8.6 **The lowest price in the basket of countries**

As is argued below, the selection of the lowest price in the basket is the most appropriate where a price free of distortions or manipulation is sought.

8.7 **Discussion**

The use of an average is appropriate in circumstances where there is a clustering of prices, i.e. where there is little variation in prices. Where the variance is high, a subgroup such as the lowest three prices is selected to overcome problems associated with wide variance.

The application of the ‘average less a percentage’ approach is based largely on a clear intention to lower prices by a particular amount. There is however no apparent rational basis for the percentage selected.

Some stakeholders argue that the average price in the basket of countries should be used. The basis of this argument is the claim that the income levels of the 7 million South Africans with medical scheme membership is higher than that average income levels (based on GDP) in the comparator countries (i.e. South Africans using the private sector should pay more than citizens of high-income countries). This argument is not accepted by the Committee for the reasons provided in Section 4.2.

Reinforcing the arguments in Section 4.2 is the finding by the Committee that, in the majority of cases, the weighted average South African price (including public and private sector markets) is higher than the average price in the basket of benchmark countries. A comparison of the weighted average of the South African price with the lowest price in the basket of countries, shows that 63% of products have a South African price that is greater than the lowest price in the benchmark countries.

*The Committee therefore finds no rational reason for not using the lowest price if it reflects the least distorted price and is the closest to paying normal profits to a manufacturer.*

As the medicines are commercially sold within the basket of countries, there is a furthermore reasonable presumption that the prices provide a return over-and-above the cost of production, i.e. they are commercially viable prices.

Where a company has chosen to deviate from this principle, i.e. sell a medicine at a price which allows for a very minimal or no profit, it is reasonable to presume that it has done so of its own free will and consistent with some commercial logic.

Where such conduct arises as a result of a price discrimination policy to maximise super-profits, the Committee can find no grounds for accommodation through the benchmarking methodology. *However, where pricing is distorted downward for a reason beyond the control of the manufacturer, accommodation should be considered on a case-by-case basis.*

*To allow for reasonable consideration of exceptions, the Committee recommends that a phased approach be adopted toward the implementation of a benchmark based on the lowest price in the selected basket of countries. It is*
furthermore recommended that an interim approach be considered which uses an average of the three lowest prices in the basket of countries.

8.8 Additional possible approaches suggested by stakeholders

8.8.1 Upward adjustment in prices

Industry stakeholders have argued that a fair benchmarking methodology will allow prices to be increased where the South African private sector price is lower than the benchmark price. The basis for this argument is an interpretation of regulation 5(2)e, which indicates that each medicine will be required to “conform with international benchmarks”; some stakeholders interpret this to imply price adjustments that are both upwards and downwards.

The objective of international benchmarking is to bring South African prices in line with international pricing where these prices have been excessive, i.e. subject to price distortion that is detrimental to patient access. The objective of benchmarking is not to adjust prices to higher levels where the manufacturer has opted to sell them at a lower price.

An assessment of products that are priced in South Africa below the benchmark price indicated that these products are priced at lower levels due to competition from generics or medicines in similar pharmacological or therapeutic classes. The majority of medicines that are below the benchmark price have at least three competing products for the same indication. Those products that do not have competing products, but have a South African price below the benchmark price, are mainly antiretrovirals and related HIV and AIDS therapies.

The impact assessment in Section 10 also reveals that for a number of alternative approaches, permitting prices to rise as well as fall will permit net increases in the average cost of medicines in the South African private sector. At best therefore, permitting prices to rise could neutralise the effect of price reductions due to benchmarking.

8.8.2 Company by Company assessment

Certain industry stakeholders have argued that prices be permitted to adjust up and down within a company. This is similar to the ‘up and down’ adjustment of prices discussed in Section 8.8.1.

The Committee is of the view that this approach would permit price distortions to remain as the relatively over-priced products within a particular company would neutralise the prices of those products within that same company that are relatively under-priced.
9. INTERNATIONAL BENCHMARKING OF COMBINATION PRODUCTS

9.1 Overview

This section provides the Committee’s recommended approach in respect of “combination products”. As combination products incorporate more than one medicine in a single product, difficulties arise with respect to benchmarking. In many instances no comparator product will exist for the combination, although comparators will exist for the individual medicines.

9.2 Definitions

9.2.1 Combination Product

For the purposes of international benchmarking, combination products are defined as:

1. A product comprised of two or more components, which are regulated by the schedules in the Medicines and Related Substances Act 101 of 1965, which have been combined or mixed and produced as a single entity.

2. Two or more separate medicinal products co-packed together in a single package.

9.2.2 Primary Mode of Action

The primary mode of action of a combination product is the most important registered indication of the combination product. The primary mode of action is the registered indication expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

9.2.3 Anatomical Therapeutic and Chemical (ATC) classification system

For the purposes of classifying therapeutic effects the Committee has adopted the World Health Organisation’s Anatomical Therapeutic and Chemical (“ATC”) classification system. In this classification system, medicines are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.

Medicines are classified in groups at five different levels. The medicines are divided into fourteen main groups (1st level), with one pharmacological/therapeutic subgroup (2nd level). The 3rd and 4th levels are chemical/pharmacological/therapeutic subgroups and the 5th level is the chemical substance.

The complete classification of metformin provided in Table 9.1 illustrates the structure of the code.
Table 9.1: Complete Classification of Metformin

<table>
<thead>
<tr>
<th>Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st level</td>
<td>A</td>
</tr>
<tr>
<td>Anatomical main group</td>
<td>A1</td>
</tr>
<tr>
<td>2nd level</td>
<td>A10</td>
</tr>
<tr>
<td>Therapeutic subgroup</td>
<td>A10B</td>
</tr>
<tr>
<td>3rd level</td>
<td></td>
</tr>
<tr>
<td>Pharmacological subgroup</td>
<td></td>
</tr>
<tr>
<td>4th level</td>
<td>A10BA</td>
</tr>
<tr>
<td>Chemical subgroup</td>
<td></td>
</tr>
<tr>
<td>5th level</td>
<td>A10BA02</td>
</tr>
<tr>
<td>Chemical substance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Metformin</td>
</tr>
</tbody>
</table>

9.3 Methodology for benchmarking combination products

9.3.1 Overview

This section specifies the Committee's recommended methodology for benchmarking combination products.

9.3.2 Comparator exists for a combination product

In cases where a medicine has a comparator in the basket of benchmark countries it is logical to make use of the comparator. It is therefore recommended that the international benchmarking methodology for originator medicines, outlined in Section 7, applies.

9.3.3 No comparator is identified

Where no comparator is identified two scenarios arise:

1. The combination can exist as a single product; or

2. The combination of products can be co-packaged.

With respect to (1) above the Committee recommends as follows:

1. The applicant designates the primary mode of action and therapeutic category according to the definitions above.

2. Once the benchmarking of originator products for which there are comparators has been finalised, the average price for that ATC will then be calculated by the Committee.

3. For the purposes of this application the 4th level of the ATC will be used.

4. The average price within the ATC will then become the single exit price for all combination products that do not have a comparator in the benchmark countries.

5. If the applicant has good quality evidence in the form of a randomized controlled clinical trial that demonstrates superior efficacy, safety or improved adherence for the combination product against an
appropriate set of comparators, then they may submit their product for pharmacoeconomic review.

With respect to (2) the Committee recommends that the SEP for each individual product be summed together and the total decreased by 10%, given that there will be a saving on the packaging costs for co-packaged products as opposed to each product being individually packaged.

9.3.4 Other options considered by the Pricing Committee

Based upon submissions by various parties, as well as the deliberations of the Committee, the following options were considered but rejected.

1. The SEP for each scheduled substance be summed.
   a. Assessment: As this approach does not reflect the true input cost, it would create commercial incentives for combination products whilst the national drug policy limits combinations to those that meet specified criteria.

2. Once benchmarking has been completed for all products with a comparator, single as well as combination products, the Committee determines the average decrease in single exit price. This average decrease is then applied to those combination products without comparators.
   a. Assessment: This approach does not address the utility of the final product and would maintain distortions in the current market place.

3. The SEP for the primary mode of action is determined and then the cost of each regulated substance added to the benchmark of the primary mode of action.
   a. Assessment: The Committee was of the opinion that this methodology would be difficult to audit and would prove administratively onerous.

4. The average decrease in SEP is determined for a given manufacturer and the decrease applied to those combination products without a comparator produced by this manufacturer.
   a. Assessment: This approach would maintain the current price distortions in the market place.
10. EVALUATION OF POLICY OUTCOMES

The aim of international price benchmarking, as stated in section 3, is to ensure that economically fair prices are charged to the domestic health system. This section briefly indicates the estimated impact of the alternative and selected benchmark modalities on the private health system in South Africa. The data underpinning the analysis is as follows:

1. **Price data**: sourced from the benchmark countries and/or the pharmaceutical manufacturers;

2. **Volumes (demand) in South Africa**: sourced from pharmaceutical manufacturers;

3. **Exchange Rate data**: underlying data sourced from the South African Reserve Bank;

4. **Inflation Rate data**: underlying data sourced from the South African Reserve Bank.

The alternatives quantified are:

1. Average of all prices in the basket;

2. Median of all prices in the basket;

3. Average of the two lowest prices in the basket;

4. Average of the three lowest prices in the basket; and

5. Lowest price in the basket.

Two alternatives, apart from 5, are evaluated for each scenario:

1. Prices are only permitted to adjust down, which is consistent with an approach which includes South Africa in the basket of chosen countries ("down"); and

2. Prices are permitted to adjust up if the prices are above those in South Africa, which is consistent with leaving South Africa outside the basket of chosen countries ("down & up").

For all scenarios the exchange rate options (options 1 to 4) discussed in Section 7.4 are also evaluated. The results are presented in Table 10.1 and Figure 10.1.

The results reveal the following:

1. The Committee recommended exchange rate approach reduces the impact from the option originally considered by the Committee. It also reduces the impact relative to the industry recommendations (option 2) and the average based on inflation differentials (option 3).
2. In all options where an upward and downward price adjustment is permitted creates the possibility of significant real increases in medicine expenditure.

3. Neither the "average" or "median" scenarios significantly impact on medicine costs, even where prices can only adjust down, with option 4 showing decreases of 6.9% and 7.5% respectively.

4. The 2-stage (phased) approach, recommended by the Committee in this report, suggests that the initial phase (average of the lowest 3 prices, with prices permitted to move down only) will result in an 10.0% aggregate reduction in medicine costs. Phase 2 will result in an estimated residual 9.9% (19.9% in total) reduction in medicine costs.

Table 10.1: Evaluation of alternative benchmark modalities

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Adjustment</th>
<th>Expenditure (R'000)</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Option 1</td>
<td>Option 2</td>
<td>Option 3</td>
<td>Option 4</td>
<td></td>
</tr>
<tr>
<td>Present</td>
<td>n/a</td>
<td>5,721,590</td>
<td>5,725,464</td>
<td>5,741,803</td>
<td>5,775,409</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>Down</td>
<td>-7.8%</td>
<td>-7.7%</td>
<td>-7.5%</td>
<td>-6.9%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>down &amp; up</td>
<td>9,184,643</td>
<td>9,327,153</td>
<td>9,473,418</td>
<td>9,788,466</td>
<td></td>
</tr>
<tr>
<td></td>
<td>change (%)</td>
<td>48.0%</td>
<td>50.3%</td>
<td>52.7%</td>
<td>57.4%</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>Down</td>
<td>-8.7%</td>
<td>-8.4%</td>
<td>-7.8%</td>
<td>-7.5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>down &amp; up</td>
<td>9,953,491</td>
<td>9,062,375</td>
<td>9,254,810</td>
<td>9,477,680</td>
<td></td>
</tr>
<tr>
<td></td>
<td>change (%)</td>
<td>44.3%</td>
<td>46.0%</td>
<td>49.1%</td>
<td>52.7%</td>
<td></td>
</tr>
<tr>
<td>Ave lowest 2</td>
<td>Down</td>
<td>-16.2%</td>
<td>-15.8%</td>
<td>-15.3%</td>
<td>-14.3%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>down &amp; up</td>
<td>6,956,781</td>
<td>7,033,775</td>
<td>7,096,321</td>
<td>7,304,134</td>
<td></td>
</tr>
<tr>
<td></td>
<td>change (%)</td>
<td>12.1%</td>
<td>13.3%</td>
<td>14.4%</td>
<td>17.7%</td>
<td></td>
</tr>
<tr>
<td>Ave lowest 3</td>
<td>Down</td>
<td>-11.5%</td>
<td>-11.2%</td>
<td>-10.8%</td>
<td>-10.0%</td>
<td></td>
</tr>
<tr>
<td>(phase 1)</td>
<td>down &amp; up</td>
<td>7,975,216</td>
<td>8,067,175</td>
<td>8,136,356</td>
<td>8,405,960</td>
<td></td>
</tr>
<tr>
<td></td>
<td>change (%)</td>
<td>28.5%</td>
<td>30.0%</td>
<td>31.1%</td>
<td>35.5%</td>
<td></td>
</tr>
<tr>
<td>Lowest</td>
<td>Down</td>
<td>-22.3%</td>
<td>-21.6%</td>
<td>-21.1%</td>
<td>-19.9%</td>
<td></td>
</tr>
<tr>
<td>(phase 2)</td>
<td>change (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The Committee is of the view that the magnitude of these prices reductions will not translate into an inability of the pharmaceutical industry to secure normal profits, particularly given that it is recommended that benchmarking be phased in over a two year period and that exemption applications are permitted.

It is a matter of considerable urgency that the price of medicines in South Africa be brought in line with prices in other countries, which through various regulatory interventions and the existence of considerable purchasing power in their health systems have achieved medicine prices that are relatively free from distortions related to market imperfections. The Committee urges that these recommendations be given urgent consideration and be implemented at the earliest possible date.
REFERENCES


Pharmaceutical Task Group ("PTG"), Submission by the Pharmaceutical Task Group to the Pricing Committee and the Department of Health on International Medicine Benchmarking, April 2007.


http://www.anzhealthpolicy.com/content/4/1/7 08/01/2008

http://www.ingentaconnect.com/content/adis/iprn/2003/00000017/art00007/art/00007 08/01/2008

http://www.piribo.com/publications/country/asia_pacific/australia/pharmaceuticals_ma 08/01/2008


http://www.hc-sc.gc.ca/abc-asc/pubs/hpfb-dgpsa/access-therapeutics_access-therapeutique_e.html#2
APPENDIX A: PROCESS ADOPTED BY COMMITTEE IN ARRIVING AT RECOMMENDATIONS

In this appendix, reference is made to the Pharmaceutical Task Group (PTG). The PTG, according to its submission to the Pricing Committee, "represents the interests of multinational research-based companies operating in South Africa, local / generic manufacturers and manufacturers of self medication products .... This group represents almost the entire market share of suppliers of medicine to the South African public and private markets." The PTG contracted with a range of different consultants to prepare elements of their submission to the Pricing Committee. In particular, reference is made to Grant Thornton below, which was contracted by PTG to analyse the impact of the draft international benchmarking recommendations on PTG companies. Thus, Grant Thornton was not an independent agent making submissions to the Pricing Committee of its own accord. It should be recognised that PTG is essentially Grant Thornton's client.

In order to arrive at the recommendations presented in this report, the following process was adopted:

- On 30 October 2006, key stakeholders attended a briefing by officials of the national Department of Health and the Chairperson of the Pricing Committee on the draft international benchmarking methodology.

- On 1 December 2006, Government Gazette No. 29443 formalised this process by indicating that a methodology for international benchmarking of medicine prices was to be published and inviting comment from interested parties. Copies of the draft methodology were made available to interested groups and posted on the Department of Health's website.

- During December 2006 and January 2007, stakeholders sought clarity on certain aspects of the draft methodology through written correspondence with the national Department of Health and the Chairperson of the Pricing Committee, and through meetings with officials of the national Department of Health.

- During this period, pharmaceutical companies also collected information about the prices of their products in the benchmark countries. Nineteen companies supplied this information to Grant Thornton to assess the impact on each company and the overall impact. In February 2007, the PTG reported that the proposed methodology would produce a 35% reduction in medicine prices.

- The secretariat of the Pricing Committee requested data from all medicine manufacturers and importers on the current single exit price (SEP), the ex-manufacturer price, the logistics fee and the price in each of the benchmark country for every product. None of the manufacturers responded to these verbal and written requests for data. The PTG responded on behalf of their members and refused to submit this information (which was reiterated in their submission).
• The initial deadline for submissions was set for 19 February 2007. On the basis of requests from pharmaceutical manufacturer representative associations, this deadline was extended several times and submissions finally closed at the end of April 2007.

While waiting for stakeholder submissions, the Pricing Committee met regularly to consider available data on manufacturer prices and further scrutinise international experience on international benchmarking and other price regulatory mechanisms.

After much persuasion, some (18) pharmaceutical manufacturers made available their manufacturer price in the suggested benchmark countries, either shortly before or after the submission of comments on the draft methodology by the *Pharmaceutical Task Group* ("PTG").

Four of the 19 companies that supplied information to Grant Thornton did not supply this information to the Pricing Committee. These companies provided no written explanation of why they have chosen not to comply with the request. Discussions with one of the Managing Director’s suggest that these companies chose not to supply their information since the international benchmarking methodology would not have a significant impact on their current South African prices. Furthermore, the addition of data from these companies would dilute the overall industry impact as calculated by Grant Thornton.

It is not clear whether the fifteen companies submitted the same information to Grant Thornton and the Pricing Committee.

Three of the eighteen companies that supplied information to the Pricing committee did not supply their information to Grant Thornton.

Once stakeholder submissions had been received, these were extensively interrogated by the Pricing Committee. A detailed list of questions of clarification was compiled on certain submissions and sent to the respective stakeholder groups.

Further review of analyses of international benchmarking options using the available data, and extensive discussion of these options continued within the Pricing Committee.

The stakeholder responses to the questions of clarification also underwent extensive scrutiny and were discussed by the Pricing Committee.

Finally, a meeting of officials of the National Department of Health and a limited number of Pricing Committee members was held with the PTG on 25 October 2007 in order to clarify certain issues from the PTG submission that remained unclear after the written correspondence.

At the meeting of 25 October 2007, members of the PTG agreed that the secretariat of the Pricing Committee could meet with Grant Thornton to compare data and identify the reasons for the apparent difference in the impact of the benchmarking methodology as estimated by Grant Thornton compared to that estimated by the secretariat. Despite this agreement, the PTG reportedly instructed Grant Thornton not to provide the secretariat with impact data at product level. This approach made it impossible to determine the exact reason for the differences between the secretariat’s and Grant Thornton’s calculations.
APPENDIX B: INTERNATIONAL PRACTICES IN RELATION TO MEDICINE PRICES

Table B.1: Overview of the use of pharmacoeconomic studies

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>YES / NO</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Yes</td>
<td>No explicit guidelines. Includes Health Economic Evaluation according to stated requirements</td>
</tr>
<tr>
<td>Belgium</td>
<td>Yes</td>
<td>Standard Report format. Therapeutic value and trade off between value and cost of treatment are key criteria</td>
</tr>
<tr>
<td>Cyprus</td>
<td>No</td>
<td>Plays an important role for inclusion on the positive list. Significant medical benefit over existing treatment at similar price level.</td>
</tr>
<tr>
<td>Czech</td>
<td>No</td>
<td>No clear guidelines</td>
</tr>
<tr>
<td>Denmark</td>
<td>No</td>
<td>Companies not obliged to present PE evaluation. DMA – PE evaluation minor relevance (quality submitted insufficient)</td>
</tr>
<tr>
<td>Estonia</td>
<td>Yes</td>
<td>Baltic guideline for Economic Evaluation</td>
</tr>
<tr>
<td>Finland</td>
<td>Yes</td>
<td>Innovator Pharmaceutical and if required by HILA for other applicants (new pharmaceutical form of molecule already on Finnish market)</td>
</tr>
<tr>
<td>France</td>
<td>No</td>
<td>No official requirement</td>
</tr>
<tr>
<td>Germany</td>
<td>Yes</td>
<td>Voluntary guidelines by scientific community</td>
</tr>
<tr>
<td>Greece</td>
<td>Yes</td>
<td>For ref price system. New pharmaceuticals - comprehensive guideline</td>
</tr>
<tr>
<td>Hungary</td>
<td>Yes</td>
<td>INN – required with new indications/ price increase</td>
</tr>
<tr>
<td>Portugal</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Slovakia</td>
<td>No</td>
<td>No clear guidelines</td>
</tr>
<tr>
<td>Slovenia</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>Yes</td>
<td>NICE guidelines</td>
</tr>
<tr>
<td>EU Country</td>
<td>Price Level controlled</td>
<td>Price Referencing</td>
</tr>
<tr>
<td>---------------</td>
<td>------------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Austria</td>
<td>Manufacturer Price</td>
<td>External Price Referencing</td>
</tr>
<tr>
<td>Belgium</td>
<td>Manufacturer Price</td>
<td>External &amp; Internal Price Referencing</td>
</tr>
<tr>
<td>Cyprus</td>
<td>Wholesale Price for Imported ph. And Man price for locally produced</td>
<td>External Price Referencing</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>Manufacturer Price</td>
<td>External Price Referencing</td>
</tr>
<tr>
<td>Denmark</td>
<td>Wholesale Price</td>
<td>Internal Price Ref</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estonia</td>
<td>Manufacturer Price</td>
<td>External Price Referencing, price-volume agreements between the ministry and the ph. Companies</td>
</tr>
<tr>
<td>Finland</td>
<td>Wholesale Price</td>
<td>External &amp; Internal Price Referencing</td>
</tr>
<tr>
<td>France</td>
<td>Manufacturer Price</td>
<td>External Price Ref</td>
</tr>
<tr>
<td>Germany</td>
<td>Manufacturer Price</td>
<td>Internal Price Ref</td>
</tr>
<tr>
<td>EU Country</td>
<td>Price Level controlled</td>
<td>Price Referencing</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Greece</td>
<td>Manufacturer Price</td>
<td>External Price Ref</td>
</tr>
<tr>
<td>Hungary</td>
<td>Manufacturer Price</td>
<td>External &amp; Internal Price Referencing</td>
</tr>
<tr>
<td>Ireland</td>
<td>Manufacturer Price</td>
<td>External Price Ref</td>
</tr>
<tr>
<td>Italy</td>
<td>Manufacturer Price</td>
<td>External Price Ref</td>
</tr>
<tr>
<td>Latvia</td>
<td>Wholesale Price</td>
<td>External &amp; Internal Price Referencing</td>
</tr>
<tr>
<td>Lithuania</td>
<td>Manufacturer price/CIP Price</td>
<td>External &amp; Internal Price Referencing</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>Pharmacy Retail Price</td>
<td>External Price Ref</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Wholesale Price</td>
<td>External Price Ref</td>
</tr>
<tr>
<td>EU Country</td>
<td>Price Level controlled</td>
<td>Price Referencing</td>
</tr>
<tr>
<td>------------</td>
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<td>Slovakia</td>
<td>Pharmacy Retail Price</td>
<td>External Price Ref</td>
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<td>Wholesale Price</td>
<td>External Price Ref</td>
</tr>
<tr>
<td>Spain</td>
<td>Manufacturer Price</td>
<td>External Price Ref</td>
</tr>
<tr>
<td>Sweden</td>
<td>Wholesale Price</td>
<td></td>
</tr>
<tr>
<td>United Kingdom</td>
<td>Wholesale Price</td>
<td></td>
</tr>
</tbody>
</table>

| | | | No external Price Ref. |
List of Abbreviations used:

EU  European Union
PC  Pricing Committee
Ph. Pharmaceuticals
BMGF Federal Ministry of Health and Women’s Issues (Austria)
HILA Pharmaceuticals Pricing Board (Finland)
CIP Cost, Insurance and packaging

Sources:

Fact Sheets. Sabine Vogler, Katja Antony, Danielle Arts, Claudia Habl, Barbara Froschl, Christine Leopold, Ingrid Rosian-Schikuta, Heifi Sturzlinger, Marion Weigl, Romana Landauer. October 2006. OBIG.

APPENDIX C: ECONOMIC RATIONALE FOR INTERNATIONAL BENCHMARKING

The fundamental goal of the Pricing Committee’s recommended regulations is to ensure that medicine prices experienced within both the public and private health care sectors are free from distortion or manipulation. Health care, particularly within the private sector, is vulnerable to supplier-induced demand and excessive pricing due to market failures. Price regulation of pharmaceuticals is necessary to address the significant market imperfections that exist and to achieve public health policy goals. It is a government intervention that is entirely distinct from and not in conflict with policies that are intended to promote the development of specific industries. The sustainability of a specific industry should not be dependent on its ability to distort prices relative to what would prevail in a perfectly competitive environment.

The market for pharmaceutical products

In a competitive market it is assumed that there will be an upward sloping supply curve (which reflects an increasing quantity supplied as price increases), that there will be a downward sloping demand curve (which reflects an increase in the quantity demanded the lower the price) and that that one price will clear the market. This price occurs where supply equals demand. In Figure C.1 this is at \( p_0 q_0 \), i.e. the market clearing price is at \( p_0 \). The triangle above \( p_0 \) and below the demand curve \( D_0 \) is traditionally regarded as the consumer surplus. This is because all the people who would have accepted a higher price, for example \( p_1 \), benefit from the market price \( p_0 \). They benefit by the price difference between \( p_0 \) and \( p_1 \).

Figure C.1: Standard illustration of a perfectly competitive market

![Diagram of a perfectly competitive market](image)

The advantage obtained by the supplier of charging the price \( p_0 \), is that the total value of the volumes traded are much higher than they would be if they charged \( p_2 \) and had a resulting volume traded equivalent to \( q_2 \). In other words, the shaded area of \( p_0 \times q_0 \) is greater than \( p_2 \times q_2 \). Any price below the market clearing price would result in lower total returns, although volumes may be much higher.

Government interventions such as international benchmarking or other forms of price regulation should theoretically not be necessary in competitive markets. The problem is that a ‘free’ or competitive market cannot be said to operate for pharmaceutical
products. Of particular importance is that the theory of perfect competition assumes that consumers have perfect knowledge about the goods or services that they consume. However, in the health sector, there is an asymmetry of information between health professionals and patients. Patients are not in a position to diagnose their illness or to assess whether a prescribed treatment is necessary or appropriate. In effect, the patient or consumer does not directly demand the medicine but the health professional operates as an agent for the patient and makes decisions regarding the patient’s use of medicines. In the case of health care, ignoring the prescriptions of a health professional could result in continued ill-health, long-term disability or even premature death. This feature of the market for pharmaceuticals translates into manufacturers of these products being able to charge high prices without dramatically influencing demand for or use of them (i.e. the price can be set by the manufacturer at a much higher price than the socially optimal price of $p_0$ illustrated in Figure 1).

Another key market failure in relation to pharmaceutical products is the existence of monopolies. While this particularly occurs while a medicine is under patent (so that only the patent holder may produce that medicine), the initial patent holder still maintains considerable market power after the patent has expired (particularly as doctors are most familiar with this brand, have been subject to considerable marketing by the manufacturer and may have been provided with various ‘incentives’ to preferentially prescribe or dispense the branded product). This once again allows manufacturers to charge prices that are higher than what would be charged in a competitive market.

Prices that are above what would occur in a competitive market cannot be described as socially optimal — they leave society worse off than they would have been under competitive conditions. Under these conditions, government frequently introduces some form of regulatory mechanism to promote prices that would be regarded as efficient (i.e. prices that would be closer to what would exist in a competitive market, which is $p_0$ in Figure C.1).

The theory of market segmentation and differential pricing

Market segmentation refers to the practice of charging different prices in different ‘markets’ (or countries). It is argued that with market segmentation, prices vary proportionally to per capita income levels. Countries with higher income levels (or parts of the ‘market’ within a country with higher income levels), and thus greater willingness to pay for medicines, would be charged a higher price (or mark-up above marginal costs) than lower income countries. It has been argued that market segmentation is necessary in the case of pharmaceutical products so that manufacturers can recover research and development (R&D) costs involved in developing that particular medicine (from higher income countries or higher income sections of the ‘market’ within a county), while allowing more people (particularly in low income countries or low income sections of the ‘market’ within a country) to use the product than would be possible if a single price was charged across countries (called Ramsey pricing). Thus, the basic argument behind market segmentation is that it would enhance overall welfare, particularly in lower income countries or lower income sections of ‘markets’ within a country.

Returning to the theory of competitive markets, in such a market a single price will exist because of the difficulty associated with segmenting markets. For instance, selling Pepsi at significantly different prices in Alexandra relative to Sandton should result in round tripping (or some other form of price arbitrage), i.e. people will bulk
buy the lower cost identical product in the cheaper market and re-sell it in the higher priced market. Eventually the prices in both markets will converge on a single price.

However, if a supplier can divide a market in such a way that no leakage occurs between the segments, i.e. eliminate round tripping (e.g. between the public and private health sectors or between two countries), two prices can be charged in the different markets. This is beneficial to suppliers who can “capture” more of the “consumer surplus” than they would if there were a single price, but is not beneficial to consumers, particularly those who have to pay prices above that which would occur in a competitive market.

Market segmentation can occur explicitly between countries where it is possible to sell the same drug at very different prices. This is made possible by the market rigidities resulting from strict registration processes in individual countries. Parallel importation, if applied more generally internationally, would tend to create a convergence on a single price internationally. Such a single price would also be consistent with normal profits.

In Figure C.2 where no price discrimination occurs, the supplier receives \( p_0 \times q_0 \), i.e. the grey block. If the supplier is allowed to price discriminate by being able to charge two additional prices in specific markets, e.g. \( p_1 \) and \( p_2 \), then the consumer surplus is diminished by the cross-hatched area below the triangle. This cross-hatched area is added to the grey area, which all accrues as additional revenue to the supplier. However, as the supplier would have been profitable at \( P_0 \), the additional revenue from a price greater than \( P_0 \) is all profit.

**Figure C.2:** Standard illustration of the economic implications of price discrimination

The experience of market segmentation and differential pricing

Even though the theory clearly indicates that market segmentation does not benefit the general public and only translates into higher than normal profits for pharmaceutical manufacturers, it is worthwhile considering whether the principles of Ramsey pricing, which pharmaceutical manufacturers argue vociferously for, actually applies in
practice. While empirical studies indicate that there is some relationship (or positive correlation) between national income and medicine price levels, this relationship is not uniform and there are all too many examples of medicine prices being higher in low- and middle-income countries than in high-income countries. There are several reasons why this may occur.

An important reason why medicine prices may be lower in high-income countries is that many of these countries are able to use their monopsony (i.e. there is a single, large purchaser) purchasing power to enforce lower prices. This occurs where almost the entire population is covered under some form of mandatory (social or national) health insurance, or where there is a tax-funded national health service purchasing health care on behalf of the population. ‘Holding the purse-strings’ gives such countries considerable power in establishing medicine prices. They are effectively able to establish prices that approximate a price free of distortions.

Another issue is that some researchers have highlighted the particularly strong relationship between medicine prices and income inequality; the higher the degree of income inequality within a country, the higher the price of medicines in that country. Thus, in low- and middle-income countries with high levels of income inequality, pharmaceutical manufacturers may choose to charge a relatively high price and supply the medicine only to a small group of high-income consumers with relatively inelastic demand (i.e. their demand for the medicine is not influenced substantially by changes in price). A person’s demand for a medicine may also be inelastic if they are covered by a health insurance scheme; as the person does not pay directly for the medicine (their insurance scheme does), they are less likely to be influenced by high prices of medicines.

Both of these issues seem to be affecting the price of medicines in South Africa relative to other countries (particularly high-income countries). Many of these high-income countries have been able to effectively achieve lower medicine prices than South Africa, largely through monopsony purchasing power and/or effective medicine price regulation. In addition, there are very high levels of income inequalities in South Africa (one of the highest in the world) and patent-holding pharmaceutical companies see their primary market as the highest income groups, most of whom are medical scheme members, whose demand for medicines is less price sensitive. Manufacturers, thus, feel at liberty to charge relatively high prices in this market.

**Market segmentation and price discrimination in relation to the SA Competition Act**

It is worth noting that section 9 of the *Competition Act* (No. 89 of 1998) prohibits price discrimination by a “dominant firm” if:

(a) “it is likely to have the effect of substantially preventing or lessening competition;

(b) “It relates to the sale, in equivalent transactions, of goods or services of like grade and quality to different purchasers; and

(c) “It involves discriminating between those purchasers in terms of –

i. “the price charged for the goods or services;
ii. "any discount, allowance, rebate or credit given or allowed in relation to the supply of goods or services;

iii. "the provision of services in respect of the goods or services; or

iv. "payment for services provided in respect of the goods or services."

Section 9 of the Competition Act does permit price competition by a dominant firm where it can be shown that:

(a) "makes only reasonable allowance for differences in cost or likely cost of manufacture, distribution, sale, promotion or delivery resulting from the differing places to which, methods by which, or quantities in which, goods or services are supplied to different purchasers;

(b) "is constituted by doing acts in good faith to meet a price or benefit offered by a competitor; or

(c) "is in response to changing conditions affecting the market for the goods or services concerned, including –

i. "any action in response to the actual or imminent deterioration of perishable goods;

ii. "any action in response to the obsolescence of goods;

iii. "a sale pursuant to a liquidation or sequestration procedure; or

iv. "a sale in good faith in discontinuance of business in the goods or services concerned.

The exercise of international benchmarking as proposed in South Africa is focused on the elimination of price differentials that cannot be explained by reasonable economic factors. Medicines under patent are in a position of market dominance and therefore are in a position to exercise a significant degree of market power.

Price discrimination is clearly identified by the Competition Act as a prohibited practice because it is one form of market conduct that derives directly from the existence of market power. In terms of this Act a firm is regarded as "dominant" if it controls more than 40% of a given "market”.

Central to the assessment of a market is the identification of the "product market" and the "geographic market". The former defines the product itself, while the latter specifies the geography of the market, i.e. its spatial characteristics.

The product market is defined in relation to a good or service and all its potential substitutes. It is conventional practice to apply the so-called "hypothetical monopolist test" in this exercise. A product market is specified when it is found that a price increase implemented by a hypothetical monopolist for specified goods or services faces no competitive constraint from alternative goods or services provided by another supplier.

Medicines under patent that have no substitutes are clearly in a position of monopoly (there is no need for any hypothetical test). Such medicines are clearly at greatest risk of monopoly pricing and price discrimination.
The economic argument for international benchmarking

Many countries, including the Netherlands, Switzerland; Canada and Saudi Arabia, use international benchmarking, also called internationally-based price regulation (IBPR), as a mechanism for promoting prices that are not subject to distortion by ensuring that the price of medicine within their country is comparable to prices in other countries which have been able to use monopsony purchasing power or other means to counter-balance market imperfections favouring pharmaceutical manufacturers, particularly where they hold a monopoly position on a specific product. International benchmarking is seen as a particularly relevant approach for countries that have low or no purchasing power in relation to pharmaceutical companies, such as where there are many small insurance schemes as is the case in the South African private health sector.

Some may argue that if a country such as South Africa implements international benchmarking, this can limit a pharmaceutical manufacturer’s ability to recover their research and development costs through their careful market segmentation strategies. However, it should be recognised that the monopoly power held by patent-holding pharmaceutical manufacturers enable them to charge prices that yield what are termed ‘super-normal’ profits. There is little transparency in relation to the actual costs of manufacturing medicines, although it is clear that the cost of active ingredients are generally a tiny proportion of the price charged for a medicine. In addition, it is known that expenditure by pharmaceutical manufacturers on ‘marketing’ far exceeds their expenditure on research and development. The onus would be on pharmaceutical manufacturers to provide documented evidence that an international benchmarking strategy undermines their ability to cover their costs of production, research and development and a ‘normal’ profit.
APPENDIX D: OVERVIEW OF THE SELECTED BENCHMARK COUNTRIES

D1. AUSTRALIA

D1.1 Regulatory environment

Australia has an advanced health care system and demand for all types of pharmaceuticals is high. Prices in Australia tend to be low for a developed country, principally due to tight public pricing and reimbursement regulations through the Pharmaceutical Benefits Scheme (PBS). The PBS has come under attack from the multinational industry, and the US government has pressed for changes as part of negotiations for the Free Trade Agreement, which took effect in 2005. The Australian government has, however, consistently affirmed that alterations to the PBS have not been part of any trade deals.

Australia has a small but growing domestic industry, augmented by the presence of many multinational producers. The market remains heavily reliant on imported drugs; local R&D has yet to reach significant proportions, despite continuing government incentives. The majority of pharmaceutical imports are sourced from the European Union. Low prices for branded products mean that generics are not yet widely used.

Regulatory procedures aim to ensure that the quality, safety and efficacy of therapeutic goods available in Australia are of acceptable standard. Overall control of the supply of medicinal drugs in Australia is exerted through three main processes:

- The pre-market evaluation and approval of products intended for supply in Australia;
- The licensing of manufacturers; and
- Post market surveillance.

D1.2 Pricing of pharmaceuticals

Demand for prescription pharmaceuticals is significantly influenced by the operation of the tax-funded Pharmaceutical Benefits Scheme (PBS). Accordingly, pharmaceutical firms are keen for their products to be listed on the PBS to generate sales.

Products will be considered for listing after receiving marketing approval from the Therapeutic Goods Administration (TGA), which considers safety and efficacy issues. Applications for listing on the PBS are considered by the independent Pharmaceutical Benefits Advisory Committee (PBAC). The Committee consists of medical specialists, general practitioners, a pharmacist and a consumer representative. When recommending which drugs and medicinal preparations should be subsidised through the PBS, the Committee must be assured that the drug is effective, safe and cost-effective in comparison with other available treatments. Prior to consideration by the Committee, its Economics Sub-Committee considers the economic aspects of the submission and provides advice to the PBAC on the strength of the evidence of cost-effectiveness. The Sub-Committee consists of clinicians and health economists. The requirement that drugs must be cost-effective before listing on the PBS has been in
place since 1991. Since then, pharmaceutical manufacturers have been required to provide both clinical and economic evidence in their submissions to support the listing of a drug on the PBS. These submissions are subject to rigorous evaluation.

The main mechanism to determine initial prices is the advice from the Pharmaceutical Benefits Advisory Committee (PBAC) which is an independent body of medical experts established to advise the Minister for Health about which products and for what indications products should be subsidised by the Government. PBAC provides advice on clinical effectiveness and cost-effectiveness (value for money). It has been a requirement for drugs sponsors to submit cost-effectiveness data on new items since the start of 1993.

The prices of all products listed on the PBS are reviewed annually by the Pharmaceutical Benefits Pricing Authority (PBPA), an independent non-statutory body with the objective of securing a reliable supply of pharmaceutical products at the most reasonable cost. The price reviewed and agreed to with suppliers is at the 'into-pharmacy' level (which includes a 10% wholesaler's margin). In reviewing the price of listed items and in considering the price of items recommended for listing, the Authority takes into account the following factors:

1. The Pharmaceutical Benefits Advisory Committee's comments on clinical and cost-effectiveness aspects of items;
2. The price of alternative brands of a drug;
3. Comparative prices of drugs in the same therapeutic group;
4. Cost information provided by the supplier;
5. Prescription volumes, economies of scale and other factors such as expiry dating, storage requirements, product stability and special manufacturing requirements;
6. The level of activity being undertaken by a company in Australia, including new investment, production, research and development;
7. Prices of the drug in reasonably comparable countries;
8. Other relevant factors which the applicant company may wish the Authority to consider; and
9. Any directions of the Minister.

In recent years, the PBPA has increasingly recommended the use of price/volume arrangements (unit prices decrease as volume increases), particularly where unit prices are reasonably high and there is the potential for significant volumes or where there is uncertainty about future volumes.

The Pharmaceutical Benefits Pricing Authority uses different pricing methods:

a. Benchmark Pricing

When reviewing prices, the Pharmaceutical Benefits Pricing Authority (PBPA) considers drugs in their therapeutic sub groups. The Department of Health and Aged Care, on behalf of the Minister, participates in negotiations. A benchmark product is chosen on the basis of having the lowest costs - either the price the manufacturer is
prepared to supply at or the lowest cost of production (cost submitted by the manufacturer). Other products are priced in line with the benchmark product. A premium above the benchmark price is allowed where the supplier of the product is able to demonstrate an advantage in clinical and cost-effectiveness terms. Most products listed on the PBS are priced under this method. When recommending the listing of a new product, the PBAC advises on specific relativities between drugs. This relativity is maintained by the PBPA through price adjustments. For example, sponsors at times list new drugs at lower prices than currently listed comparators. When this occurs, the PBPA will approach the existing suppliers to reduce their price or demonstrate that their product is cost-effective at the higher price.

b. Cost Plus Method

Under this approach, the price recommended by the PBPA is based on the cost of manufacture plus a margin. Costs allowed under this method do not include distribution costs, promotional or marketing activity or general administration. This method is used for stand-alone items and for benchmark products. It relies on pharmaceutical suppliers providing the PBPA with accurate cost data. The margin provided under this approach can vary from 15% to 40% (equivalent to a mark-up of between 18% and 67%) depending on a number of factors including the price sought by the supplier, the estimated usage, the unit price and prices in other countries.

c. Average Monthly Treatment Cost

This is a variation of the reference price method, which can be applied within a therapeutic sub-group usually where a medicine used to treat chronic conditions is supplied in a number of strengths. The method takes into account actual clinical usage and requires detailed utilisation data. Under this approach, the weighted average monthly treatment cost is calculated for each of the drugs in the sub-group and these costs are compared. Prices can be adjusted up or down to bring products into line with the alternatives.

D1.3 Coverage and reimbursement policies

The Pharmaceutical Benefits Scheme (PBS) serves to provide timely, reliable and affordable access for the community to needed and cost-effective pharmaceuticals and forms the framework for reimbursement. Approximately 90 per cent of prescriptions in the Australian pharmaceutical market are prescribed for PBS items. Pharmaceuticals not covered by the PBS may be purchased by individual patients at full market price.

Concessional patients pay a reduced maximum annual amount (currently $A171.60) for their PBS items. Once this limit is reached they receive their PBS items free of charge for the remainder of that year. A higher maximum amount applies to general patients (currently $A631.20). Once this level is reached they pay $A3.30 for each PBS item for the remainder of that year. This patient contribution is indexed and adjusted annually. In addition, eligible pensioners such as veterans, people on sickness allowance and other recipients of income support, receive a pharmaceutical allowance to help defray their out-of-pocket pharmaceutical expenses.

This scheme has been in operation in Australia for more than 50 years and currently covers about 560 drug substances available in about 1,350 forms and strengths and marketed as about 2,000 different brands.
Pharmaceuticals listed under the PBS fall into three broad categories:

- Unrestricted Benefit – These medications have no restrictions on their therapeutic uses;

- Restricted Benefit – The listing in the PBS Schedule details the specific therapeutic uses for which these medications can be prescribed; and

- Authority Required Benefit – As with the Restricted Benefit, the Schedule lists the specific uses for which these medications can be prescribed. In addition, for items listed under this category, the prescriber is required to obtain prior approval from the Government’s Health Insurance Commission.

D1.4 Policies relating to generic products

The use of generics has been encouraged since December 1994 under the PBS arrangements for brand substitution by pharmacists. Under the PBS, the Government subsidises up to the price of the lowest priced brand (except in those instances where the lowest priced brand has, as part of its price, a therapeutic group premium). This means that consumers may have to pay extra for more expensive brands (those with a brand premium). Brand substitution by pharmacists without reference to the prescriber is permitted for PBS prescriptions under certain conditions. Where the patient agrees to the substitution; the brands are identified in the Schedule of Pharmaceutical benefits as being interchangeable.

The market share held by generics supplied through the PBS has increased constantly over the past 15 years.

The policy for alternative brands has had the effect of making prescribers and patients more aware of the price of drugs. The policy also allows companies to establish prices taking into account competition and the heightened consumer awareness of price differentials.

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D2. CANADA

D2.1 Regulatory environment

In 2006, about 20,750 human drugs were available in Canada, of which 6,400 are prescription-only medications; 1,090 are “ethicals”, which do not need prescription but are generally prescribed by physicians; 8,429 are OTC drugs and 4,846 are in the category called Natural Health Products (includes vitamins, minerals, herbal products, and homeopathic medicines). Provinces may impose further restrictions on drug dispensing.
Health Canada, through its Health Products and Food Branch, is responsible for regulating the manufacturing, sale and import of therapeutic products. Health care is a responsibility that is shared with provincial and territorial partners.

The provincial and territorial governments are responsible for:

- managing and delivering health care services;
- planning and evaluating the provision of hospital care, physician care and allied health care services;
- providing public drug benefit plans to certain segments of their population -- all provinces and territories provide coverage to seniors and those receiving social assistance;
- managing drug formularies (a list of drugs for which public reimbursement from government drug plans is available) -- in some cases, drugs have a restricted status limiting coverage to particular types of patients or situations; and
- the practice of medicine/pharmacy and the regulation of health professionals.

Review of drugs and medical devices at the provincial level includes:

- assessing whether a brand-name drug and its generic competitor are interchangeable. If products are deemed to be interchangeable, provincial reimbursement is typically limited to the price of the lower-cost generic;
- reviewing the therapeutic value and cost-effectiveness of new drugs and medical devices on behalf of most federal, provincial and territorial drug plans by the Canadian Coordinating Office for Health Technology Assessment (see below); and
- prior to including a drug or medical device in a formulary and thereby making it eligible for coverage, provinces typically assess how such a decision will affect the public purse.

**D2.2 Pricing of pharmaceuticals**

Prices of off-patent original products and generic products are not directly regulated in Canada. Since 1987, prices of patented medicines have been regulated at the federal level to ensure that they are not 'excessive'. The authority for regulating the prices of patented medicines is the Patented Medicine Prices Review Board (PMPRB), which was created in 1987 through amendments to the Patent Act. The PMPRB mandate is limited to the regulation of manufacturers' prices of all patented drugs for the duration of their patent life, whatever their status (available OTC or by prescription-only, for human or veterinary use). The Board does not regulate off-patent drugs, and does not consider determinants of the prices paid by consumers, such as wholesalers’ and pharmacists’ margins. The Board’s authority extends to the prices of existing drugs as well as new drugs. PMPRB must report annually to Parliament on its activities, on R&D spending by drug patentees and on drug pricing trends.

The PMPRB compares the proposed Canadian price either to prices of existing drugs in Canada, or to prices in seven markets designated in the regulations: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.
These comparator countries were selected as ones that had or aspired to have a strong national presence of the pharmaceutical industry. Price increases are limited to changes in the Consumer Price Index (CPI). In addition, the price of a patented drug may, at no time, exceed the highest price of the same drug in the seven foreign countries. To assess the compliance with the rules regarding price increases, the price of a product in a particular year is compared to its price three years before, adjusted by 3-year cumulative CPI. In addition, the price cannot increase by more than 1.5 times the CPI increase for a given year.

The ‘excessive price’ criterion used in assessing the price of a new drug depends on the ‘degree of innovation’ of the new product, as categorised by the PMPRB using a three-tiered scale:

- Category 1 comprises drug products that are a new strength (e.g., 50 mg vs. 100 mg) or a new dosage form (e.g., tablet vs. capsule) of an existing medicine. The price is considered excessive if it does not bear a "reasonable relationship" to the average price of the existing medicine in comparable dosage forms.

- Category 2 comprises drug products that represent a therapeutic breakthrough or provide substantial improvement (including cost savings) over comparable existing medicines. The price is excessive if it exceeds the prices of comparable products in the therapeutic class and the international median price of the medicine.

- Category 3 comprises drug products that provide moderate, little or no therapeutic advantage over comparable medicines. For these so-called ‘me-too’ drugs, the price is judged excessive if it exceeds the price of comparable products in the Canadian market. PMPRB may use the international median price as a reference when it is impossible or inappropriate to identify comparable drugs in Canada.

Drugs are classified in the above three categories by experts of the Human Drug Advisory Panel (HDAP), which reviews all the available information on the drug and its comparators. The Human Drug Advisory Panel is composed of three designated members, chosen for their scientific expertise in drug therapy, clinical research methodology, statistical analysis and the evaluation of new drugs. HDAP also relies on scientific assessments made by PMPRB staff.

Manufacturers are requested to furnish price levels for four classes of customer (hospitals, pharmacies, wholesalers and other) in all provinces of Canada, as well as prices in the seven comparator countries, when relevant. Although the PMPRB considers the national Average Transaction Price (ATP), it retains authority to act on the basis of any manufacturer’s price found to be excessive for any class of customer in any market in Canada.

Upon the request of a manufacturer, the PMPRB will assess the price of a new drug prior to its launch in the market and issue an Advance Ruling Certificate (ARC). This provides the manufacturer with some assurance that the price proposed will not be found to exceed the maximum allowable price resulting from the PMPRB’s price guidelines. ARCs are non-binding for PMPRB, however. PMPRB issued one ARC in 2004 and none in 2005.
When the PMPRB considers a price to be excessive according to the criteria defined above, there are two alternatives:

1. If the company agrees to cut its price and to pay to the government of Canada some compensation for the excess revenues earned, it must submit a Voluntary Compliance Undertaking (VCU);

2. If the company does not agree with the PMPRB, the Board holds a public hearing to reconsider the conclusion of excessive price and, if affirmed, make a judgment regarding penalty. If the public hearing confirms that the price is excessive, the company may appeal to the Federal Court of Canada to ask that the Board decision be overruled.

In 2005, the PMPRB reviewed the prices of 66 new patented drugs, of which 15 appeared to be priced outside the guidelines and were subject to further investigation.

According to PMPRB estimates, Canadian prices have moved closer to median international prices since price regulation commenced in 1987. In 1987, Canadian prices for medicines exceeded the international median by more than 20%. After a fairly consistent annual decrease until 1994, the prices have since stabilized at or up to 10% below the median in seven comparator countries. In 2005, prices of patented drugs in Canada were about 8% lower than the median prices of the seven comparator countries. These data suggest that Canadian price regulation has had a dampening effect on relative price levels in Canada, bringing them closer to the median price paid in a selected set of countries.

**D2.3 Coverage and reimbursement policies**

Coverage in Canada is distinct from many other OECD countries with respect to the significant role of private insurance as a source of coverage for drugs prescribed for use outside the hospital setting. Another notable characteristic is the decentralisation of public drug program administration and delivery, which is distributed among the country’s 13 jurisdictions (10 provinces and 3 territories), plus certain drug plans under federal jurisdiction. Finally, drug coverage in Canada has to be put in the context of free provision of all medical services guaranteed by the Canadian Health Act.

Given the growing cost of medicines and the unpredictability of need, drug coverage is an important determinant of the accessibility of medicines. Within the various public and private plans, formulary restrictions, reimbursement policies and cost-sharing requirements have a role to play in determining access.

While drugs administered in hospitals are covered through the universal, publicly financed Medicare programme, other prescription drugs are not included among the insured benefits guaranteed by the Canada Health Act. Consequently, about two-thirds of Canadian residents are covered for prescription drugs by private insurance obtained through their employer or purchased on an individual basis. Provinces and territories administer publicly financed programmes to provide prescription drug coverage concentrated on seniors, social assistance recipients (including disabled citizens), and persons with special needs (e.g., high drug expenditures relative to income), while federal programmes exist for indigenous persons (First Nations and Inuit peoples), veterans, Canadian Forces members, Royal Canadian Mounted Police members, certain designated classes of immigrants, and inmates of federal penitentiaries, including some former inmates on parole. According to the Auditor
General of Canada (2004), about one million Canadians are eligible for federal drug benefits and more than nine million people are covered by provincial plans. According to estimates for 2000, 98% of the Canadian population has some form of public or private sector drug plan coverage that provides a degree of protection against severe drug expenditures.

Degrees of coverage by public drug plans vary across provinces and territories.

Four provinces offer 'universal eligibility' for public drug coverage: Alberta, Manitoba, Saskatchewan and British Columbia. In Alberta, residents not covered by other plans may apply for coverage in the public programs (for which they are required to pay premiums and co-payments). In the three other provinces, all residents are entitled to enrol in the public plan but deductibles may dissuade them from doing so, especially if they have high income and/or have access to more generous coverage through private insurance.

Québec implemented a universal drug coverage scheme in 1997. The system requires workers to subscribe to private plans offered by their employer and provides publicly financed drug coverage for all residents who are not otherwise covered by a private group insurance plan. The system is funded by various parties at different rates. For the public plan, the premium (paid through the contributor's income tax return), deductibles and co-payments that a resident pays depends on age, net family income, and whether or not they are recipients of certain social programs. Residents who have access to a private plan do not partake in the public plan, but must also pay premiums, though how this is paid and the amount varies by plan. In 2005, 43% of Québec residents were covered by the public provincial scheme, either because they had no access to private coverage (24%) or because they were entitled to public coverage (19%) as seniors or as social assistance beneficiaries of the province's "Employment Assistance Program". Almost all other residents are covered by private insurance. The public regime requires the payment of a means-tested annual premium, ranging from $0 to $538, above a revenue threshold (for the period July 2006 to June 2007).

In Ontario, the Ontario Drug Benefit program (ODB) offers drug coverage to Ontario residents who are beneficiaries of the Ontario Health Insurance Plan (public coverage of medical services) and belong to one of the following categories: people 65 years and older, residents of long-term care facilities, residents of homes for special care, people receiving professional services under the Home Care programme, and recipients of social assistance programs. In 2004, the ODB covered 2.9 million people (23% of the Ontario population) and other public programs (such as federal programs) covered 246,000 people (2%). Another 7.5 million (58%) Ontario residents were covered by private insurance, while 2.2 million people (17%) were uninsured (Government of Ontario, 2006).

In British Columbia, PharmaCare was launched in 1974 as a social assistance programme for seniors and low-income residents. PharmaCare now includes a variety of plans covering prescription drugs for eligible populations, including permanent residents of long-term care facilities, recipients of income assistance, and children who qualify for aid. Other plans provide coverage for those who meet eligibility criteria and require certain types of drugs, including psychiatric drugs, palliative care drugs, and treatment for cystic fibrosis and HIV/AIDS. On the top of these plans, Fair PharmaCare was introduced in May 2003 to improve the equity of financial assistance for purchase of prescription drugs. It functions as a safety net, providing means-tested assistance for the purchase of prescription drugs. Every British Columbia resident is eligible for this programme but people covered by private insurance have generally no
incentive to enrol unless they face exceptional drug expenditures since deductibles are high (deductibles are means-tested: the annual deductible is 0 if the net family income is less than Can$15,000, 2% of the income if income is between $15,000 and $30,000 and 3% beyond). In 2003, PharmaCare covered 899,700 people, i.e. 21.7% of the population of British Columbia, including more than three-quarters of those residents aged 65 and older.

The Non-insured Health Benefits (NIHB) is a federal program administered by Health Canada. Its aim is to ‘support First Nations and Inuit people in reaching an overall health status that is comparable with other Canadians’ (NIHB website), by covering health goods and services not covered through other private or provincial/territorial health insurance plans. The NIHB program provides coverage for a specified range of drugs, dental care, vision care, medical supplies and equipment, short-term crisis intervention and mental health counselling. Drug coverage is its most important component, representing more than 44% of NIHB’s expenditures. The NIHB program covers about 765,000 people. The enrolled population is relatively young, with an average age of 29 years and only 4.5% being more than 65 years.

A drug’s inclusion in a formulary, or list of medicines eligible for reimbursement by a third-party payer, is an important determinant of the accessibility of that medicine to persons covered by insurance. In Canada, where Medicare covers hospital care including medicines furnished to hospital patients on an inpatient basis, individual hospitals are responsible for developing their own formularies. Private insurers are free to draw up their own formularies. Provinces make their own decisions regarding the formularies used by provincial drug plans.

Following the recommendations of the Commission on the Future of Health Care in Canada (2002), also known as the Romanow Commission, a Common Drug Review (CDR) was launched in 2003. The CDR is an intergovernmental collaborative body which aims at evaluating new chemical entities (NCEs) and new combinations to inform an official recommendation as to whether a drug should be included in the formularies of participating publicly financed drug plans.

The CDR is part of the Canadian Agency for Drugs and Technology in Health (CADTH). This agency, until recently known as the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), was created in 1989 to assess medical services and to inform decision-makers’ health technology choices. CADTH is funded by Canadian federal, provincial and territorial governments.

Processes and rules for formulary listing differ among provinces and territories, reflecting both historical development and policy objectives. Except for Québec, all other Canadian jurisdictions now consider CDR recommendations when making their own decisions. Decision criteria and methods vary. Generally, formulary decisions are made by the respective provincial or territorial Ministry of Health based on the recommendations of a committee.

Economic considerations are often taken into account, even if these considerations are not always predominant in formulary decisions or explicitly outlined in decision-making criteria. What is meant by economic considerations ranges from simple budget impact analysis to more elaborate cost-effectiveness studies provided by the manufacturer. Pharmaco-economic assessment has been formally taken into account in reimbursement decisions for several years in Ontario and British Columbia. However, no explicit cost-effectiveness threshold has been defined by any jurisdiction. In cases where provinces decide against formulary inclusion on the
grounds that the drug is not cost-effective at the proposed price, manufacturers are not constrained from presenting a new application with a lower price.

Canadian hospitals operate under fixed budgets and/or payment per case, which they use to procure drugs provided free-of-charge to their patients. Hospitals typically use group purchasing programs to establish group contracts for set prices. The hospital then buys directly from the manufacturer at the contract price.

Private health insurance plans tend to act as passive payers, typically reimbursing plan members (who normally must pay out-of-pocket first and then seek reimbursement) for the costs of prescribed medicines used by their enrollees that are included in a given plan’s formulary, less any cost-sharing amount. The reimbursement arrangements may or may not cover the dispensing fee charged by the pharmacist.

Provincial, territorial and federal drug plans define reimbursement prices for pharmaceutical products covered under their formularies and, in some instances, use elaborate methodologies for determining reimbursement amounts. The reimbursed prices may differ from manufacturer’s list prices.

Public plans use different formulas to pay for prescription drug purchases and distribution services. When pharmacy reimbursement prices are pre-defined, this is generally the price paid to the pharmacy by the plan; in other cases the pharmacy’s actual acquisition price is paid. Wholesale margins paid by the pharmacist are generally compensated according to a fixed or capped mark-up. Types and amounts of dispensing fees paid are defined by each plan.

Reimbursement prices are paid to retailers, whereas wholesalers or retailers purchase drugs at the price set by the manufacturer.
### Table D1: Formulas used by public plans to reimburse drugs and related pricing policies

<table>
<thead>
<tr>
<th>States</th>
<th>Reimbursement of drugs by the public plan</th>
<th>Special pricing policies</th>
</tr>
</thead>
<tbody>
<tr>
<td>British Columbia</td>
<td>Actual acquisition cost (capped to a maximum price) + wholesaler’s mark up (capped at 7%) + dispensing fee (capped to a maximum)</td>
<td>Reference prices for five therapeutic classes: H2-receptor antagonists (treatment of non-ulcer dyspepsia or upper gastrointestinal tract complaints), Nitrates (treatment of angina), NSAIDs (treatments of osteoarthritis and rheumatism), ACE inhibitors and Calcium Channel Blockers (both for hypertension) Cost of the cheapest proton pump inhibitors (ulcer treatment) for first-line treatment Low-cost alternative program: cost of the least expensive drug in generic groups</td>
</tr>
<tr>
<td>Saskatchewan</td>
<td>Actual acquisition cost + mark-up allowance (three-tiered scale markup ranging from 30% to 10%) + dispensing fee (capped to $8.21).</td>
<td>Lowest cost alternative in generic groups Standing-offer contracts for generics Maximum allowable costs (reference price) since July 2004, only for proton pump inhibitors – to be expanded.</td>
</tr>
<tr>
<td>Alberta</td>
<td>Actual acquisition cost + Professional fee (three-tiered mark-up ranging from CAN$10.22 to CAN$20.94) + inventory allowance (three-tier sliding scale, ranging from CAN$0.71 to CAN$0.03).</td>
<td>Lowest cost alternative within generic groups Maximum allowable cost (reference price) in groups of interchangeable drugs Generic price capped at 75% of the original product price</td>
</tr>
<tr>
<td>Manitoba</td>
<td>Actual acquisition cost + Professional fees</td>
<td></td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>Actual acquisition cost + Professional fees (two-tiered markup ranging from CAN$10.42 to CAN$15.64) + 10% for some products.</td>
<td>Maximum allowable cost price for interchangeable products, primarily generic drug products</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>Actual acquisition cost + dispensing fee (ten-tiered, ranging from $8.40 to $161)</td>
<td>Maximum allowable price for generic groups</td>
</tr>
<tr>
<td>Prince Edward Island</td>
<td>List price</td>
<td></td>
</tr>
<tr>
<td>Newfoundland</td>
<td>List price</td>
<td>Maximum allowable cost for 11 generic groups of over-the-counter drugs</td>
</tr>
<tr>
<td>Québec</td>
<td>“Acquisition price”, which is either the price guaranteed by the manufacturer for wholesalers or the price guaranteed for sales to pharmacist + the actual wholesale markup27 (capped to $20 for costly drugs).</td>
<td>Requires the best available price in Canada for listed drugs</td>
</tr>
<tr>
<td>Ontario</td>
<td>List price + mark up + Pharmacist fee</td>
<td>Price-volume agreements with manufacturers Generic price capped at 50% of the original product price</td>
</tr>
<tr>
<td>NIHB</td>
<td>Acquisition cost + mark-up + pharmacist fee</td>
<td>Best price alternative in generic group and in reference price groups when applicable in the province.</td>
</tr>
</tbody>
</table>
As the most important third-party payer in their jurisdiction, provincial plans have significant purchasing power, enabling them to institute a range of reimbursement policies for price control and cost-containment. Almost all publicly financed third-party payers employ some policies aimed at containing pharmaceutical costs. Several tools are used by the plans to control reimbursement prices of drugs: direct negotiations with manufacturers, constraints imposed on manufacturers, use of reference prices or lowest cost alternatives, bids and across-the-board price freezes.

Provincial drug plans engage in very little direct negotiation with manufacturers regarding reimbursement prices. Ontario introduced in 1998 so-called “cost-sharing arrangements” linking prices to expected volumes of sales. This regulation requires written agreements between the product sponsor and the Ministry of Health for all new brand-name drugs listed in the ODB formulary. Manufacturers have to provide sales forecasts for the 3 years following listing and, if sales later exceed the forecasts, may be asked to demonstrate that no inappropriate use occurred (for instance, if new uses have been approved). An audit conducted in 2001 revealed that, in most cases, actual expenditures were at least 10% below the forecast provided by the manufacturer.

The price guaranteed by the manufacturer may be higher for direct sales to pharmacists than for wholesalers, but the difference between the two prices cannot exceed 9%. If this difference is greater than 5%, the price paid by the public plan is the price guaranteed for pharmacists and includes payment for the wholesaler. If this difference is lower than 5%, the price paid is the price guaranteed for wholesalers + the actual wholesale markup.

Since 1998, Ontario has required that the price of the first generic listed on the formulary not exceed 70% of the brand-name product price and that prices of subsequent generic entrants not exceed 90% of the price of the first generic product. As of October 2006, generics will have to be priced 50% lower than the comparator product to be listed in the Ontario drug benefit formulary. Alberta also limits the price of generic entrants to 75% of the brand-name price. As a consequence of its own regulation requiring the “best available price”, Québec benefits from the regulation adopted in Ontario. In a policy paper issued by the Québec Ministry of Health in December 2004, the government proposed to further regulate the price of generics by limiting the price of the first entrant to 60% of the originator’s brand-name price and the price of following entrants to 54% of that price.

British Columbia is the only province using so-called internal or therapeutic price referencing. This system, established in 1995, sets reimbursement caps below the level established by PMPRB price guidelines. The reimbursement price is defined as the price of the most cost-effective drug of the therapeutic class. Reference prices exist for five therapeutic classes. Similarly, in 2003, British Columbia limited the reimbursement for proton pump inhibitors (PPIs) to the cost of the least expensive PPI product for first-line treatment. British Columbia’s reference price system was highly contested by the pharmaceutical industry. Independent researchers concluded that the public drug plan realised net savings by implementing this policy, even if the reform seems to have had a one-time effect in some drug classes with cost growth resuming at the former rate. Several plans set reimbursement prices at the level of the least costly alternative in generic groups. Québec adopted such a policy with a particular feature: the rule applies only 15 years after the listing of the brand-name product in the positive list. In the interval between patent expiry and this deadline, generics are
authorised and reimbursed but originator drugs are still reimbursed at their initial price.

Reimbursement price freezes have been used in at least two provinces. Since 1994, Ontario has introduced freezes on the retail price it will pay for drugs listed on its formulary. In Québec, prices of drugs included in the positive list are not allowed to increase, except in exceptional circumstances (such as an increase in the cost of an input).

Both public and private plans usually require patients to contribute to the cost of medicines through some form of cost-sharing. Private drug plans generally impose deductibles and copayments. Employer-sponsored drug plans have lower levels of cost sharing than do individual plans, typically setting annual deductibles at about CAN$ 25 for individuals or CAN$ 50 per family and copayments at 20% of the cost (however, copayments vary from 0 to 30%). In 2000, about 29% of private plans did not require any co-payment. Out-of-pocket payments are regularly capped at $2,000 per year. Enrolees may have to pay pharmacists’ fees.

Co-payment is the most common form of patient cost-sharing in public drug plans. Total out-of-pocket spending amounts are sometimes capped. Deductibles are also frequently used. Enrolees sometimes have to pay pharmacists’ fees. Cost-sharing requirements tend to be set at higher levels, as compared to private employer-sponsored plans.

D2.4 Policies relating to generic products

In addition to patent policy and policies pertaining to the approval process, a number of other policies affect the prescribing and dispensing decisions that determine the share of prescriptions that are filled with generic formulations of pharmaceutical products.

Provinces usually establish lists of interchangeable products after generic market approval by Health Canada. These lists generally apply only to public drug plans but some provinces (British Columbia, Manitoba, New Brunswick and Nova Scotia) extended interchangeability rules to the whole market. This means that provincial scientific committees re-assess the equivalence of generic drugs imposing further delays for substitution and introducing discrepancies in substitution possibilities across provinces. Generic manufacturers claim for immediate interchangeability after Health Canada approval. This rule already applies in British Columbia where, since mid-2003, pharmacists have been allowed to rely on data published by Health Canada or on information from their professional association to make judgements on drug interchangeability.

Financial incentives for generic utilisation differ from one province to another but are generally directed to patients rather than to pharmacists. They consist of reimbursement policies that require patients to pay out-of-pocket the difference between the retail price and the reimbursement level for a drug included in a reference group of interchangeable drugs. As a result of discrepancies among provincial policies, there is significant variation across Canada in the extent to which generic alternatives are dispensed in place of brand-name products, providing an indication of the impact of policies relating to prescribing and dispensing of generics. For instance, generic products were dispensed for only 38% of prescriptions filled in Québec during 2005, compared with 49% in British Columbia.
Overall, Canada's drug patent policy aims to achieve a balance between adequate patent protection and timely introduction of generic drugs. Adequate patent protection is needed to encourage the development of better drug therapies, while timely introduction of generic drugs, coupled with patented medicine price regulation, helps to contain drug costs. The Patent Act of 1923 and its subsequent amendments define patent rights in Canada. Before 1987, patents pertaining to drug and food were for shorter terms than in some other developed countries, and were subject to compulsory license to manufacture (since 1923) and to import (since 1969). In 1987, amendments to the Patent Act were introduced (Bill C-22) to enhance patent protection of pharmaceuticals. These amendments guaranteed an increase in protection against compulsory licensing after market approval: 10 years against compulsory licensing to import and 7 years against compulsory licensing to manufacture. They also introduced the ability to issue product patents to complete the protection offered by process patents. As well, the patent protection period was extended to 20 years from date of filing instead of the previous system granting 17 years from date of patent's issue.

In 1993, following negotiations related to the General Agreement on Tariffs and Trade (GATT) and the North American Free Trade Agreement (NAFTA), the government passed Bill C-91, which substantially amended Canada’s drug patent policy. Most notably, C-91 repealed Canada’s longstanding compulsory licensing regime for patented drugs and introduced in its stead what is commonly called the “early-working” exception, as well as a provision to ensure that generic drugs will not be marketed before patent expiry.

The “early-working exception” allows generic manufacturers to use the patented invention without the patentee’s authorisation for the purpose of obtaining approval of a generic product before the patent expiration date. To prevent generic manufacturers from selling their approved drugs before patent expiry, Bill C-91 introduced the Patented Medicines (Notice of compliance) Regulations. This provision requires patentees to provide Health Canada with the list of valid patents linked to any product when seeking approval. Generic manufacturers have to check dates of patent expiry of listed patents before marketing their drugs or to make an attestation explaining why their product is not infringing on current patents. If the patentee disagrees, litigation ensues and an automatic stay is triggered that bars Health Canada from issuing the generic product a marketing authorisation for 24 months, until the litigation is resolved or the patent expires, whichever comes first. These amendments also introduced the prices regulatory body, which later became the PMPRB.

As of May 2005, Canada permits compulsory licenses to be issued to manufacturers to produce certain drugs for export to a developing country for treatment of designated public health problems (e.g., HIV/AIDS, tuberculosis, malaria and other epidemics), providing the ability for Canada to export generic versions of patent-protected drugs to eligible importing countries unable to manufacture their own products. Compulsory licensing allowed generic manufacturers to make and sell generic versions of patented drugs before patent expiry, in exchange for royalty payments to patent holders. However, Canada repealed this provision to comply with a World Trade Organisation ruling against it.

Unlike a number of other OECD countries, Canada does not have any specific IPR policy aimed at encouraging R&D for orphan drugs, such as extended patent protection.

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D3. New Zealand

D3.1 Regulatory environment

Medsafe, a public health authority, is responsible for ensuring that, as far as possible, the medicines available in New Zealand can be expected to have greater benefits than risks if used appropriately. This is achieved through:

- Assessing the safety, quality and efficacy of medicines before they are marketed
- Auditing manufacturers, packers and wholesalers of medicines to ensure their premises and practices meet an acceptable standard.
- Monitoring the safety of medicines on the market

Medsafe applies a risk category approach to the processing of applications to market new medicines. The subsidization of medicines by government is administered by PHARMAC. This government agency uses strategies such as reference pricing and sole supply tendering to reduce the country’s drug bill. The overall effect of this agency’s policies is to create a generic industry, which is perceived as hostile to innovator companies.

D3.2 Pricing of Pharmaceuticals

To be able to sell their product in New Zealand, suppliers must gain marketing approval from Medsafe, a division of the Ministry of Health. Once this has been achieved, suppliers are able to market their products with no constraints on pricing, i.e. they are free to set their own prices – this applies equally to ethical and OTC products, as well as on patent and generics.

If suppliers wish to gain a government subsidy for their product, they have to gain listing on the Pharmaceutical Schedule. The Schedule is a list of all medicines subsidised for use in community care. It specifies the price and subsidy of the medicine. In some cases these are the same, in others the price may be greater than the subsidy. In some cases the supplier is bound by contract to set the price no higher than the subsidy. The Schedule includes some items that are OTC, and also includes both patent (brand name) and generic products.
D3.3 Coverage and reimbursement policies

The same process as for gaining a government subsidy applies to the reimbursement of all pharmaceuticals, whether or not they are on patent or generic, or OTC or prescription only.

PHARMAC, the Pharmaceutical Management Agency of New Zealand, a government agency, decides which products should be subsidized. The items are listed on the Pharmaceutical Schedule. PHARMAC's Board makes reimbursement decisions, which specify the drugs that are listed on the Pharmaceutical Schedule. The Board currently comprises six members who have a range of roles and responsibilities within other parts of the health sector.

The Board decides to list an item (or make other changes to the Pharmaceutical Schedule) after considering a set of criteria. These cover the health needs of the population, how these needs are met by the particular pharmaceutical concerned, the cost-effectiveness of this therapy compared with other options for treating that condition and other uses of health funds, and the overall impact on the pharmaceutical budget. Prior to the Board making a final decision, there is consultation on the proposal. Other pharmaceutical suppliers, medical groups, pharmacy groups and relevant patient groups are usually included within the consultation. Decisions of the Board are made known by publishing updates to the Schedule each month.

PHARMAC's overall goal in managing the Pharmaceutical Schedule is to improve the value (in terms of patient healthcare) from the government's expenditure on pharmaceutical subsidies. It uses a variety of means to try and influence the price and subsidy paid for the pharmaceutical. These include:

- Reference pricing of pharmaceuticals, that is setting a common subsidy across those pharmaceuticals in a therapeutic sub-group;
- Contracting with a supplier to fix the price and subsidy of a medicine for a specified period;
- Contracting with a supplier to list one product on the Pharmaceutical Schedule in exchange for a price and subsidy reduction on another;
- Contracting with a supplier to pay a rebate if aggregate expenditure on an item exceeds a specified level;
- Tendering for the sole brand of a chemical listed on the Pharmaceutical Schedule for a given period.

Patients are required to pay prescription charges on each subsidised item. Currently the maximum prescription charge is NZ$15 for 3 months supply of the item. Patients pay lower amounts depending on age (patients under 6 years of age receive free medicines) and income. If a family has more than 20 prescriptions within a year, the charge falls to between NZ$0 and NZ$2.17

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D3.4 Policies relating to generic products

Pharmaceutical companies wishing to market generic medicines must provide information to Medsafe to show that their medicine has the same effect as the innovator medicine.

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D4. SPAIN

D4.1 Regulatory environment

In 1986, the General Health Law established a National Health System (NHS) in Spain. It is a highly decentralised system, with universal coverage and finance from general taxation. This has replaced a more centrally organised system. There are 17 Autonomous Communities, which have complete power regarding public health and health care services planning. Financing of the health system remains centralised and is distributed to the Autonomous Communities according to a capitation formula. Health care is provided free of charge except for pharmaceuticals. Only 15% of the Spanish population is covered by private health insurance.

The most relevant actors in the pharmaceutical system are:

- The Directorate General of Pharmacy and Health Products of the Ministry of Health.

- The General Subdirectorate of Quality of Medicines and Health Products within the Directorate General of Pharmacy and Health Products of the Ministry of Health

- The Interministerial Commission on Pharmaceutical Prices (Comision Interministerial de Precios de los Medicamentos)

- The Spanish Medicines Agency (Agencia Española del Medicamento y Productos Sanitarios, AEMPS)

Spain is a growing centre for pharmaceutical research and development (R&D). The pharmaceutical sector is widely considered to be the most innovative industry in Spain. There are currently around 250 pharmaceutical companies with production activities in Spain.

D4.2 Pricing of pharmaceuticals

Until the end of 1997, the prices of all pharmaceuticals were statutorily regulated. The pricing of non-reimbursable pharmaceuticals is now unregulated. The pricing of reimbursable prescription-only pharmaceuticals is carried out by the Interministerial Commission on Pharmaceutical Prices operating under the Ministry of Health, which
is made up of representatives of the Ministry of Health, the Ministry of Finance and the Ministry of Industry, although it is the former of these that has the most say.

The Ministry of Health may set a time period for which the price acceptable for reimbursement is valid, and prices may be revised due to technical, budgetary or health-related issues. However, there are no formal post-launch price reviews and, with the exception of a very small number of pharmaceuticals, once the price of a pharmaceutical has been agreed, the government will generally not seek to revise it.

In setting the manufacturer price of reimbursable prescription-only medicines, the Interministerial Commission on Pharmaceutical Prices assesses the following criteria:

- The therapeutic value of a pharmaceutical;
- Sales forecast (if the company exceeds this forecast, it is penalised);
- Prices of similar pharmaceuticals in Spain and other European countries;
- The overall cost of R&D, production costs and the price of raw materials.

The pricing decision is based mainly on the calculation of the “total cost” of the pharmaceutical, which includes R&D costs, production costs and a certain level of profit. The profit level per company is set within an industry range, which is calculated on a yearly basis by the Governmental Delegate Committee for Economic Issues within the Treasury. Manufacturers may apply for individual price revisions. The process is similar to that for obtaining an initial price, although companies also have to submit an application for modification of the price and a document justifying why the price should be increased. The aim is to set a price that would generate a return of approximately 12-18% on the company’s investment, i.e. profit must not exceed 12-18% of capital employed. Generics manufacturers are legally obliged to price their products at or below the reference price level. Most have opted to cut their prices below the reference price for competitive reasons.

Pharmaco-economic studies are beginning to be used in several decision making contexts, although their submission is not mandatory, nor is it clear to what extent they actually influence the outcome of price and reimbursement decisions. Providing pharmaco-economic evidence is not mandatory but companies normally submit a pharmaco-economic report showing the pharmaceutical’s budgetary benefits along with the pricing dossier. Although these data are used to some extent in deciding access to reimbursement for pharmaceuticals likely to have a large budgetary impact, European average prices, volumes / unit price trade-offs and company turnover are more important factors in the pricing and reimbursement process than economic evaluations.

There is strong government pressure on all pharmaceutical prices. In 2005, central government decreed an across-the-board 4.2% cut in prices, followed by a further 2% cut in 2006 for all products that had been on the market for over one year and have not been subject to the reference price system. Also in 2005 a law came into effect requiring companies to make a contribution of between 1.5% and 4.5% of their sales to the public system, according to each company’s sales to the NHS.

A royal decree has been issued in connection with a new pharmaceutical law, approved by the Spanish Congress in June 2006. The decree sets in place the mechanisms for the new reference-pricing system effective from March 2007. The
government hopes that the new system alone will reduce government's annual health care expenditure by approximately €600 million.

Under the new system, the prices of prescription drugs reimbursed by the state, which have been marketed in the country for 10 years or more and have a generic equivalent in Spain, will be set at the average price of the three lowest generics. If a second indication has been approved for a given product, it can stay outside the reference pricing system until it has been on the market for 11 years, rather than 10.

Innovator drugs, or drugs with no generic equivalents available in Spain will be exempt from the system for five years. This rule will also apply to products offering methods of administering other than those originally approved, for example if the new method is easier, safer or presents clear clinical benefits. All state-reimbursed prescription drugs in the market for 10 years or more but with no lower-priced generic equivalent available within the EU will have their price reduced by 20%. In cases where the new reference-pricing system causes the price to fall by more than 30%, manufacturers are permitted to reduce prices by 30% annually until they reach the set reference price.

Farmaindustria, the Spanish pharmaceutical industry association, estimates that branded manufacturers have to expect a €750 million reduction in overall revenue in the first year after the introduction of the reference pricing system, approximately a 7.5% fall in total annual sales of branded drugs.

Low prices have always made Spain a major source of parallel-trade pharmaceuticals in the European Union. Spain's exports of finished pharmaceutical products amounted to €4,371 million in 2005, an increase of 23.5% as compared to 2004, of which approximately a third went to the UK and Germany.

In 2005 the average price of medicines sold in Spain was €7.49 (ex-manufacturer), an average of €4.34 for a generic product and €14.78 for pharmaceutical specialities for chronic conditions. Spain has a standard VAT rate of 16% and a reduced VAT rate for medicines of 4%.

In 2005, pharmaceutical sales in Spain reached €11.328 million, a 6% rise on the previous year, of these 76.9% were through retail pharmacies and the rest through hospitals. Spain's prescription market (96% of retail sales) has risen only moderately at 5.7% which is due to the 4.2% reduction in ex-manufacturer prices of publicly financed products and a 1% cut in the distribution margin as well as a cut in the retail pharmacy margin for generics.

The total value of prescriptions under the National Health System in 2005 was €10.051 million, 5.6% more than in 2004. At €13.50, the average cost per prescription was 0.67% more than in the previous year. Of total public expenditure for pharmaceuticals, 77% was accounted for by population groups free from co-payment, mainly pensioners. Total spending by the active population accounts for the rest. The average co-payment paid by the patient in the total reimbursed pharmacy market valued at retail prices was approximately 7.1%.

D4.3 Coverage and reimbursement policies

The decision on inclusion for reimbursement lies in the competence of the Ministry of Health (Directorate General of Pharmacy and Health Products). The Spanish regions will be included in the pharmaceutical reimbursement process under new draft
statutes for the Spanish Medicines Agency (AEMPS). The regions will participate through the creation of an Evaluation Committee for the Therapeutic Utility of Human Pharmaceuticals. This new body will be responsible for carrying out therapeutic evaluations and will be made up of a group of experts named by the regions. The evaluations will become an integral part of the pricing and reimbursement process as stated in the draft Law on Guarantees and the Rational Use of Health Products.

Pharmaceuticals having reimbursement approval receive a label with a six digit reimbursement code for identification of the reimbursement conditions, such as the reimbursement category to which the pharmaceutical belongs.

There are four reimbursement categories:

1. 100% reimbursement for hospital pharmaceuticals;
2. 90% reimbursement for pharmaceuticals for the management of chronic illnesses such as epilepsy, asthma and diabetes;
3. 60% reimbursement for the majority of prescription-only pharmaceuticals;
4. 0% reimbursement for pharmaceuticals on the negative lists.

As indicated earlier, the Interministerial Commission on Pharmaceutical Prices determines the price acceptable for reimbursement at the manufacturer level.

In Spain, there are two negative lists in operation, in order to identify pharmaceuticals which are not reimbursed. The main share of reimbursable pharmaceuticals are prescription-only. A number of non-prescription pharmaceuticals are reimbursed under the condition that they have been prescribed by a doctor.

In Spain, nearly 12,000 pharmaceuticals (counted including different pharmaceutical forms, dosages, and pack sizes) have market authorisation. 85% of these pharmaceuticals are prescription-only medicines, so they account for the core business in a pharmacy. 80% of all pharmaceuticals are reimbursable. The share of prescription-only medicines and reimbursable medicines has risen in the last five years.

The following criteria are considered when making reimbursement decisions:

- The nature of the illness
- The therapeutic value of the pharmaceutical
- The efficacy of the pharmaceutical
- The price of the pharmaceutical
- The total expenditure as compared to corresponding products, as well as expenditures incurred by the pharmaceutical to the National Health Service

D4.4 Policies relating to generic products

Spain has only recently developed a market for generic drugs. Until the early 1990s, local patent laws allowed cheap branded copy products to be marketed. Spain is still a
low price market. Generic use has been promoted by the government since 1997.
The generic market is currently growing twice as fast as the market as a whole,
although it still only accounts for 5.4% of the market by value and 9.4% by volume
(2005).

Generics follow the same pricing procedure as other reimbursed prescription
medicines. Although there are no official guidelines, generics included in the
reference price system must be priced at, or below, the reference price level. In fact,
most are now priced below the reference price level.

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### APPENDIX E: COMPARISON OF PER CAPITA INCOMES AND HEALTH EXPENDITURE FOR SELECTED OECD COUNTRIES AND SOUTH AFRICA

Table E1: Comparison of per capita Health Expenditure and GDP for a selection of Countries (2005) (US$)

<table>
<thead>
<tr>
<th>Country</th>
<th>Health Exp US$ per cap</th>
<th>Health / GDP US$ per cap</th>
<th>GDP US$ per cap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain**</td>
<td>2,905</td>
<td>11.0%</td>
<td>26,296</td>
</tr>
<tr>
<td>New Zealand**</td>
<td>2,264</td>
<td>9.2%</td>
<td>24,738</td>
</tr>
<tr>
<td>Canada**</td>
<td>3,332</td>
<td>9.5%</td>
<td>33,779</td>
</tr>
<tr>
<td>Australia**</td>
<td>3,354</td>
<td>10.7%</td>
<td>31,425</td>
</tr>
<tr>
<td>United States**</td>
<td>6,493</td>
<td>15.8%</td>
<td>41,197</td>
</tr>
<tr>
<td>South Africa total</td>
<td>331*</td>
<td>2.7%</td>
<td>12,063</td>
</tr>
<tr>
<td>South Africa medical schemes</td>
<td>1,183*</td>
<td>3.2%</td>
<td>37,323***</td>
</tr>
</tbody>
</table>

*Adjusted to US$ using the average Rand/Dollar exchange rate for 2005.
**The health expenditure was based on the 2004 OECD estimates adjusted to 2005 by carrying forward the growth rate from the previous period.
***According to PAIRS.

Sources: International Monetary Fund for per capita GDP; OECD Health Statistics for per capita Health Expenditure; South African per capita Health Expenditure based on MTT (2005); The per capita GDP for the medical schemes segment is based on the PAIRS estimate adjusted down by 4% (assuming roughly 4% growth for this segment) to provide a 2005 figure.

Table E1 compares per capita health expenditure in US$ with per capita GDP for the selection of OECD countries (referred to in inputs from the pharmaceutical industry) and for the South Africa medical schemes’ market.

This data shows that the South African medical schemes’ market spends significantly less per capita than any of the countries in the comparison. If the estimated per capita GDP of the PAIRS study is used on an unqualified basis (adjusted to 2005), the calculated per capita expenditure would represent 3.2% of GDP. This is significantly below the equivalent ratio for the comparator countries. In fact none of the comparator countries show spending of less than 9% of GDP. Spain in fact shows a figure of 11% which is higher than any of the other countries in the sample barring the United States.

Spain’s per capita expenditure is more than double that of the South African medical schemes’ “market segment” while that of New Zealand is roughly double.

Interestingly per capita income does not vary consistently with variations in per capita GDP. For instance, whereas the per capita GDP of the United Kingdom is 80.9% of that for the United States, it spends 41.6% of the per capita health expenditure of the United States. Spain, which has 63.8% of the per capita GDP of the United States, has 44.7% of its per capita health expenditure (more
than the United Kingdom). This inconsistency can be found in all the comparator countries.

These results challenge the relevance of per capita GDP (or "income") in selecting countries for the purposes of benchmarking, given that per capita GDP does not even explain variations in per capita health expenditure. From this one can also reasonably conclude that price variations will similarly not be explained by variations in per capita GDP.