).

Figure F.3 shows the difference between the US and Australian prices for *salmeterol*, as at December 1994, and at 30 June 2000. Over the period, price differences for *salmeterol* have increased for all comparison countries.

Figure F.3 **Relative price of Salmeterol (Serevent), December 1994 and 30 June 2000**



Data sources: ABS (2000b); DHAC (pers. comm., 25 June 20001); EconData (1999); GSK (pers. comm., 20 June 20001).

Between December 1994 and June 2000, the Australian price of *salmeterol* fell in nominal terms by around 36 per cent. Approximately one-third of this reduction occurred in the period between the market launch and it being listed on the PBS.

According to GSK, a significant portion of the price reduction occurred at the time the volume controls on the product were altered. *Salmeterol* initially was listed as an Authority Required item for 'patients with frequent episodes of *nocturnal asthma* who are receiving treatment with oral corticosteroids or *maximal* doses of inhaled corticosteroids'. The restrictions on the use of the product were then eased in exchange for a significant price reduction. At 30 June 2000, it was classified as a restricted benefit item for 'patients with frequent episodes of *asthma* who are

receiving treatment with oral corticosteroids or *optimal* doses of inhaled corticosteroids'.

According to GSK, price changes in the comparison countries also contributed to the change in price differences for *salmeterol*. Nominal prices in:

- the US increased by 38 per cent over the period. Again, the rise should be treated with caution. It was found that the FSS price for *salmeterol* (US$42.81) at November 2000 was around 26 per cent below the list price (US$57.93) at 30 June 2000.
- Spain rose 12 per cent. The price initially fell due to the Government imposing general price cuts for pharmaceuticals in September 1994. However, in April 1997 the price was increased when the supplier reached an agreement with the Government that allowed higher prices in exchange for the company committing to local investments in R&D and manufacturing.
- France fell by 14 per cent due to price reductions (in July 1995 and September 1998) under the terms of a price-volume agreement.

The Australian dollar denominated prices of *salmeterol* in the comparison countries also were influenced by relatively small changes in exchange rates.

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