GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 1211 **17 December 2010**

MEDICINES AND RELATED SUBSTANCES ACT, 1965

REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES:

(METHODOLOGY FOR INTERNATIONAL BENCHMARKING OF PRICES OF MEDICINES AND SCHEDULED SUBSTANCES IN SOUTH AFRICA)

The Minister of Health, in terms of regulation 5(2) (e) of the Regulations Relating to a Transparent Pricing System for Medicine and Scheduled Substances Act, 1965 (Act No. 101 of 1965), on the recommendation of the Pricing Committee, intends to publish the Methodology for International Benchmarking for Prices of Medicines and Scheduled Substances in South Africa in the Schedule.

Interested persons are invited to submit any substantiated comments or representations in writing, on a compact disc and hard copy, on the proposed methodology within three months of publication of this notice to the Minister of Health (for the attention of the Director: Pharmaceutical economic Evaluations, Private Bag X828, Pretoria 0001)

SCHEDULE

METHODOLOGY FOR INTERNATIONAL BENCKMARKING OF PRICES OF MEDICINES AND SCHEDULED SUBSTANCES IN SOUTH AFRICA

DR A MOTSOALEDI, MP

MINISTER OF HEALTH

CONTENTS

TABLES

FIGURES

G10-121827—B

EXECUTIVE SUMMARY

This report contains the recommendations of the Pricing Committee, for consideration by the Minister of Health, on an approach to regulating *originator* medicine manufacturer prices through international benchmarking. Recommendations on an approach to regulating generic medicine prices at the manufacturer level will be made at a later date. The report contains detailed information on the process adopted by the Committee in arriving at these recommendations, the international and South African context within which these recommendations should be considered, a clear rationale for the regulation of manufacturer prices and a detailed explanation of the recommended international benchmarking methodology. Wherever possible, stakeholder views are explicitly discussed.

The *aim* of international benchmarking, together with other regulatory interventions, is to:

> *Protect the South African health system from paying distorted prices for medicines through the elimination of price distortions and price distorting behaviour.*

The recommendations are therefore based on the need to address price distortions arising from the existence of substantial imperfections in the market for pharmaceutical products. Regulation of medicine prices is widely practiced internationally; regulation is the only means available to achieve prices that are relatively free of distortion arising from market imperfections. Internationally most countries have used across the board price cuts and price freezes to address price distortions in *existing products*, and international benchmarking primarily for new products. However, the *Committee* recognises that prices of different products are subject to distortion to greater or lesser degrees and that across the board price cuts or long-term price freezes will be unfair to products that are not presently distorted. For this reason the *Committee* believes that international benchmarking is superior to generalised price cuts as it is more able to discriminate between prices with and without significant distortion.

The *key elements of the Committee's recommendations* can be summarised as follows:

- The price of originator medicines should be *benchmarked against the prices of these medicines in Australia, Canada, New Zealand and Spain.* These countries were selected on the basis of meeting the following criteria:
    1. Having regulatory authorities that licence and ensure the quality of medicines;
    2. Have systems in place for the effective regulation of medicine prices, particularly through powerful purchasing structures;
    3. Have accessible, structured pricing information that is regularly updated and reflective of the actual prices at which medicines are sold; and
    4. Have implemented internationally accepted rules on patent and intellectual property rights protection.

- The *lowest price in the basket of countries should be used as the* ***ultimate*** *price for the purposes of international benchmarking*. South Africa is included in the basket; thus if the price of a medicine is lowest in South Africa, that price will remain. The basis for this recommendation is that the most rational assumption is that the lowest price reflects the least distorted price and that it is the price that is closest to paying normal profits to a manufacturer. As the medicines are commercially sold within the basket of countries, it is a reasonable presumption that the lowest price is a commercially viable price.

- However, the Committee recommends *that a phased approach be adopted toward the implementation of this ultimate benchmark.* As an *interim approach,* it is recommended that *the average of the three lowest prices in the basket of countries – Australia, Canada, New Zealand, South Africa and Spain* be used for a period of two years.

- It is recommended that the *exchange rate* used for conversion of prices in the benchmark countries into South African Rands is a *projection of exchange rates for the benchmark year, based on a three year linear regression model.*

- Identical products will be compared wherever possible, with specific guidelines on how to deal with medicines of different strengths and pack sizes. Where there is *no appropriate comparator* in the benchmark countries, including for combination medicines, these products will be *subject to pharmacological or therapeutic class reference pricing* (at ATC 4 level), through an application to the Pricing Committee. As a last resort, a pharmacoeconomic analysis will be used as the basis for a price determination by the Committee. In the case of co-packaged products, the Committee recommends that the *SEP for each individual product be summed together and the total decreased by 10%.*

- The recommended implementation process includes:

  1. **Regulation 5(2)(e) (Government Gazette No. 26304 of 30 April 2004)** requires that the SEP be set in compliance with the international benchmarking methodology "*within 3 months of publication of such methodology*". Thus, it is recommended that information on the SEP that will prevail using the average of the lowest three prices in the basket be submitted within 2 months of the publication of the benchmarking methodology.

  2. The *final benchmark* (lowest price in the basket of countries) *will apply automatically two years after the introduction of the interim benchmark* (average of the lowest three prices in the basket). However, applicants will be required to submit full data on the application of the final benchmark methodology to each of their products within nine months of publication of the benchmarking methodology.

  3. Both the *interim* and the *final* benchmark price values will be calculated annually by the affected companies and provided to the *Department of Health*. The Committee will review the benchmarked prices on a regular basis.

4. An *exemption from the final benchmark will be permissible*, on application, only where an affected company can demonstrate to the satisfaction of the Committee that the resulting price is distorted and prejudicial to the manufacturer, based on the *full disclosure of all aspects of the pricing of a product*. Applications for exemption from the final benchmark must be submitted one year before the date for implementation of the final benchmark. In *exceptional circumstances*, an applicant may apply for *exemption from the interim benchmark*, but will be required to provide complete disclosure on all factors relevant to the matter.

5. Any medicine coming onto the market after the publication of the international benchmarking methodology must comply immediately with the *final benchmark*, i.e. must set their ex-manufacturer price at the lowest price in the basket of benchmark countries.

Based on data available to the Committee, the implementation of the recommended pricing regime would *result in an immediate 10.0% general cost reduction*, based on the average of the lowest three prices, which would be sustained for two years. Thereafter *the full regime*, based on the lowest price, *would result in a further 9.9% reduction in costs*.

The Pricing Committee strongly urges that these recommendations be implemented at the earliest possible date. The introduction of the SEP is unlikely to have had any significant impact on *pharmaceutical manufacturers' "super-profits"*. The only impact on manufacturers so far arose from the fact that the 2004 SEP was based on 2003 prices and that an increase in the SEP was only permitted two years after the initial SEP regulations were introduced. However, the net effect of changes in prices and foreign exchange rates between 2004 and 2006 was only an increase of approximately 2.6% per year. 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.

SECTION A: BACKGROUND, INTERNATIONAL AND SOUTH AFRICAN CONTEXT AND RATIONALE FOR BENCHMARKING

This section provides the context underpinning the rationale for international benchmarking as a lever to ensure fair medicine prices in South Africa. An overview is provided of: the domestic pricing regulatory framework; relevant aspects of the South African health system; domestic cost trends; and international perspectives on medicine price regulation.

1. INTRODUCTION

As specified in **section 22G** of the **Medicines and Related Substances Control Act**, the *Pricing Committee* ("Committee") has a statutory responsibility to make recommendations to the Minister of Health ("Minister") on issues related to medicine pricing regulations. **Regulation 5(2)e** published in terms of this Act (**Government Gazette Number 28214** of **11 November 2005**) indicates that "*a methodology for conforming with international benchmarks*" will be published.

The purpose of this report is to make recommendations to the Minister on an approach to regulating *originator medicine prices* at the manufacturer level through international benchmarking. Recommendations on an approach to regulating generic medicine prices at the manufacturer level will be made at a later date. In addition, this report provides information on the process adopted by the Committee, and the substantive basis, for arriving at these recommendations.

The aim of these proposals derives from the overall intention of **section 22G**, which was interpreted by the *Constitutional Court* to be that of *promoting access in terms of both the affordability and availability of pharmaceuticals and associated services*.

To arrive at the recommendations in this report, the Committee adopted an approach which included:

1. Publication of draft regulations on a methodology;
2. Receiving and reviewing submissions from affected stakeholders;
3. Seeking clarification from certain stakeholders on their inputs;
4. Requesting and obtaining data on impacts from affected stakeholders; and
5. Quantitative assessments of alternative methodologies.

A more detailed overview of the process adopted by the Committee is provided in Appendix A.

Part A of this report therefore focuses on the contextual issues underpinning options for regulating medicine prices in South Africa. Part B then follows with recommendations on a specific approach.

2. INTERNATIONAL AND SOUTH AFRICAN CONTEXT FOR THE INTERNATIONAL BENCHMARKING RECOMMENDATIONS

2.1 The international perspective

Pharmaceutical regulation is a prominent policy issue in all Organization of Economic Co-operation and Development ("OECD") countries. This reflects the general consensus that the market for pharmaceuticals is imperfect and subject to substantial price distortions if not regulated. Internationally, a variety of approaches are used to regulate pharmaceutical markets determined in large part by the characteristics of the local health system. The main regulatory approaches or instruments are summarised below.

2.1.1 Internal Price Referencing

Internal reference pricing is one of the major methods used for medicine price regulation. In some countries, such as Germany, it is the only regulatory method, while in other countries, such as Ireland, it plays no role. Medicines that have the same active *moeity*, pharmacological or therapeutic action (i.e. substitutable medicines) will be reimbursed at the price of the cheapest existing treatment alternative in the case of innovator pharmaceuticals. In relation to generics, the general approach is to set the reimbursement price at a specified percentage below that of the originator product. For example, in Belgium the reimbursement price of generics must be at least 30% lower than the originator pharmaceutical in the reference price system, while in the Czech Republic, generics are reimbursed at 55% of the original pharmaceutical. In France, the prices of existing generics were cut by 10% in 2005, resulting in reimbursement prices of 40-60% lower than those of originator off-patent pharmaceuticals. New generics are now automatically priced at 50% below the price of the originator medicines.

2.1.2 External price referencing or international benchmarking

External price referencing or *international benchmarking* is often most usefully applied to *innovator pharmaceuticals*, with the goal of establishing the price of a new medicine. Benchmarking generally focuses on the manufacturer price, although some countries target the wholesale price level.

There are different approaches to international benchmarking or *external price referencing*. Some countries use the *'European Union ("EU") Average Price System'*, introduced in 2004, which is based on the average price across all European countries. Examples of other approaches include:

- **France**: The French price is benchmarked against prices in the United Kingdom ("UK"), Germany, Spain and Italy, using the guideline that the price in France must not be lower than the *lowest price* in the selected benchmark countries. If the price of the medicine declines in any of the benchmark countries, the price in France is adjusted accordingly.

- **Greece**: Pharmaceuticals are set at the *average of the three lowest prices* in Europe.

- **Hungary**: Pharmaceutical prices must be lower than the price of the product in selected reference countries.

2.1.3 Price freezes

Price freezes may involve a voluntary agreement between the relevant authority and the pharmaceutical industry or they can be imposed by statute on all reimbursable pharmaceuticals[1]. Price freezes are generally imposed where manufacturers have higher than expected prices relative to benchmark countries or where they have gained unduly from a change in legislation. In such cases, price freezes are implemented in order to create and maintain a new price base for each medicine over a period of time. Prices may be frozen, i.e. not be allowed to increase, for one or more years.

Following a price freeze, the prices within the country applying the freeze are constantly monitored against the prices of selected comparator countries. In cases where prices in the comparator countries differ from that in the country imposing a price freeze by more than a specified percentage, a price increase is allowed (Ireland).

2.1.4 Price Cuts

From time to time, some countries have introduced price cuts, which may be as high as 53% (as occurred in Greece). Price cuts are generally phased in rather than being applied at one point in time, especially where the price cut is relatively large. Price cuts may be introduced in different ways, including:

1. 'Automatic' price cuts may be required when a medicine reaches its anniversary' of registration or product launch, or on a set date (e.g. within two months) following the 'anniversary'.

2. Price cuts may be restricted to reimbursable medicines which are not able to be subjected to internal reference pricing (e.g. where there are no substitute medicines).

3. Price cuts may also be applied some time after an originator medicine has come 'off patent' and where generic equivalents have been developed. For example, the Netherlands decreased the prices of branded pharmaceuticals that had generic alternatives by 40%.

4. Sometimes, there may be a contract between a pharmaceutical manufacturer and a large purchaser (e.g. a social or national health insurance, or a Ministry of Health where health services are primarily tax funded) which stipulates that price cuts may be implemented in the event of increases in sales volumes (e.g. in France).

[1] The term 'reimbursable medicine' refers to the fact that many of these regulatory approaches are applied within the context of a health system that has a single (or a limited number of) large purchaser(s) – such as a social or national health insurance scheme – where prices are regulated in relation to how much will be reimbursed for the medicine by the purchaser or insurance scheme.

In 2004, Italy applied price cuts to 300 of its high selling pharmaceuticals, which had an increase in sales of more than the average of the whole market in the first half of the year.

2.1.5 Price Volume arrangements

This approach is similar to that mentioned above, whereby there are agreements between a pharmaceutical manufacturer and a large purchaser relating to the volume and price of a particular product. If volume increases above a certain level, there may either be a price cut or manufacturers are expected to pay back a certain percentage of their revenue from the sale of this product to the purchaser or another designated body.

2.1.6 Link to inflation rates

The extent to which companies may increase their prices is often linked to inflation rates within the country. In some countries, prices may be increased up to the inflation rate, while in others the increase is allowed as long as it is below the inflation rate (Hungary).

2.1.7 Pharmacoeconomic analyses

Regulatory authorities worldwide are making *evidence–informed* decisions in relation to the introduction of a new medicine. In addition to safety, quality and efficacy information, pharmaceutical manufacturers are required in some countries to provide evidence on the cost-effectiveness of their product relative to existing medicines or other treatment interventions. Where this is required, detailed guidelines are provided on how to conduct pharmacoeconomic evaluations. (**Table B.1** in **Appendix B** provides an overview of which OECD countries require pharmacoeconomic analyses for new medicines).

2.1.8 Combinations of regulatory instruments

Most countries do not use a single medicine pricing regulatory instrument, but rather use a combination of regulations. Examples of such combinations include:

- **Belgium** applies: pharmacoeconomic guidelines; internal reference pricing; price freezes (in 1996, between 1998 and 2003 and in 2005); and profit controls via the so-called *Taxe Busquin*.

- **Denmark** applies: pharmacoeconomic guidelines; internal and external reference pricing (the latter on an informal basis); and price freezes and profit margin cuts.

- **France**, within its social health insurance system (*Couverture Maladie Universelle*, "CMU"), uses pharmacoeconomic guidelines; internal and external reference pricing (the latter for new reimbursable pharmaceuticals, particularly innovator pharmaceuticals); profit margin cuts (1999 and 2004) and company profit controls.

- **Italy** has been using internal reference pricing since 2001, applied a price freeze until January 2007 and requires companies to allocate the

equivalent of 5% of their marketing expenses to an independent scientific information fund.

- In **Spain**, the application of pharmacoeconomic guidelines is not yet mandatory; internal and external reference pricing are applied, although the process has yet to be finalised; it has also instituted profit margin cuts, the last of which occurred in February 2006.

- The **United Kingdom** features the most stringent application of pharmacoeconomic guidelines via the *National Institute for Health and Clinical Excellence* ("NICE"). Further measures include internal reference pricing for the calculation of the reimbursement price for reimbursable generics, price freezes (most recently from 1 January 2005 to 1 January 2006), and company profit controls for branded National Health Service ("NHS") pharmaceuticals.

- **Canada** uses pharmacoeconomic analyses; internal reference pricing; external reference pricing using France, Germany, Italy, Sweden, Switzerland, the UK and the United States ("US") as the benchmark countries.

2.1.9 Key issues from international context

There is no single approach to the regulation of medicine prices that is applied, or that is even appropriate, across OECD countries, i.e. there is no such thing as 'international best practice'. This is unsurprising given that regulatory interventions have to be tailored to the context of each country's health system. Although there are a wide variety of regulatory approaches, all have a common goal, namely, to ensure that medicine prices are fair and free from price manipulation or distortion arising from market imperfections.

South Africa's health system is unique and thus the regulatory strategies that are appropriate must be developed domestically drawing on international experience as an input.

2.2 The South African context

This section describes the context within which medicines are traded in South Africa, with a focus on the challenges facing the private health sector. It also considers which regulatory instruments have been applied in South Africa to date and any outstanding measures.

2.2.1 The health system context and trends in private sector health care expenditure

The South African health system exhibits a high degree of polarization with a large public and private system. Significant differences exist in the distribution of limited health resources between the private and public health sectors:

- Around 14.8% of the population are covered by medical schemes, and through the resulting risk-pooling, are able to secure most of their health services in the private sector. The per capita annual expenditure on this group, combining both medical scheme expenditure and out-of-

pocket payments by medical scheme members was equivalent to approximately R9,500 per beneficiary in 2005.

- A further 21% of the population make use of the private sector on an out-of-pocket basis mainly for primary care, but are likely to be entirely dependent on the public sector for hospital (particularly inpatient) care. The per capita annual expenditure on this group, including their out-of-pocket payments to private primary care providers and government spending on hospital care, was equivalent to nearly R1,500 per person in 2005.

- The remaining 64.2% of the population can be said to be entirely dependent on the public sector for all their health care services. For this group, less than R1,300 was spent per person for government primary care and hospital services.

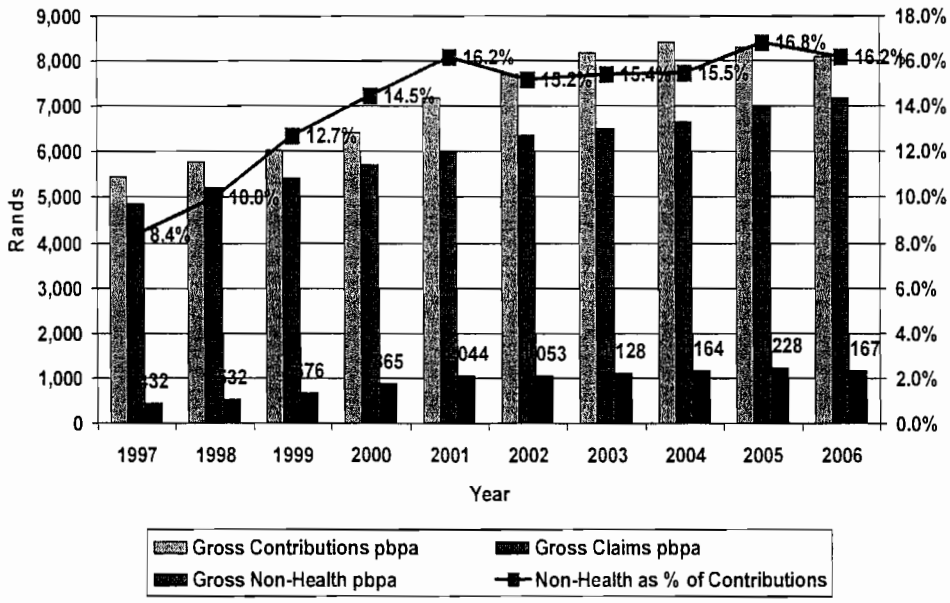
Real[2] per capita government spending on health care has remained relatively stagnant for the past decade, while that by medical schemes has soared over this period (note that medical schemes are focused on due to the availability of data and because they account for the majority of private sector expenditure). Medical schemes have faced significant expenditure increases since the mid-1980s, with the major expenditure drivers until the early- to mid-1990s being that of medicines, private hospitals and specialists.

Overall medical scheme contribution income per beneficiary has levelled from 2002, mostly due to a flattening and even real decline in non-health expenses. Against this trend claims costs on benefits has continued to rise in real terms (see **Figure 2.1**.). Not all of the medical cost increases are visible however, as many medical schemes compensate for rising costs by reducing benefits.

[2] "Real" refers to costs that have been adjusted for general inflation, revealing cost changes in excess of general inflation.

8

Figure 2.1: Medical Scheme Expenditure Trends from 1997 to 2006 (2006 prices) (per average beneficiary per month)



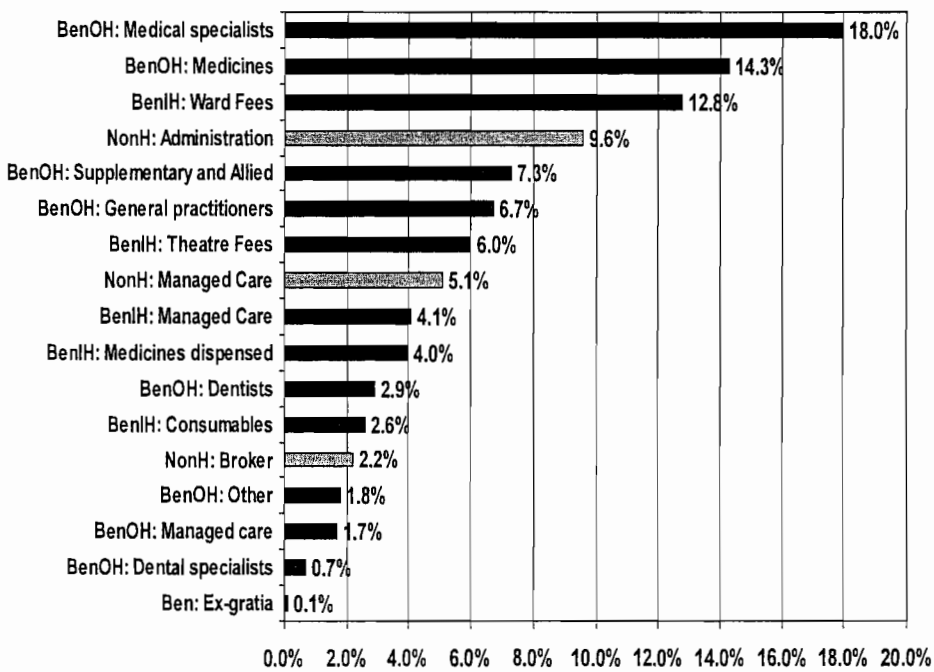
Source: Council for Medical Schemes, Annual Reports for the period 1997 to 2006

It is clear from **Figure 2.2** that out-of-hospital medicines, specialists and private hospitals are the main cost items at present. (Note that hospital expenditure has been broken down into its various components: ward, theatre, medicines, etc.). Hospitals account for 29.4% of overall expenditure while medicines account for 18.4%, the second largest aggregate cost item. Specialists are the next largest cost item at 18%.

Although administration expenditure is significant at 9.6% of the total, it has stabilized in cost from 2002. It should be noted that non-health expenditure cost containment is primarily a governance concern whereas health care cost increases derive primarily from an imbalance in the power relationships between the funder and the health service provider.

9

Figure 2.2: Medical Scheme Expenditure by Category, percentage of total (2006)



Source: Council for Medical Schemes, Annual Report 2006-7

Note: "OH" refers to "out-of-hospital" while "IH" refers to "in-hospital.

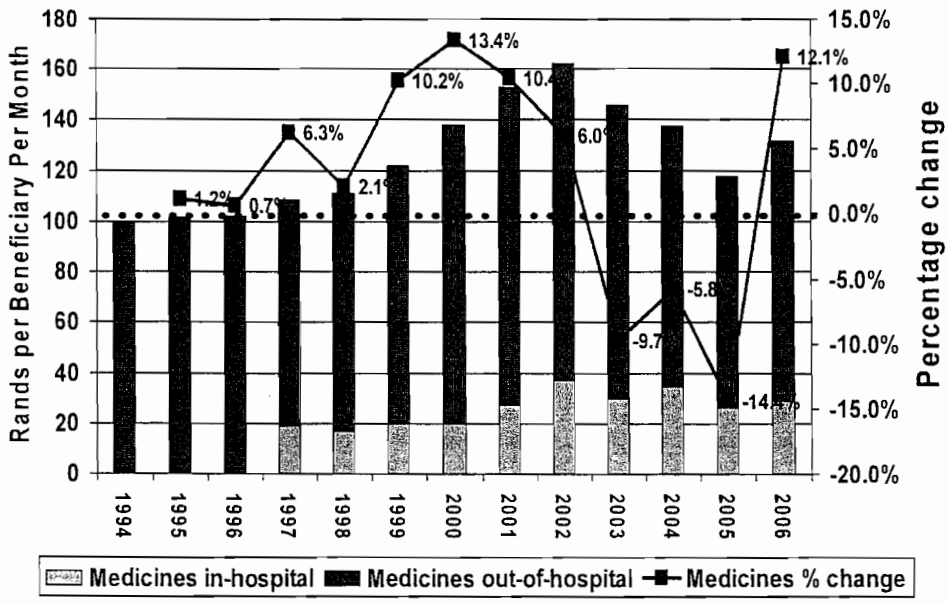
Figure 2.3 shows that per capita spending on medicines, funded through medical schemes, started to decline from 2002 influenced by a combination of factors:

- Regulatory changes, particularly affecting medical schemes[3];
- Exchange rate appreciation from 2003;
- Increases in generic substitution.

From 2004 medicine costs decline steeply into 2005, attributable primarily to the introduction of the SEP. However, there is an apparent cost rebound discernable into 2006.

[3] The introduction of prescribed minimum benefits for chronic conditions from 2004 resulted in the implementation of formularies for chronic medication. This forced pharmaceutical manufacturers to compete for inclusion in scheme formularies, driving prices down.

Figure 2.3: Medical Scheme Medicine Expenditure Trends from 1994 to 2006 (2006 prices) (per average beneficiary per month)



Source: Council for Medical Schemes, Annual Reports for the period 1994 to 2006

The trends indicate that although certain private health care costs have been on the rise, a degree of stability is evident in recent medical scheme trends. It is clear that private health care costs have been influenced by the tighter regulatory framework affecting medical schemes and medicines. However, the effectiveness of cost containment into the future will be determined by the continued implementation of a number of measures to offset market imperfections.

2.2.2 The regulatory context

Section 22G of the **Medicines and Related Substances Control Act** makes provision for a *Pricing Committee* which makes recommendations to the Minister in relation to mechanisms for achieving a transparent pricing system for medicines in South Africa, and includes:

- A framework to guide the setting of SEPs by manufacturers;
- Guidelines on wholesaler and distributor fees;
- Guidelines on dispensing fees and fees for other retailers of S0 medicines; and
- Strategies for promoting transparency in the system.

The initial set of regulations published in 2004 included a dispensing fee for pharmacists and dispensing doctors. The dispensing fee was intended to move these health care providers to a situation where they are receiving a fee for the professional dispensing service they provide as opposed to receiving an income from trading in medicines.

Regrettably, due to repeated court action, dispensing fee regulations for pharmacists are not yet in place. Nevertheless, many pharmacies are charging dispensing fees in line with the initial regulations, although there remain a significant number of retail pharmacies placing high mark-ups on the medicines they sell.

The 2004 regulations allowed for a logistics fee to be determined in terms of negotiations between individual manufacturers and logistics service providers. The Minister has indicated that she is considering the imposition of a maximum cap on these fees. This option is currently under consideration by the Committee [4].

In relation to manufacturers, the **Medicines and Related Substances Control Act** prohibited *discounting* and other perverse incentives in the medicine supply chain.

The regulations introduced on the basis of recommendations of the Committee in 2004 required manufacturers to sell at a 'Single Exit Price' (SEP, i.e. sell at the same price to all purchasers). Previously, purchasers such as private hospitals and dispensing doctors were granted substantial "discounts", which were not passed on to final consumers, as an inducement to increase dispensing and to favour certain products. The combined effect of the prohibition on "discounts" and "rebates" and the SEP has largely removed this practice from the market.

Small retail pharmacies paid the highest price for medicines. The SEP regulations required manufacturers to reduce their pre-regulation list price by the value of all discounts and rebates previously granted. As indicated in **Figure 2.3**, this had a dramatic impact on the price of medicines and on total medicine expenditure levels.

The information provided by the Council for Medical Schemes is corroborated by the Mediscor reports of 2004 and 2005 (Bester and Hammann 2005; Bester *et al.* 2006). In relation to the schemes they service, the average cost per item of medicines dispensed to medical scheme members decreased by 24.4% between 2003 and 2004, and by a further 8.7% between 2004 and 2005. This provides a good indicator of the impact of the SEP regulations (and also increased generic substitution given that utilisation of generics increased from 35% of items in 2003 to 40% in 2004 and 44% in 2005).

2.2.3 Residual issues to be addressed through regulation

Certain components of the initial regulatory framework still need to be implemented. This includes:

1. The dispensing fee for retail pharmacy;

[4] Some stakeholders were of the view that capping of the logistics fee should precede international benchmarking. However, regulation of the logistics fee and the ex-manufacturer price are separate regulatory interventions which do not need to be implemented simultaneously or sequentially.

2. The capping of logistics fees;

3. The more stringent licensing of dispensing doctors;

4. The review of the dispensing fee for dispensing doctors; and

5. The removal of price distortions in ex-manufacturer prices.

Of these measures, the most important gap relates to (5) where to date none of the regulatory approaches adopted internationally have been introduced in South Africa. Although the Maximum Medical Aid Price ('MMAP") is a form of *internal reference pricing*, it merely provides some guidance to medical schemes on reimbursement levels for certain medicines and has no statutory or regulatory force. Private forms of reference pricing are also vulnerable to conflicts of interest.

The introduction of the SEP is unlikely to have had any significant impact on pharmaceutical manufacturers' "super-profits"[5]. The only impact on manufacturers arose from the fact that the 2004 SEP was based on 2003 prices and that an increase in the SEP was only permitted two years after the initial SEP regulations were introduced. However, the net effect of changes in prices and foreign exchange rates between 2004 and 2006 was only an increase of approximately 2.6% per year.

The purpose of the SEP is to enforce *transparency* of manufacturer prices, and to remove any possibility of unfair price distortions resulting from conflicts of interest. The SEP does *not* eliminate distortions in medicine prices arising from systemic market imperfections. These include: excessive pricing due to monopoly power; and price discrimination between segmented markets. (See **Section 4** and **Appendix C**).

The introduction of the SEP was therefore only the first phase in addressing medicine price issues at the manufacturer level. The second phase is that of international benchmarking, where the explicit intention is to address the price distortions existing in the South African pharmaceutical market.

[5] "Super-normal profits" refer to profits in excess of what would occur in an undistorted and competitive market.

3. AIMS AND OBJECTIVES OF INTERNATIONAL BENCHMARKING

To clarify the specific purpose of international benchmarking the specific aims and objectives of the intervention need to be formally specified.

3.1 Aims

The aims of international benchmarking, in conjunction with other interventions, are to:

Protect the South African health system from paying distorted prices for medicines through the elimination of price distortions and price distorting behaviour.

3.2 Objectives

The objectives of international benchmarking are to:

1. *Achieve undistorted medicine prices for the domestic health system through:*
    a. *The identification of benchmark prices internationally; and*
    b. *The application of benchmark prices domestically;*
2. *Ensure that the regulation of medicine prices through international benchmarking is subject to a fair and reasonable process to ensure that price adjustments are not unfair to any legitimate market participant.*

4. RATIONALE FOR INTERNATIONAL BENCHMARKING

4.1 Market imperfections

Private markets for health care in general are vulnerable to market failure evident as over-pricing and the over-supply of goods and services. The market for pharmaceuticals follows both this general rule but also exhibits some additional and unique features which make protection of the public necessary. Internationally such protection has taken the form of price regulation of various forms specific to pharmaceuticals.

Distortions in health care markets are related to the following:

1. Health care goods and services are complex in nature and cannot be directly purchased by "consumers" in the absence of advice by an "agent", i.e. the doctor. Patients are essentially compelled to follow the advice of doctors, who therefore *determine* their "demand" for health goods and services.

2. Even in the absence of perverse incentives, doctors often make decisions without consideration of any budget constraints, particularly when a patient is covered by some form of insurance.

3. The purchasing of health care also involves some agent, whether public or private, that pools risk (at the very least) for serious health conditions. As a consequence, members of a risk pooling arrangement have no incentive to restrict demand to necessary health care.

4. Health care purchases involve interventions to prevent death and disability. Consequently "consumers" are vulnerable to price/cost abuse (over-charging) and over-servicing. Even in the face of severe cost increases, many individuals will continue to fund insurance payments (out of a fear of the consequences of not having insurance when a serious medical condition occurs)[6]. In fact, the higher the cost of health care goods and services, the greater the consequences of not being insured.

5. Where agents rather than the final consumer determine demand, conflicts of interest will result in the supply of unnecessary goods and services at prices that are significantly above their true cost (including normal profits). These conflicts are rife in all health care markets where they have not been regulated out of existence. The South African market exhibits these distortions particularly in the following areas (among others):

    a. Pharmaceuticals;

    b. Radiology;

[6] Economists define health markets as being characterized by "inelastic" demand curves. That is, demand does not drop significantly when prices/costs increase.

c. Pathology; and

d. Hospital-based surgicals and medical devices.

6. Certain health care products are produced under patent. Where the product is essential for the treatment of serious conditions and has no close competitors, typically the case with pharmaceutical products, it is possible to set monopoly prices.

When the above are seen together, the conditions exist for severe cost increases with consequences for health care access in both the public and private sectors. The "inelastic" demand curve for health care (see previous footnote) combined with the incentives and capacity of suppliers to over-service and over-price health care goods and services establishes the conditions for severe market failure with significant social implications.

Figure 4.1 provides a formal illustration of how a private market for health care behaves, including the market for pharmaceuticals, taking into account the factors noted above. The private market for health care is represented by *supply* and *demand* curves with *price/cost* on the vertical axis and *quantity* of health care resources (within a discrete period of time) on the horizontal axis.

The *inelastic* nature of *demand* for *health insurance* is illustrated by the near vertical *demand curve* (**D(i)1**), which illustrates that even with significant increases in the price/cost of health care insurance, there is only a small drop in the quantity of health care insurance demanded.

The *supply* of *health care goods and services* are shown as *elastic*, which is normal, i.e. it shows how changes in supply respond more than proportionately to changes in price.[7]

If a market begins at the equilibrium point (assumed here to be the socially optimal point of health care costs, quantity supplied and quantity demanded) indicated by the intersection of the points **p0** and **q0** ("**A**"), the total value of goods and services sold will be represented by areas "*a*" and "*b*" (or **p0** x **q0**).

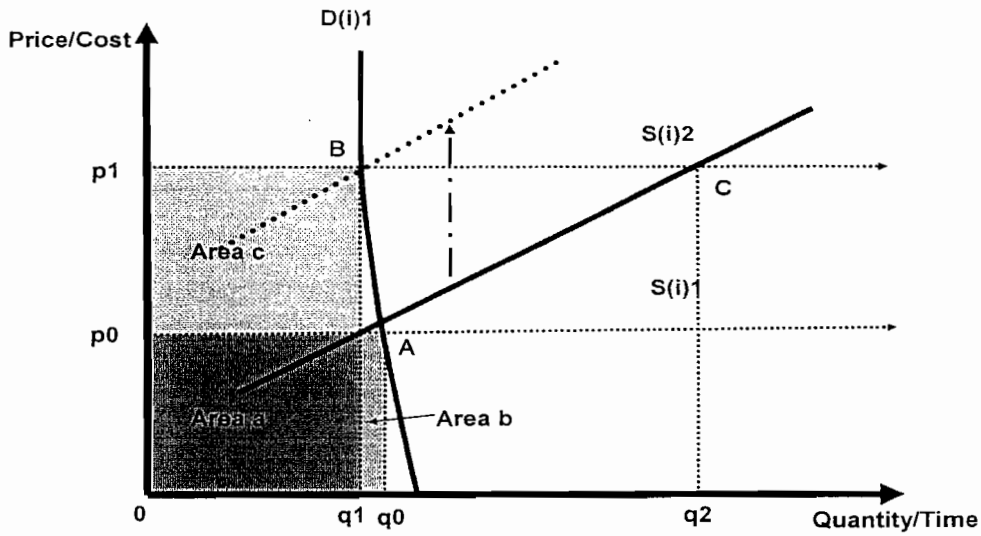
However, given the ability of service suppliers to increase the price and cost of a fixed set of health care entitlements, the supply curve can move up. Given the inelasticity of demand such a move can be illustrated by a movement of the supply curve up from **S(i)1** to **S(i)2**. At this point the cost of health insurance is reflected by **p1** which is twice **p0**. However, the quantity of health insurance declines very slightly from **q0** to **q1**. Health care suppliers therefore lose *area b* (which is small) but gain *area c* (which is almost double the existing expenditure).

Health care suppliers would however be prepared to vastly increase their supply of services at price **p1** to **q2**. The market is however constrained by the "need" for health services. Although doctors can increase demand for health

[7] A supply curve shows the responsiveness of suppliers of products to changes in the market price of a product. The upward slope illustrates that the higher the market price the more suppliers will bring to the market for sale. The final market price is reflected by the intersection of the demand curve (reflecting what consumers are willing to pay for certain quantities of a product) with the supply curve.

services unnecessarily for those who are in need of care, the core demand arises from ill-health or child-bearing which doctors do not directly influence. Essentially, if someone does not break an arm or does not fall pregnant, they have no need for the related health care goods and services. For this reason consumers do not desire to consume at **q2**, via insurance, as this would require that they become more ill.

Figure 4.1: Formal illustration of central features of a private insured market for health care



Government, in the exercise of its stewardship over private health markets therefore needs to regulate market interactions such that **point A** (**Figure 4.1**) is achieved rather than **point B**. **Point B** in essence represents the outcome of an unregulated health care market. Although the failures characteristic of health care markets derive from common structural features of health systems (risk pooling, information asymmetries, complex products, reliance on agents, etc.), their mitigation requires that specific attention be given to different components of the system. Therefore, interventions applicable to private hospitals will of necessity be different to those for dealing with specialists or pharmaceuticals.

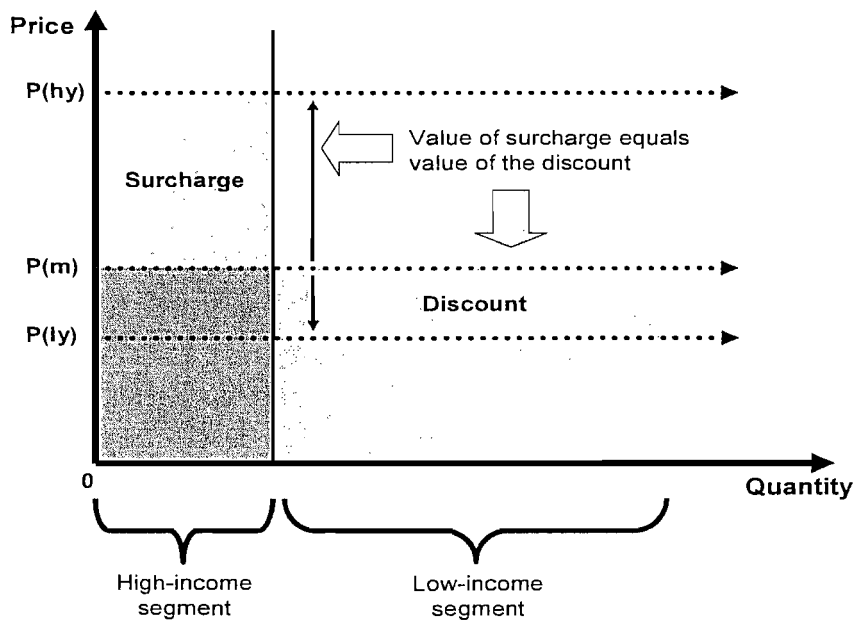
4.2 Market segmentation and differential pricing

Market segmentation refers to the practice of charging different prices in different 'markets' (or countries). Proponents of market segmentation argue that, where it applies, prices vary in line with per capita income levels with positive welfare affects due to progressive income cross-subsidies.

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 or market segments (who will theoretically be charged a discount on the marginal cost).

It is 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 country, while allowing more people, particularly in low-income countries or low-income segments of the 'market' within a country, to use the product than would be possible if a single price was charged across countries. This argument is illustrated in **Figure 4.2**.

Figure 4.2: Pharmaceutical price discounting with cross-subsidisation between high- and low-income settings



Note: P(hy) is the price charged to high-income groups or countries and P(ly) is the price charged to low-income groups or countries. P(m) is the average price that manufacturers argue they would need to charge to recoup the R&D costs.

This explanation for differential pricing in relation to medicines is however not accepted by the Committee on the following grounds:

1. There is no empirical evidence to suggest that low prices coincide with low-income market segments;

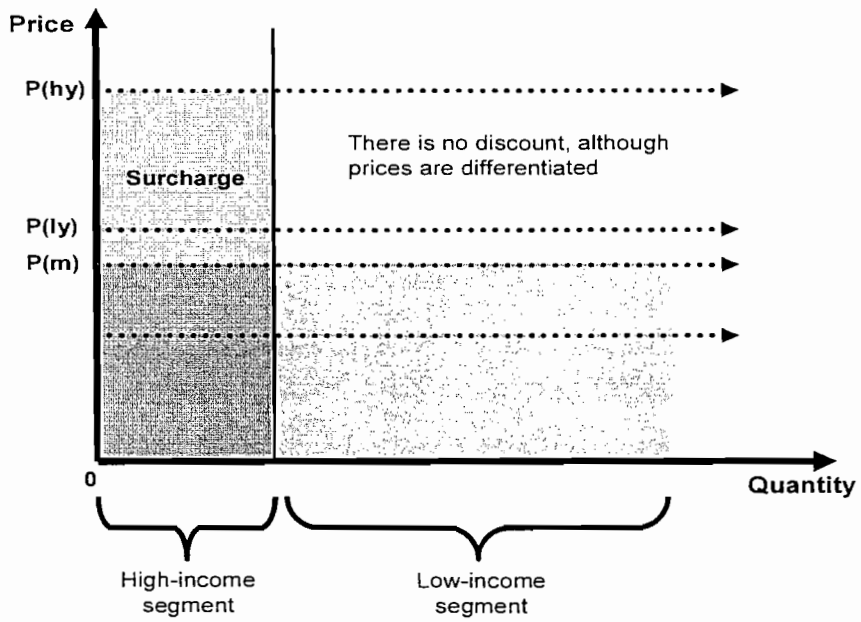
2. The evidence clearly indicates that low-prices primarily arise from purchasing behaviour and price regulation rather than variations in income;

3. Where prices are lower in low-income settings there is no evidence to suggest that this involves any income transfer from high-income groups (see **Appendix C**); and

4. Given the opaque environment within which prices are set, price differentiation between market segments is most likely to reflect profit maximising behaviour, given the significant market power of pharmaceutical manufacturers. (See **Appendix C**).

The essence of this view, adopted by the Committee, is that it is possible to differentiate prices between market segments without any income transfer. This is illustrated in **Figure 4.3**.

Figure 4.3: Pharmaceutical price differentiation with no cross-subsidisation



Certain pharmaceutical industry stakeholders have questioned whether the South African private sector should be benchmarked against countries such as Spain, New Zealand, Australia, and Canada given that the *per capita income* in these countries was below that of the South African private market segment (i.e. the catchment population in medical schemes). (PTG, April 2007, PAIRS, April 2007).

The argument is made that the higher incomes of the South African private market segment explained the higher prices experienced relative to the relevant OECD countries. According to this view the pharmaceutical manufacturers are entitled to charge South African medical scheme members more than, for instance, the citizens of Spain as they on average have a lower income.

This argument is not supported by the analysis of the Committee for the following reasons:

- Irrespective of the country under consideration, their health care is funded via some form of risk-pooling arrangement. Pooling occurs either via private insurance or some public arrangement (social insurance or general government expenditure). Pooling eliminates point-of-service expenses associated with the purchase of medical goods and services and essentially places all income groups in the same position.

- A consequence of pooling, therefore, is that prices are not determined in relation to the budget constraints of individual households. Pooling makes it possible for an individual to purchase health services in accordance with

need, rather than household income. They are therefore unaffected by the pricing of health care and their health-seeking behaviour does not take it into account.

- Prices are however affected by the interaction between the purchaser (the risk-pool) and the suppliers of health care. If the risk pool is a poor or weak purchaser of health care, prices will be high and demand (at point-of-service) will exceed need. The converse will therefore also be true.

- In certain countries some risk-pooling agents will be in a weak bargaining position relative to suppliers of medical goods and services, as is the case of South African private medical schemes. In such situations the state can (and should) intervene to ensure that price and demand are at appropriate levels. Small private markets are typically vulnerable to supplier over-pricing and supplier-induced demand.

- As a consequence medicine price variations between countries, and/or between private and public sectors, are a function of purchasing behaviour and government intervention rather than household incomes. The best interventions result in the best prices and better prioritised supply.

- Individual household income is consequently of little relevance in the determination of medicine prices. Most risk pooling arrangements deal with the problem of affordability by curtailing services or coverage (in the case of insurance). Financially constrained health care markets will consequently face high prices if they are either poor purchasers of medicines (where for instance they do not directly negotiate price) and/or are in a weak bargaining position (where the sellers are monopolists).

- An examination of the per capita incomes and health expenditure of various OECD countries compared to the South African private sector market segment reveal no consistent relationship. Furthermore, countries proposed as benchmarks for South Africa spend considerably more on health care than the South African private sector. This clearly calls into question the analysis by the pharmaceutical industry that the reason Spain, Australia, New Zealand, and Canada have lower pharmaceutical prices than the South African private sector is because they have a lower-income market segment than the South African medical schemes' population.

    - **Table 4.1** 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 (April 2007) 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 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 health expenditure is more than double that of the South African medical schemes' "market segment" while that of New Zealand is roughly double.

- Per capita income does not vary consistently with variations in per capita GDP. For instance, whereas the per capita GDP of the UK 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.

Table 4.1: Comparison of per capita Health Expenditure and GDP for a selection of Countries (2005) (US$)

Country	Health Exp US$ per cap	Health / GDP US$ per cap	GDP US$ per cap
Spain**	2,905	11.0%	26,296
New Zealand**	2,264	9.2%	24,738
Canada**	3,332	9.9%	33,779
Australia**	3,354	10.7%	31,425
United States**	6,493	15.8%	41,197
South Africa total	**331***	**2.7%**	**12,063**
South Africa medical schemes	**1,183***	**3.2%**	**37,323*****

*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.

The conclusion of the Committee is therefore that price variations are caused predominantly by purchasing modalities[8] rather than the income levels of market segments. **Figure 4.4** illustrates this view using a two-dimensional representation of factors that could account for price variations between market segments.

In this illustration of the Committee's view, the South African public sector only obtains lower prices because it is a more efficient purchaser (as it is a large single purchaser) of medicines than the South African private sector[9]. It also illustrates the view that price variations are not a function of income but rather "purchasing modalities". Where a country or market segment is a "strong" purchaser of pharmaceuticals prices will be lower.

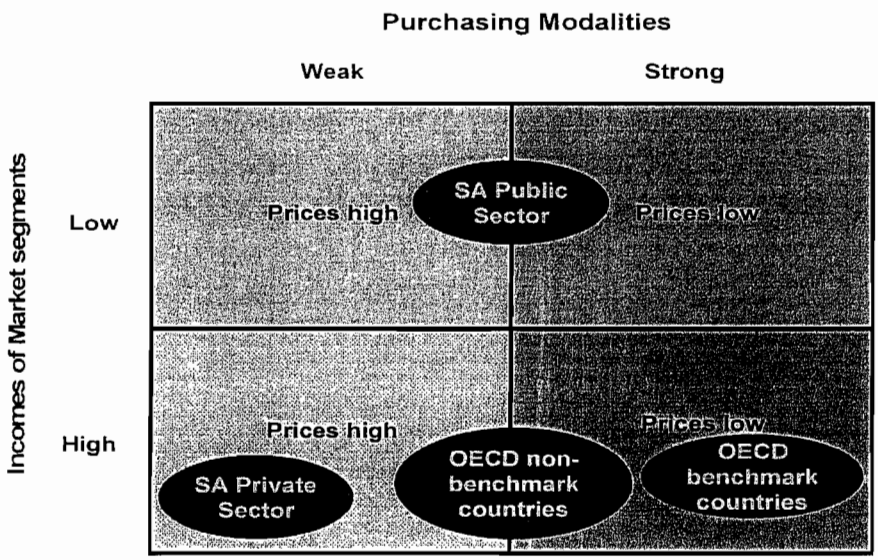
Figure 4.4 further illustrates the view that OECD benchmark countries are very high income but should face predominantly lower prices because as a

[8] These refer to single purchaser arrangements, price regulation, etc.
[9] Given that the South African public sector is not a large market, it will still face higher prices in the absence of regulatory interventions. For this reason it is placed half-way between "weak" and "strong" purchasing modalities in **Figure 4.4**.

country they are efficient purchasers of pharmaceuticals. They do not face lower prices because they have a lower income than, for instance, the South African private sector (a view expressed by industry stakeholders), or, for that matter, other OECD countries.

An important further consideration is that segmented small country markets will also face difficulties in achieving fair pharmaceutical prices due to market size. It is for this reason that regulation is required, and used to make up for any deficit in market power required to achieve prices free from distortion.

Figure 4.4: Illustration of the Price Variations due to Income and Purchasing Modalities



4.3 The preference for international benchmarking

On the basis of the above the *Committee* continues to view *international benchmarking* as a key intervention required to remove inappropriate price distortions resulting from market segmentation and structural weaknesses in the purchasing model prevalent in the South African private health care market.

As noted earlier, other countries use international benchmarking to establish the prices of new products. The Committee is however of the view that international benchmarking should be applied both to existing originator medicines and new originator medicines.

Internationally most countries have used across the board price cuts and price freezes to address price distortions in *existing products*. The first set of recommended draft regulations (released in early 2004) suggested such an approach.

However, on reflection the *Committee* recognises that prices of different products are subject to distortion to greater or lesser degrees and that across

the board price cuts or long-term price freezes will be unfair to products that are not presently distorted. For this reason the *Committee* believes that international benchmarking is superior to generalised price cuts as it is more able to discriminate between prices with and without significant distortion.

SECTION B: BENCHMARKING METHODOLOGY

The focus of this section is on the recommended methodology for international benchmarking. This includes:

1. The recommended approach;
2. The selection approach for benchmark countries;
3. The phased implementation of the final benchmark prices;
4. The methodologies for converting prices into South African Rands; and
5. The exemption application process.

The recommendations in this section cover originator medicines and do not apply at this stage to generic products. The latter are to be addressed at a later stage.

5. PROPOSED APPROACH

This section provides the Committee's recommended approach to international benchmarking. Subsequent sections deal with more specific aspects of the methodology including motivations underpinning recommendations made by the Committee.

The proposed framework for international benchmarking adopts the position that the *lowest price in a selected basket of countries should be used as the ultimate price for the purposes of benchmarking*. This is based on the view that there is no rational reason not to use the lowest price unless it can be shown conclusively that this price is itself subject to distortion.

However, to cater for the possibility that some prices may be unfairly reduced, the recommended approach incorporates two protections for pharmaceutical manufacturer:

1. A phased approach, which delays the implementation of the ultimate benchmark by two-years; and

2. An exemption process, which permits pharmaceutical companies to challenge the ultimate benchmark price based on the full disclosure of all aspects of the pricing of a product.

The recommended approach is as follows:

1. A selection ("basket") of appropriate countries will be identified, the prices of which will be benchmarked against prevailing prices in South Africa. Countries will be selected in accordance with the criteria outlined in **Section 6**.

2. Once the basket of countries has been selected, two benchmark methodologies will be applied in sequence to existing medicines:

    a. In **Phase 1**: The average of the lowest three prices in the basket, if this is lower than the South African ex-manufacturer price, or remain at the existing South African price if this is lower than the *average of the lowest three prices* ("interim benchmark 1").

    b. In **Phase 2**: the *lowest price* in the basket will apply if this is lower than the South African ex-manufacturer price or remain at the existing South African price if this is lower than the lowest price in the benchmark ("final benchmark").

3. Price conversions into Rands will be performed in accordance with the methodology outlined in **Section 8**.

4. In exceptional circumstances, an applicant may apply for exemption from the interim benchmark, but will be required to provide complete disclosure on all factors relevant to the matter.

5. The final benchmark will apply automatically two years after the introduction of the interim benchmark. However, applicants will be

required to submit full data on the application of the final benchmark methodology to each of their products within nine months of publication of the benchmarking methodology (by the end of **December 2008** using the indicative timeline provided below).

6. Both the *interim* and the *final* benchmark price values will be calculated annually by the affected companies and provided to the *Department of Health*. The Committee will review the benchmarked prices on a regular basis.

7. An exemption from the final benchmark will be permissible, on application, only where an affected company can demonstrate to the satisfaction of the Committee that the resulting price is distorted and prejudicial to the manufacturer.

8. Applications for exemption from the final benchmark must be submitted on a form and in the manner to be prescribed to the *Directorate of Pharmaceutical Economic Evaluations* (Department of Health) one year before the date for implementation of the final benchmark (e.g. by the end of **June 2009** using the indicative timeline provided below).

9. A review panel will be established for the purpose of assessing exemption applications.

10. Any new medicine coming onto the market after the publication of the international benchmarking methodology must comply immediately with the *final benchmark*, i.e. must set their ex-manufacturer price at the lowest price in the basket of benchmark countries.

11. New medicines coming onto the market after the initiation of the reform for which an exemption from the benchmarking methodology is sought, must submit its application concurrently with their application to the Medicines Control Council ("MCC") to register a new medicine.

12. A medicine that has been registered by the MCC without any exemption application having been submitted, will not be permitted an exemption.

13. The decisions of the review panel will be made public and will include a non-confidential set of reasons. However, the information submitted to motivate for the exemption, and the full decision, will be kept confidential.

14. The review panel will be permitted to require full disclosure of all information relevant to reach a final determination. Any failure to provide this information will prejudice an application.

15. The indicative timeline for implementation is as follows:

    a. **Regulation 5(2)(e) (Government Gazette No. 26304 of 30 April 2004)** requires that the SEP be set in compliance with the international benchmarking methodology "*within 3 months of publication of such methodology*".

b. If the Committee recommendations are approved by the Minister and published by the end of **March 2008**, SEPs must comply with the interim benchmark by the beginning of **July 2008**.

c. Applicants must therefore submit full data on the application of the interim benchmark methodology to each of their products within two months of publication of the benchmarking methodology (e.g. by the end of **May 2008** using the above illustrative timeline).

6. SELECTION OF BENCHMARK COUNTRIES

This section outlines the recommended approach to selecting the "basket" of countries that will be used to benchmark pharmaceutical products sold in South Africa.

6.1 Key criteria for selection

The Committee has considered a wide range of potential criteria for the selection of a basket of benchmark countries. Account has been taken of the fact that there is no 'international best practice' in relation to such criteria.

The Committee *recommends as a fundamental point of departure that medicine prices in South Africa should be benchmarked against countries with effective systems for regulating and pricing medicines*, and incorporate the following into their pricing regime:

1. Regulatory authorities that licence and ensure the quality of medicines;
2. Have systems in place for the effective regulation of medicine prices, particularly through monopsony[10] purchasing structures;
3. Accessible, structured pricing information that is regularly updated and reflective of the actual prices at which medicines are sold (the structure of such information should allow for the calculation of the ex-manufacturer prices); and
4. Have implemented internationally accepted rules on patent and intellectual property rights protection.

6.1.1 Drug regulatory authorities that ensure product quality

Medicines are commodities that are used to save lives, prevent or limit morbidity and enhance quality of life. The safety of medicines is related to purity or absence of contamination by unnecessary chemical substances, and reliable delivery of the relevant dosage to the site of action (bioavailability). Consumers of medicines therefore require guaranteed purity, potency and bioavailability. National medicines regulatory authorities ensure the quality of medicines through a system of licensure and maintenance of good manufacturing practice (GMP).

Regulatory rigour however differs from country to country. There is furthermore no formal system for recognition of regulatory rigour. The Committee therefore *recommends that as a proxy measure membership of the Pharmaceutical Inspection Co-operation Scheme ("PICS") be used.* (See **Table 6.1** for PICS members).

The South African Medicine Control Council ("MCC") was admitted as a member of PICS in 2007, which implies that the standards for the manufacture

[10] A monopsony purchaser refers to the situation where there is a single, large purchaser (e.g. a social health insurance organisation or government in the case of tax funded services) which purchases medicines for the majority of the population.

of medicines (and consequently the quality of medicines) are similar in South Africa to other members of PICS.

The criteria of PICS membership not only ensures that benchmark countries have comparable product quality to South Africa, but as compliance with conditions of registration will impact upon the cost of entry into the market, this ensures that benchmark countries have similar cost structures in this respect. The table below lists the countries that are currently members of PICS.

Table 6.1: Members of the Pharmaceutical Inspection Co-operation Scheme

Australia*	Greece	Poland
Austria	Hungary	Portugal
Belgium	Iceland	Romania
Canada	Ireland	Singapore
Czech Republic	Italy	Slovakia
Denmark	Latvia	South Africa
Estonia	Lichtenstein	Spain
Finland	Malaysia	Sweden
France	Netherlands	Switzerland
Germany	Norway	United Kingdom

* The medicine regulatory authorities of Australia and New Zealand have merged into a single regulatory authority. Hence, quality standards as applied by PICS will be applicable to both Australia and New Zealand.

6.1.2 Effective regulation of medicine prices

The Committee is of the view that *any country selected for recognition in the basket must have in place a reasonable and effective regime for eliminating price distortions*. It would clearly be self-defeating and inconsistent with the *aims and objectives* of this intervention (outlined in **Section 3**) for the basket to include countries that permit price distortions to be retained.

A country meeting this criterion would have characteristics or interventions that include the following:

- **Presence of a large monopsony purchaser of medicines**: A health system where the State or a large-scale mandatory health insurance scheme is the major (or almost exclusive) purchaser of medicines i.e. a monopsony purchaser of medicines. This is generally one of the most effective ways of counteracting price distortions arising from imperfections in the market for medicines. The relative effectiveness of this purchasing power depends on the percentage of the population covered by the 'monopsony'

purchaser, as well as the regulatory measures used to establish medicine price levels [11].

- **The existence of strong price regulation**: The prices of medicines are directly regulated through measures such as: limitations on the extent of price increases; price cuts; and price freezes.

- **The presence of internal reference pricing**: Internal reference pricing should be present and applied at the *active ingredient* level, and/or *pharmacological class* and/or *therapeutic class level*. Countries that apply internal reference pricing have demonstrated significant moderation in their medicine expenditure (Ioannides-Demos *et al.* 2002). The use of reference pricing in health systems with a monopsony purchaser has been particularly effective in moderating medicine prices. Some countries, such as the Netherlands, have introduced international benchmarking in addition to internal reference pricing in an effort to address the problem of compensatory increases in prices of medicines not subject to reference pricing (*ibid*).

- **The presence of international benchmarking**: International benchmarking should be applied in the pricing of medicines in the reference country. Here the focus should be on those countries that are most referenced as benchmark countries rather than the countries doing the referencing. This approach reduces the size of the basket by indirectly rather than directly including countries in the basket.

- **The application of cost-effectiveness assessments**: Cost effectiveness assessments are applied within that country to determine whether the medicine offers value for money at a particular price. Pharmaceutical manufacturers often request relatively high prices for originator medicines. Manufacturers typically make public interest claims arguing that the medicine offers significant benefits to society and that these benefits outweigh the higher price (compared to drugs currently in use) being requested for the drug. In a number of countries, these claims are assessed by comparing the incremental costs and benefits using pharmacoeconomic techniques (cost-effectiveness analyses). The decision to permit access for a new medicine at a given price is then based on a qualified value judgement of whether the additional benefits are worth the additional price.

In selecting benchmark countries, the Committee has placed an emphasis on countries that use a combination of these methods.

[11] In order to determine relevance of the monopsony purchaser in a particular country, the percentage of total health care expenditure attributed to public sources (tax and mandatory health insurance combined) within each country is used. To determine a 'cut-off' point, the weighted average for all OECD countries is calculated (with each country being weighted according to the size of its total health care expenditure). Overall, the weighted average of public sources' share of total health care expenditure for all OECD countries is assessed at 60%. This is relatively low as an indicator of purchasing power, and is attributable to the influence of the United States (which accounts for 50% of all OECD health expenditure) where public sources account for only 45% of total spending. Nevertheless, this weighted average is regarded by the Committee as a sufficiently sound mechanism for identifying countries with an above average degree of purchasing power.

6.1.3 Maintenance of an accurate list of medicine prices

The Committee is of the view that *countries selected to be included in the basket should have accessible price lists which can be reduced to a valid and undistorted ex-manufacturer price*.

Price lists may sometimes include rebates and discounts and do not reflect the net price at which medicines are sold. The benchmarking methodology compares ex-manufacturer prices therefore the price list should reflect actual prices at ex-manufacturer level, net of any discounts or rebates.

In circumstances where the price list does not reflect ex-manufacturer prices, then a reliable method for calculating the ex-manufacturer price must exist (e.g. clearly defined logistics and dispensing fees).

In addition, price information must be available by International Non-Proprietary Name ("INN") and must either be available in English or in a language that can be routinely translated.

Finally, it is necessary to have access to this information, either through a public domain website, a government ministry/department or through a regulatory authority.

6.1.4 Countries that recognise internationally accepted rules on patent protection (TRIPS compliant)

The Committee is of the view that *only countries that respect property rights to the same degree as South Africa should be included in the basket. Any signatory of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), of which South Africa is one, will be regarded as compliant with this criterion*.

The Agreement on TRIPS was concluded as part of the text of the Final Act of the Uruguay Round of negotiations on 15 December 1993. The Final Act was signed on 15 April 1994 and came into operation on 1 January 1995.

The pharmaceutical industry argues that the high research and development costs of bringing a drug to market require that there is a period of exclusivity to recoup the significant costs of drug development, and refer to the TRIPS agreement to uphold their entitlement to this period of exclusivity. The patent holder (or its licensees) becomes the sole supplier of the medicine during the period of exclusivity.

In countries that are not TRIPS signatories and the least developed countries, there is no patent protection and the manufacturer of the originator has to compete with other manufacturers that produce a similar product. In such environments the manufacturer of the originator medicine may choose not sell such a medicine given the severe price competition with other manufacturers.

Originator medicines in South Africa are patent protected. The countries selected for the basket must also offer patent protection to originator medicines so that the comparison is fair.

There is no agreed means of identifying whether a country is TRIPS compliant or not. For the purposes of selecting countries to include in the benchmarking

basket, it is therefore regarded as sufficient that the country is a TRIPS signatory[12].

6.1.5 Rationale for focusing on OECD countries for benchmarking

The Committee is of the view that *only OECD countries should be considered for incorporation within the basket*.

Pharmaceutical regulation is a prominent policy issue in the majority of OECD countries.

The OECD is one of the most reliable sources of comparable statistics, including economic and social data. Member countries have a commitment to democracy and market economy principles.

The OECD helps governments to share information; compare policy experiences; and also to identify good practice to assist in the implementation of various policies.

Table 6.2: Members of the Organisation for Economic Co-operation and Development ("OECD")

Australia	Korea
Austria	Luxembourg
Belgium	Mexico
Canada	Netherlands
Czech Republic	New Zeeland
Denmark	Norway
Finland	Portugal
France	Poland
Germany	Slovak Republic
Greece	Spain
Hungary	Sweden
Iceland	Switzerland
Ireland	Turkey
Italy	United Kingdom
Japan	United States

[12] If a country is a TRIPS signatory and does not comply, a dispute will be lodged with the World Trade Organisation ("WTO") and a determination made. Signatory countries are required to act in accordance with this determination.

6.2 Rationale for limiting the number of reference countries for the purpose of benchmarking

The Committee is of the view that *the basket should be limited to a small number of relevant countries to reduce the difficulty of obtaining price information from manufacturers*.

Originator manufacturers have indicated that obtaining medicine prices from their parent company's country offices is extremely difficult. Thus, the bigger the basket of countries, the larger the administrative burden on manufacturers and importers.

International experience shows that many countries typically select a limited basket of benchmark countries, usually between 3 and 7 [13].

As noted previously (**Section 6.1.2**), by selecting highly referenced countries there is an indirect benchmarking to a much larger basket of countries.

6.3 Selected benchmark countries (the "basket")

The application of the criteria outlined above to all 30 OECD countries is summarised in **Table 6.3**. Four countries met all the criteria:

1. Australia;
2. Canada;
3. New Zealand; and
4. Spain.

The Committee consequently recommends that Australia, Canada, New Zealand, and Spain (along with South Africa) make up the initial basket.

A small number of countries were excluded on the basis that there was no "access to information". These countries are: Belgium, Hungary, Netherlands, Poland, and Portugal.

As the extent to which individual countries meet the criteria outlined above could change over the next few years, *the Committee recommends that the country basket be reviewed at least every two years*.

[13] For example, France uses 3 reference countries while Belgium, Spain, Portugal and Australia use 4 reference countries.

Table 6.3: Evaluation of Benchmark Countries

Country	PICS Member	Internal reference pricing	Internat. benchmark / External reference pricing	Use of Pharmaco-Economic evaluations	Purchasing Power		TRIPS Compliance	Access to information (Pricing data)
					Public spending as % total health care expend	Share exceeding 60%		
Australia	**YES**	**YES**	**YES**	**YES**	**67.5**	**YES**	**YES**	**YES**
Austria	YES	NO	YES	YES	70.7	YES	YES	NO
Belgium	YES	YES	YES	YES	71.1	YES	YES	NO
Canada	**YES**	**YES**	**YES**	**YES**	**69.8**	**YES**	**YES**	**YES**
Czech Rep.	YES	YES	YES	NO	89.2	YES	YES	NO
Denmark	YES	YES	YES	NO	82.3	YES	YES	NO
Finland	YES	NO	YES	YES	77.2	YES	YES	NO
France	YES	YES	YES	NO	78.4	YES	YES	NO
Germany	YES	YES	NO	YES	76.9	YES	YES	NO
Greece	YES	YES	YES	YES	52.8	NO	YES	NO
Hungary	YES	YES	YES	YES	71.6	YES	YES	NO
Iceland	YES	N/I*	N/I*	N/I*	83.4	YES	YES	NO
Ireland	YES	NO	YES	YES	79.5	YES	YES	NO
Italy	YES	YES	YES	NO	75.1	YES	YES	NO
Japan	NO	N/I*	N/I*	N/I*	81	YES	YES	NO
Korea	NO	N/I*	N/I*	N/I*	51.4	NO	YES	NO
Luxembourg	NO	N/I*	N/I*	N/I*	90.4	YES	YES	NO
Mexico	NO	N/I*	N/I*	N/I*	46.4	NO	YES	NO
Netherlands	YES	YES	YES	YES	62.4	YES	YES	NO
N. Zealand	**YES**	**YES**	**YES**	**YES**	**77.4**	**YES**	**YES**	**YES**
Norway	YES	YES	N/I*	N/I*	83.5	YES	YES	NO

STAATSKOERANT, 17 DESEMBER 2010 No. 33878 45

Country	PICS Member	Internal reference pricing	Internat. benchmark / External reference pricing	Use of Pharmaco-Economic evaluations	Purchasing Power		TRIPS Compliance	Access to information (Pricing data)
					Public spending as % total health care expend	Share exceeding 60%		
Poland	YES	YES	YES	YES	68.6	YES	YES	NO
Portugal	YES	YES	YES	YES	71.6	YES	YES	NO
Slovakia	YES	YES	YES	NO	73.8	YES	YES	NO
Spain	**YES**	**YES**	**YES**	**YES**	**70.9**	**YES**	**YES**	**YES**
Sweden	YES	NO	NO	YES	84.9	YES	YES	NO
Switzerland	YES	YES	N/I*	N/I*	58.5	NO	YES	NO
Turkey	NO	YES	N/I*	N/I*	72.3	YES	YES	NO
UK	YES	NO	NO	YES	86.3	YES	YES	NO
US	NO	YES	N/I*	N/I*	44.7	NO	YES	NO

* N/I: No Information This refers to countries where information was not published, not accessible or it was deemed unnecessary to continue searching for data as the countries have failed to meet one or two of the other crucial criteria.

Sources:

- Claudia Habl, Katja Antony, Danielle Arts, Michael Entleitner, Barbara Froschl, Christine Leopold, Heidi Sturzlinger, Sabine Vogler, Romana Landauer (2006). *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States.* Commissioned by European Commission - DG Competition. Vienna: OBIG Health Economics.
- Sabine Vogler, Danielle Arts, Claudia Habl, Christine Leopold, Romana Landauer (2006). *Pharmaceutical Systems in the EU 2006: Comparative Analysis*. Vienna: OBIG
- Office of Fair Trading. (2007) *The Pharmaceutical Price Regulation Scheme. An OFT market study*.
- Productivity Commission (2001). *International pharmaceutical Price Differences,* Research Report. Canberra: AusInfo.

7. IDENTIFICATION OF COMPARATOR PRODUCT AND PRICE

7.1 Overview

This section outlines the recommended approach for identifying comparator products and their prices. In this respect the Committee recommends that:

1. *Originator products with the same INN, strength, dosage form and exact or closest pack size be used for the comparison.*

2. *The comparator price be the Rand equivalent of the ex-manufacturer price; and*

3. *The responsibility be placed on the manufacturer to identify and supply the relevant information on the products and their associated prices as they occur in the benchmark countries.*

7.2 Product identification

The organisation that applied for the registration of a particular medicine (the "applicant") needs to identify the INN name(s) of all the products being sold in South Africa.

Thereafter, the identical product must be identified in each of the benchmark countries. In circumstances where there is no identical INN, the product will be placed on a list of 'no comparator' items.

After matching the INNs, the strength and dosage form must also be identical. If there is no identical strength available in a benchmark country, then the lowest common strength should be used (e.g. a milligram for milligram price comparison of the active ingredients).

This process should be applied in *each* benchmark country. So, for example if the identical strength and dosage form is available in two of the benchmark countries, but different strengths are available in the remaining benchmark countries, a milligram for milligram comparison must be done in these countries. This will ensure that the product is benchmarked for the full basket of countries wherever possible.

In circumstances where there is no identical dosage form, the product will be placed on a list of 'no comparator' items.

The pack size must be identical for every product in the basket. Where the pack size varies then a unit price comparator for the closest pack size will be used (e.g. price per tablet, millilitre, or capsule, etc.).

Following benchmarking, it is recommended that those products on the 'no comparator' list be subject to pharmacological or therapeutic class reference pricing (at ATC 4 level) (see **Section 9** on combination products for more details of this process), which is done through an application to the Committee.

Should the applicant be convinced that internal reference pricing does not provide a fair price for their product, then it is recommended that the applicant be permitted to submit a pharmacoeconomic analysis as the basis for a price determination by the Committee.

7.3 Price Identification

To determine the comparator ex-manufacturer price, it is proposed that the regulated Pharmacy Purchase Price ("PPP") for each product in the basket must be identified. The comparator price should determined as follows:

- Ex-manufacturer price = Pharmacy purchase price less all add on charges (wholesale fee, logistics fee, taxes, rebates and all discounts). This will provide the ex-manufacturer price in the foreign currency.
- The ex-manufacturer price in South Africa is determined as follows:
  - Ex-manufacturer = (SEP – Logistic fee) – VAT

Where more than one selling price occurs in a benchmark country, *it is recommended by the Committee that the price used in the largest ambulatory sector be selected*. This is in line with the rationale outlined in **Section 6.1.2** for benchmarking against the price of a purchaser with considerable purchasing power.

Where the unit price differs for different pack sizes, *it is recommended that the price of the closest pack size be used for the comparison*.

7.4 Exchange rate conversion[14]

The prices of pharmaceutical products in the basket of countries are denominated in their various currencies. To properly benchmark the currencies requires that an appropriate conversion rate is used to the South African Rand. The provisional methodology of the Committee proposed a 12-month historical average. Industry inputs to the Committee proposed instead a 6-month historical average.

After consideration of the issues the Committee has decided that both these methods are problematic as they do not properly estimate the exchange rate in the period for which the benchmarked prices are to occur. The problem in essence is that an average exchange rate applicable to the 2007 period would be applied for the 2008 period.

This will be most problematic where a systemic long-term trend is in place resulting in the appreciation or depreciation of the nominal exchange rates. Such a systemic trend will be expected particularly where differential inflation rates exist between South Africa and the relevant countries.

The Committee consequently considered and evaluated the following options:

[14] All exchange rate and inflation data was sourced from the South African Reserve Bank.

1. **Option 1 - Twelve-month historical average**: this uses the average exchange rate during the year immediately prior to the benchmark year. This was the original Committee proposal.

2. **Option 2 - Six-month historical average**: this uses the average exchange rate for the 6-month period immediately prior to the benchmark year. The approach (preferred by industry) is essentially the same as that of the Committee except that it eliminates data from further in the past in the determination of the average.

3. **Option 3 - Projected twelve-month average based on inflation differentials**: this uses the inflation differentials between South Africa and the basket of countries to project the nominal exchange rate in the benchmark year. The average exchange rate for the 12-months prior to the benchmark year is adjusted in accordance with the inflation differentials.

4. **Option 4 - Three-year linear regression**: A 3-year linear regression, using monthly exchange rate averages, is used to produce a projection of the monthly nominal exchange rates in the benchmark year. The average of the monthly rates is used as the conversion rate for benchmarking. This approach essentially applies the formula produced by the regression analysis to project forward the nominal exchange rate monthly averages for the benchmark year (2008 in this instance). (See **Table 7.1** for the equations used and **Figure 7.1**).

Of the above, **option 4** was regarded as the most reliable and appropriate basis for determining the conversion rate. In reaching this decision, note was taken of the extent to which the alternative options compared to the *actual* exchange rates in the years 2006 and 2007 when the method is applied as if those were the benchmark years. Of the different approaches **option 4** resulted in the lowest variances from the actual averages (see **Table 7.2**).[15] In particular it was able to eliminate the substantial variances in the 2007 year.

Table 7.1: Option 4 Equations

Australian Dollar ("AUD"):	$Y = 0.0457X + 4.4415$
European Euro ("Euro"):	$Y = 0.0733X + 7.3358$
New Zealand Dollar ("NZD"):	$Y = 0.0302X + 4.1366$
Canadian Dollar ("CAN"):	$Y = 0.0605X + 4.8233$

[15] An exact match in a given 12-month period would not be expected as some short-term deviations from a long-term trend will in some instances fall into a subsequent calendar year.

Figure 7.1: **Option 4 – Actual Trends, Linear Regression Lines, Regression Equations for 36 months starting from 1 January 2005 and ending 31 December 2007[16]**

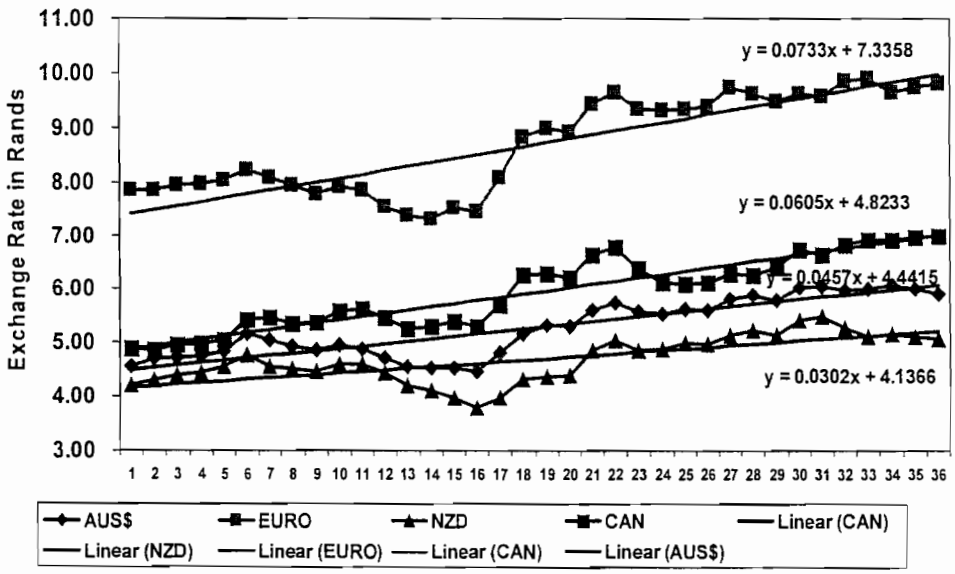
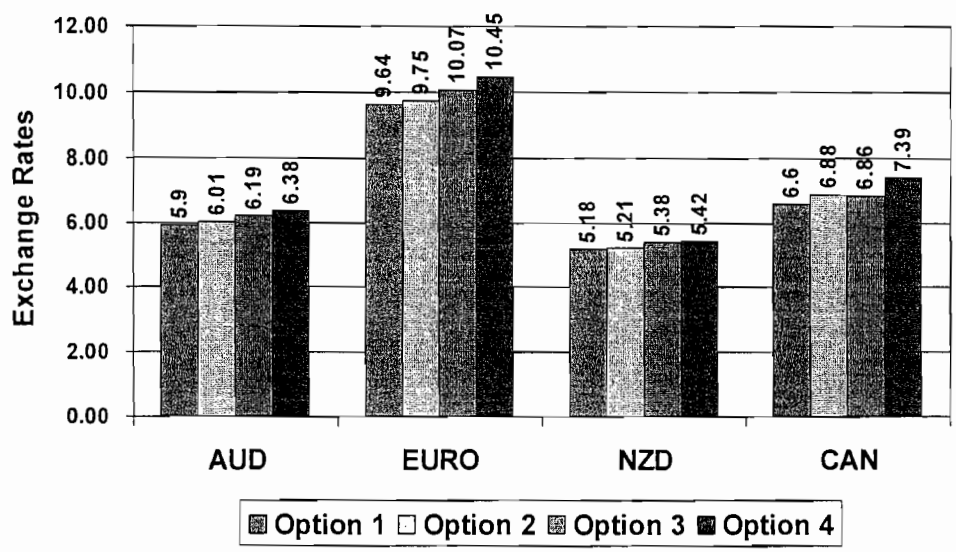


Figure 7.2: **Comparison of the 2008 Exchange Rates by Option (Rands per Foreign Currency Unit)**



[16] The general "upward" trend in the rates indicates that the nominal value of the Rand is depreciating steadily over time. This trend will primarily be a consequence of relative inflation rates. Any country with a sustained higher inflation rate will depreciate in nominal terms against the Rand.

Table 7.2: Comparison of Exchange Rate Options to Convert Pharmaceutical Prices from Foreign to Domestic Prices

Date	AUD	EURO	NZD	CAN
		ACTUAL		
2005	**4.85**	**7.91**	**4.49**	**5.26**
2006	**5.10**	**8.52**	**4.41**	**5.97**
2007	**5.90**	**9.64**	**5.18**	**6.60**
		OPTION 1		
2006	4.85	7.91	4.49	5.26
2007	5.10	8.52	4.41	5.97
2008	***5.90***	***9.64***	***5.18***	***6.60***
		OPTION 2		
2006	4.90	7.85	4.53	5.49
2007	5.52	9.28	4.75	6.41
2008	***6.01***	***9.75***	***5.21***	***6.88***
		OPTION 3		
2006	4.89	8.01	4.51	5.32
2007	5.16	8.73	4.47	6.13
2008	***6.19***	***10.07***	***5.38***	***6.86***
		OPTION 4		
2006	5.29	8.69	4.70	5.94
2007	5.84	9.57	5.06	6.67
2008	***6.38***	***10.45***	***5.42***	***7.39***
		VARIANCE FROM ACTUAL (%)		
		OPTION 1		
2006	-5.2%	-7.6%	1.9%	-13.6%
2007	-15.7%	-13.2%	-17.5%	-10.5%
		OPTION 2		
2006	-4.1%	-8.5%	2.7%	-8.8%
2007	-6.8%	-3.9%	-9.1%	-3.0%
		OPTION 3		
2006	-4.5%	-6.4%	2.2%	-12.3%
2007	-14.4%	-10.4%	-16.0%	-7.6%
		OPTION 4		
2006	3.5%	2.0%	6.1%	-0.5%
2007	-1.2%	-0.7%	-2.5%	1.0%

8. METHODS USED TO CALCULATE THE BENCHMARK PRICE

8.1 Overview

This section provides a review of alternative approaches used to calculate the benchmark price occurring internationally considered by the Committee in reaching its decision.

A review of the methods used to calculate the benchmark price in a number of OECD countries indicates that five main methods are used to calculate the benchmark price. These methods are:

- Average of all prices in the basket of countries, e.g. Austria;
- Average of the lowest prices (usually 3) in the basket of countries, e.g. Greece;
- Average of prices in the basket of countries less a percentage, e.g. Lithuania, Luxembourg and Slovenia;
- The median price in the basket of countries, e.g. Netherlands; and
- The lowest price in the basket of countries, e.g. Hungary and Latvia.

Industry stakeholders also identified the above benchmarking methods in their submissions.

8.2 Average of all prices

The average is the ideal mathematical approach when prices are normally distributed, which is not necessarily the case in relation to international medicine prices.

8.3 Average of lowest prices in the basket

The use of the average of the lowest three prices in the basket of benchmark countries is not uncommon. When prices are not available in all benchmark countries, the average of the lowest three prices will closely approximate the average of all prices.

8.4 Average of all prices minus a percentage

The use of the average of all prices in the basket minus a percent produces results that are closer to the lower prices in the basket. The rationale for a particular percentage appears to be related to the desired level of price reduction.

8.5 Median of all prices in the basket

The use of the median of all prices in the basket results in a price that is the central price of all prices in the basket. In circumstances where there is wide variance between the highest and lowest prices then the median price is preferred. The median is a useful approach when prices are not normally distributed.

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**

	Description		Example
1st level	Anatomical main group	A	Alimentary tract and metabolism
2nd level	Therapeutic subgroup	A10	Drugs used in diabetes
3rd level	Pharmacological subgroup	A10B	Oral blood glucose lowering drugs
4th level	Chemical subgroup	A10BA	Biguanides
5th level	Chemical substance	A10BA02	Metformin

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.

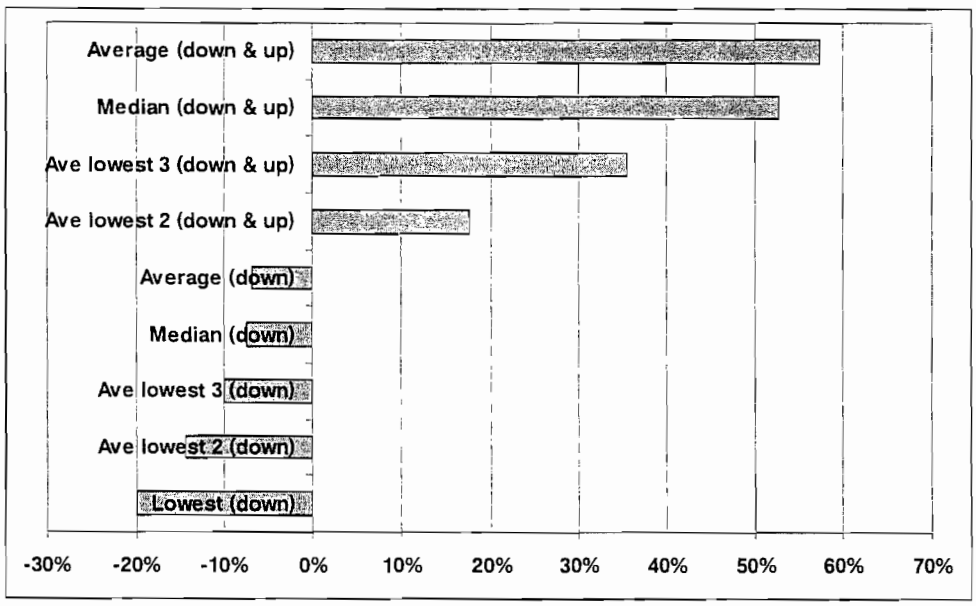
3. Neither the "average" or "median" scenarios" significantly impact on medicine costs, even where prices can only adjust down, with option 4 showing decreases of 6.9% and 7.5% respectively.

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

Scenario	Adjustment	Expenditure (R'000)			
		Option 1	Option 2	Option 3	Option 4
Present	n/a	6,205,748			
Average	Down	5,721,590	5,725,464	5,741,803	5,775,409
	change (%)	*-7.8%*	*-7.7%*	*-7.5%*	*-6.9%*
	down & up	9,184,643	9,327,153	9,473,418	9,768,466
	change (%)	*48.0%*	*50.3%*	*52.7%*	*57.4%*
Median	Down	5,667,274	5,684,784	5,713,884	5,741,905
	change (%)	*-8.7%*	*-8.4%*	*-7.9%*	*-7.5%*
	down & up	8,953,491	9,062,375	9,254,810	9,477,680
	change (%)	*44.3%*	*46.0 %*	*49.1%*	*52.7%*
Ave lowest 2	Down	5,201,289	5,225,869	5,258,132	5,316,038
	change (%)	*-16.2%*	*-15.8%*	*-15.3%*	*-14.3%*
	down & up	6,956,781	7,033,775	7,096,321	7,304,134
	change (%)	*12.1%*	*13.3%*	*14.4%*	*17.7%*
Ave lowest 3 (phase 1)	Down	**5,492,723**	**5,513,011**	**5,532,705**	**5,582,264**
	change (%)	***-11.5%***	***-11.2%***	***-10.8%***	***-10.0%***
	down & up	7,975,216	8,067,175	8,136,356	8,405,960
	change (%)	*28.5%*	*30.0 %*	*31.1%*	*35.5%*
Lowest (phase 2)	Down	**4,822,950**	**4,865,900**	**4,898,693**	**4,969,959**
	change (%)	***-22.3%***	***-21.6%***	***-21.1%***	***-19.9%***

Figure 10.1: Evaluation of alternative benchmark modalities for Option 4, percentage change from the present



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

Bester M, Hammann E. *Mediscor Medicines Review – 2004.* Mediscor Pharmaceutical Benefit Management, Centurion, 2005.

Bester M, Brews M, Hammann E. *Mediscor Medicines Review – 2005.* Mediscor Pharmaceutical Benefit Management, Centurion, 2006.

Danzon PM, Towse A. Differential pricing for pharmaceuticals: Reconciling access, R&D and patents. *International Journal of Health Care Finance and Economics*, 2003: 3(3): 183-205.

Habl C, Antony K, Arts D, Entleitner M, Fröschl B, Leopold C, Stürzlinger H, Vogler S. *Surveying, assessing and analysing the pharmaceutical sector in the 25 EU Member States: Country Profiles.* Commissioned by European Commission – DG Competition. Österreichisches Bundesinstitut für Gesundheitswesen, Vienna, 2006.

Ioannides-Demos LL, Ibrahim JE, McNeil JJ. Reference-based pricing schemes: Effect on pharmaceutical expenditure, resource utilisation and health outcomes. *Pharmacoeconomics* 2002; 20(9): 577-591.

OECD. *Health at a glance: OECD Indicators 2005.* Organisation for Economic Co-operation and Development, Paris, 2005.

Pan African Investment and Research Services ("PAIRS"), *South African Medicine Benchmark Pricing Proposals: a Technical Review*, 25 April 2007.

Paris V, Docteur E. *Pharmaceutical pricing and reimbursement policies in Canada.* Organisation for Economic Co-operation and Development, Paris, 15 February 2007.

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.

Claudia Habl, Katja Antony, Danielle Arts, Michael Entleitner, Barbara Froschl, Christine Leopold, Heidi Sturzlinger, Sabine Vogler, Romana Landauer. *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States.* Commissioned by European Commission - DG Competition. Vienna: OBIG Health Economics, 2006.

Sabine Vogler, Danielle Arts, Claudia Habl, Christine Leopold, Romana Landauer. *Pharmaceutical Systems in the EU 2006: Comparative Analysis.* Vienna: OBIG, 2006.

Office of Fair Trading. *The Pharmaceutical Price Regulation Scheme. An OFT market study.* 2007.

Productivity Commission. *International pharmaceutical Price Differences,* Research Report. Canberra: AusInfo, 2001.

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

http://www.medsafe.govt.nz/consumers/regulate.asp 08/01/2008

50

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

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

http://ec.europa.eu/enterprise/phabiocom/docs/tse/canada.pdf 8 January 2008

http://www.hc-sc.gc.ca/ahc-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

COUNTRY	YES / NO	COMMENT
Austria	Yes	No explicit guidelines. Includes Health Economic Evaluation according to stated requirements
Belgium	Yes	Standard Report format. Therapeutic value and trade off between value and cost of treatment are key criteria
Cyprus	No	Plays an important role for inclusion on the positive list. Significant medical benefit over existing treatment at similar price level.
Czech	No	No clear guidelines
Denmark	No	Companies not obliged to present PE evaluation. DMA – PE evaluation minor relevance (quality submitted insufficient)
Estonia	Yes	Baltic guideline for Economic Evaluation
Finland	Yes	Innovator Pharmaceutical and if required by HILA for other applicants (new pharmaceutical form of molecule already on Finnish market)
France	No	No official requirement Voluntary guidelines by scientific community
Germany	Yes	
Greece	Yes	For ref price system. New pharmaceuticals- comprehensive guideline
Hungary	Yes	INN – required with new indications/ price increase
Portugal	Yes	
Slovakia	No	No clear guidelines
Slovenia	Yes	
Spain	Yes	
Sweden	Yes	
UK	Yes	NICE guidelines

STAATSKOERANT, 17 DESEMBER 2010 No. 33878 65

Table B.2: Medicine pricing regulations

EU Country	Price Level controlled	Price Referencing	Methodology	Comment
Austria	Manufacturer Price	External Price Referencing	BMGF set the Ave EU price, following an advice from PC	
Belgium	Manufacturer Price	External & Internal Price Referencing		
Cyprus	Wholesale Price for Imported ph. And Man price for locally produced	External Price Referencing		For imported ph.
Czech Republic	Manufacturer Price	External Price Referencing	No specific methodology	For imported ph.
Denmark	Wholesale Price	Internal Price Ref		For reimbursed off patent and parallel imported ph. External Price Ref-minor role for evaluation purposes
Estonia	Manufacturer Price	External Price Referencing, price-volume agreements between the ministry and the ph. Companies		
Finland	Wholesale Price	External & Internal Price Referencing	For Internal ref. HILA takes in the case of off-patent pharmaceuticals, the price of the cheapest available ph.	However external price referencing is not formally performed by HILA
France	Manufacturer Price	External Price Ref	The price should not be lower than the lowest in the benchmark countries	
Germany	Manufacturer Price	Internal Price Ref		No external Price Ref

EU Country	Price Level controlled	Price Referencing	Methodology	Comment
Greece	Manufacturer Price	External Price Ref	Average of the three lowest European prices	For imported ph.
Hungary	Manufacturer Price	External & Internal Price Referencing	The lowest price of the reference countries	
Ireland	Manufacturer Price	External Price Ref	Average price of 9 EU member states	
Italy	Manufacturer Price	External Price Ref	Prices in the other EU countries	
Latvia	Wholesale Price	External & Internal Price Referencing	The lowest price of the reference countries	
Lithuania	Manufacturer price/CIP Price	External & Internal Price Referencing	Average – 5%	
Luxembourg	Pharmacy Retail Price	External Price Ref	Price of the pharmaceutical in the country of origin or provenance is taken as a reference and decreases certain percentage 1.56% Luxembourg/Belgium 0.62% products from other countries	
Netherlands	Wholesale Price	External Price Ref	Average of basket of countries	
Poland	Wholesale Price	External & Internal Price Referencing		

EU Country	Price Level controlled	Price Referencing	Methodology	Comment
Portugal	Manufacturer Price	External Price Ref	If the difference between the average and the lowest PVA is more than 30%, the lowest of the pva plus one third of the average of the two lowest PVA is applied (If available in 2 or 3 countries). Upward and downward movement allowed. Lowest IN THAT COUNTRY is used if available in one of the three reference countries	Before they were using the lowest price
Slovakia	Pharmacy Retail Price	External Price Ref		For imported ph.
Slovenia	Wholesale Price	External Price Ref	The wholesale price of a ph. may not exceed 85% of the average price determined by the price comparison. For imported products an extra 0.5% is added, and for generics the price may not exceed 96% of the aver wholesale price in 3 reference countries.	
Spain	Manufacturer Price	External Price Ref		
Sweden	Wholesale Price		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 issues.	No external Price Ref.
United Kingdom	Wholesale Price			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.**

Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States, Claudia Habl, Katja Antony, Danielle Arts, Michael Entleitner, Barbara Froschl, Christine Leopold, Heidi Sturzlinger, Sabine Vogler, Romana Landauer. Vienna, July 2006. Commissioned by European Commission - DG Competition. **OBIG Health Economics.** Pharmaceutical Systems in the EU 2006.

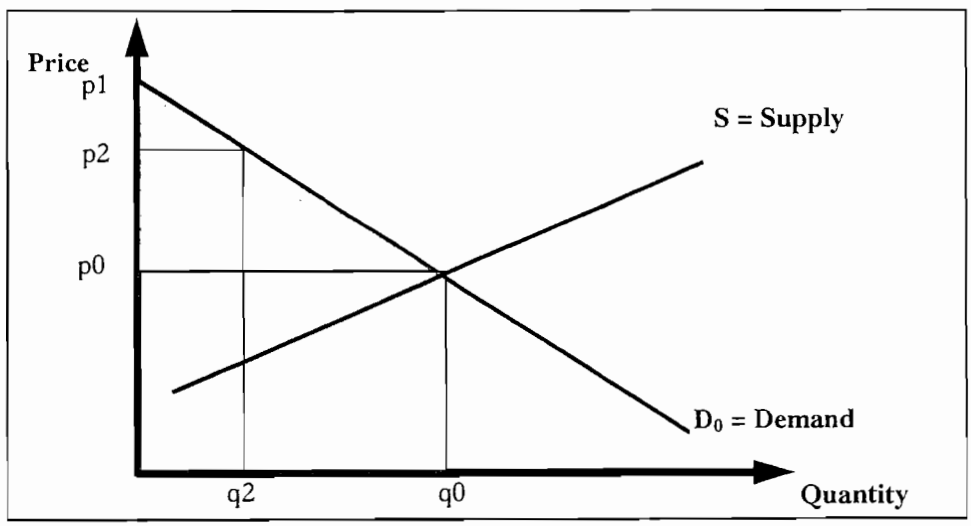
APPENDIX C: ECONOMIC RATIONALE FOR INTERNATIONAL BENCHMARKING

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 *p0q0*, i.e. the market clearing price is at *p0*. The triangle above *p0* and below the demand curve *D0* is traditionally regarded as the consumer surplus. This is because all the people who would have accepted a higher price, for example *p1*, benefit from the market price *p0*. They benefit by the price difference between *p0* and *p1*.

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



The advantage obtained by the supplier of charging the price *p0*, is that the total value of the volumes traded are much higher than they would be if they charged *p2* and had a resulting volume traded equivalent to *q2*. In other words, the shaded area of *p0 x q0* is greater than *p2 x q2*. 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 p0 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 p0 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 county 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

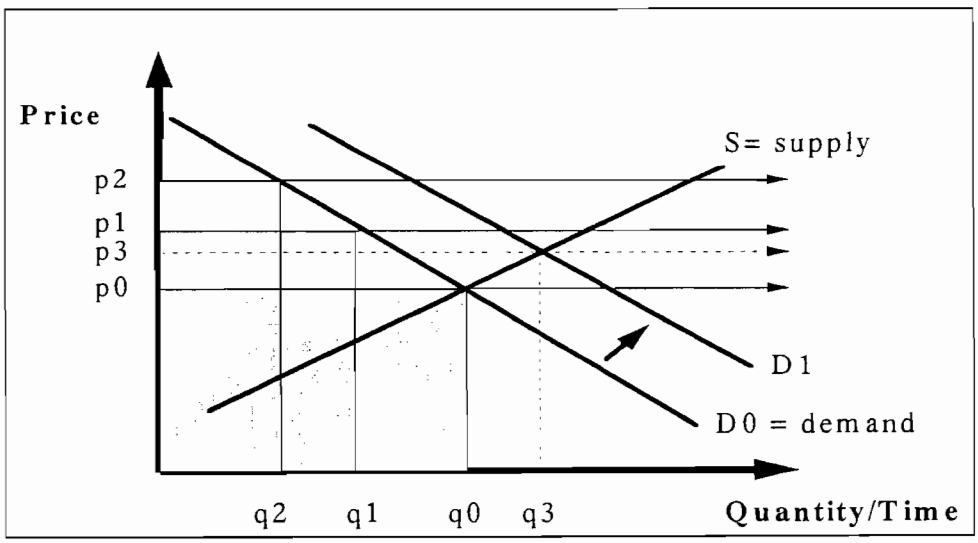
buy the lower cost identical product in the cheaper market and re-sell it in the higher priced market. Eventually the prices in both markets will converge on a single price.

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 p0 x q0, 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. *p1* and *p2*, 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 P0, the additional revenue from a price greater than P0 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.

63

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.

Sources:

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

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

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 enrolees 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

States	Reimbursement of drugs by the public plan	Special pricing policies
British Columbia	Actual acquisition cost (capped to a maximum price) + wholesaler's mark up (capped at 7%) + dispensing fee (capped to a maximum)	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
Saskatchewan	Actual acquisition cost + mark-up allowance (three-tiered scale markup ranging from 30% to 10%) + dispensing fee (capped to $8.21).	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.
Alberta	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 $5.03).	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
Manitoba	Actual acquisition cost + Professional fees	
Nova Scotia	Actual acquisition cost + Professional fees (two-tiered markup ranging from CAN$10.42 to CAN$15.64) + 10% for some products.	Maximum allowable cost price for interchangeable products, primarily generic drug products
New Brunswick	Actual acquisition cost + dispensing fee (ten-tiered, ranging from $8.40 to $161)	Maximum allowable price for generic groups
Prince Edward Island	List price	
Newfoundland	List price	Maximum allowable cost for 11 generic groups of over-the-counter drugs
Québec	"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).	Requires the best available price in Canada for listed drugs
Ontario	List price + mark up + Pharmacist fee	Price-volume agreements with manufacturers Generic price capped at 50% of the original product price
NIHB	Acquisition cost + mark-up + pharmacist fee	Best price alternative in generic group and in reference price groups when applicable in the province.

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. Quebec 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 inter-changeability 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 inter-changeability 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.

Sources:

http://ec.europa.eu/enterprise/phabiocom/docs/tse/canada.pdf 8 January 2008

http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/access-therapeutics_access-therapeutique_e.html#2

Paris V, Docteur E. ***Pharmaceutical pricing and reimbursement policies in Canada***. Organisation for Economic Co-operation and Development, Paris, 15 February 2007.

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]

[17] More detail about reimbursement policies and practices in New Zealand is available in R Braae, W McNee, D Moore (1999), Managing Pharmaceutical Expenditure while Increasing Access: The Pharmaceutical Management Agency (PHARMAC) Experience, *Pharmacoeconomics* 16 (6): 649-660.

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.

Sources:
http://ec.europa.eu/enterprise/phabiocom/docs/tse/newzealand.pdf 08/01/2008

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

http://www.medsafe.govt.nz/consumers/regulate.asp 08/01/2008

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 Espanola 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 exceed12-18% 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.

Sources:

Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States, Claudia Habl, Katja Antony, Danielle Arts, Michael Entleitner, Barbara Froschl, Christine Leopold, Heidi Sturzlinger, Sabine Vogler, Romana Landauer. Vienna, July 2006. Commissioned by European Commission - DG Competition. **OBIG Health Economics.** Pharmaceutical Systems in the EU 2006.

OECD. ***Health at a glance: OECD Indicators 2005***. Organisation for Economic Co-operation and Development, Paris, 2005.

Comparative Analysis. Sabine Vogler, Danielle Arts, Claudia Habl, Christine Leopold, Romana Landauer. October 2006. **Pharmaceutical Systems in the EU 2006**.

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$)

Country	Health Exp US$ per cap	Health / GDP US$ per cap	GDP US$ per cap
Spain**	2,905	11.0%	26,296
New Zealand**	2,264	9.2%	24,738
Canada**	3,332	9.9%	33,779
Australia**	3,354	10.7%	31,425
United States**	6,493	15.8%	41,197
South Africa total	**331***	**2.7%**	**12,063**
South Africa medical schemes	**1,183***	**3.2%**	**37,323*****

*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.