



Drug pricing

Improving access to necessary drugs requires attention to all four component parts of the access equation – ensuring rational selection, providing sustainable financing and efficient systems to distribute and use the drugs but also making sure that prices are affordable. However, comparing drugs prices across countries and health systems is not always easy. Methodological pitfalls abound, and have in the past ensnared the South African Ministry of Health. The National Drug Policy contains a variety of proposed strategies to reduce the price of medicines in South Africa. This chapter considers the complex issue of drug pricing, the policy options outlined and available, and provides recommendations on steps that will advance the implementation of such policies.

Authors

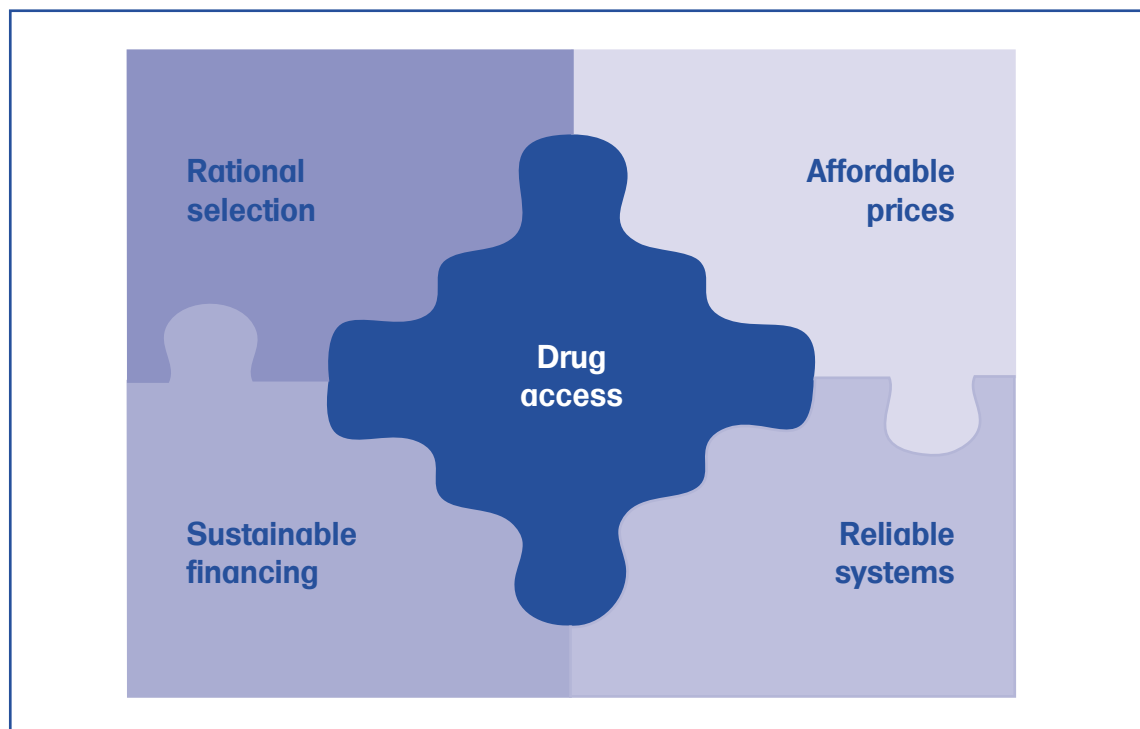
Andy Gray
School of Pharmacy and Pharmacology, University of Durban-Westville

Thulani Matsebula
Centre for Health Policy, University of the Witwatersrand

Introduction

Any government wishing to pursue equity as a policy goal will commit itself to improving access to quality health care. Access may be constrained by many factors, both geographic and economic. If economic factors predominate, these are usually related to the costs of services. Out-of-pocket expenditure^a on drugs is high in many countries, and has been quoted at being as much as 65% of total drug expenditure in sub-Saharan Africa, 81% in Asia and less than 40% in established market economies.¹ Growth in drug expenditure has been shown to have exceeded that for other components of the health care system, particularly in Europe.^{2,3} Drug prices may be considered a crucial element in determining access. Drug costs also impact directly on many policy choices, not least choices on whether or not to offer AIDS-related drug care in the public sector. The Panos Institute, an international global development think-tank, has stated that “the main reason why anti-retrovirals are not widely available in the developing world is the price of the drugs themselves”.⁴ The costs of drugs is a prime consideration in whether or not they are included in Essential Drugs Lists, both internationally and in South Africa.^{5,6,7} Their cost alone, however, does not determine access (as is depicted in Figure 1).⁸

Figure 1: Interlocking contributions to drug access



Source: WHO/EDM staff

This chapter seeks to outline the relevant policy trajectory of the South African government since 1994. First, data are presented on current drug expenditure and price movements in South Africa. The nature of the local and global pharmaceutical industry is then briefly summarised. The chapter then considers the methodological problems associated with drug

^a “Out-of-pocket” expenses refer to those made by patients themselves, rather than by the health system (e.g. the State, by providing free medicine) or paid by medical insurance (e.g. reimbursed by a medical scheme).

price comparisons, and the evidence of discriminatory pricing policies. The various policy options open to government are examined, and recommendations offered.

South African expenditure and prices

Drug acquisition costs (to either patients or health care systems) are a major part of recurrent costs. In the South African public sector drug costs are second only to personnel costs. Data on actual consumption in the State sector is patchy. Current and historical data available to the Department of Health Chief Directorate: Pharmaceutical Services is shown in Table 1. The industry estimate of total public sector purchases in 2000 is R1.96 billion.⁹

Table 1: Provincial expenditure on drugs per financial year

Provincial drug budget/expenditure per financial year (R million)							
Province	1994-95	1995-96	1996-97	1997-98	1998-99	1999-2000	2000-01
Eastern Cape	N/A	N/A	N/A	N/A	N/A	<i>78.646</i>	N/A
Free State	N/A	N/A	N/A	N/A	N/A	104.607	<i>61.390</i>
Gauteng	N/A	N/A	380.418	451.274	468.430	<i>352.314</i>	<i>453.499</i>
KwaZulu-N/Atal	188.995	207600	274.523	284.630	251.948	296.459	<i>310.000</i>
Mpumalanga	N/A	N/A	N/A	N/A	N/A	<i>103.000</i>	N/A
Northern Cape	N/A	N/A	N/A	N/A	N/A	41.148	N/A
Northern Province	N/A	N/A	123.260	126.276	127.670	146.319	<i>149.000</i>
North West	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Western Cape	112.68	157401	170.358	190.977	209.544	216.209	<i>201.411</i>

Notes: Actual expenditure is stated, where available. Where only budgets were available, these are indicated in italics. North West reported that drug expenditure could not be separated from the other items under Standard Item C (Stores and Livestock), but that payments to the Gauteng depot for 1998-2000 totaled R72.647 million, and to other suppliers for the period 1997-1999, R13.164 million. The SA Military Health Services also budgeted R100 million for drugs in the 1999-2000 financial year.

N/A = not available

Sources: National Department of Health and individual provincial Heads of Pharmaceutical Services

In the private sector, drugs are the single biggest cost driver. However, recent data on their relative contribution to costs are not available as only the 1998 figures have been reported by the Registrar of Medical Schemes.¹⁰ In that year, of a total of R18.745 billion paid out by medical aid schemes, medicines accounted for 27%. However, of the 28.5% of payments that were made to private hospitals, some were also for drugs used by inpatients and issued as discharge medication. Per capita expenditure on drugs in the public and private sectors will again be markedly different this year. The following figures are based on the projected sales figures for 2000 quoted by the Pharmaceutical Manufacturers Association (PMA) and the estimated numbers of South Africans belonging to a medical aid scheme.⁹ The total

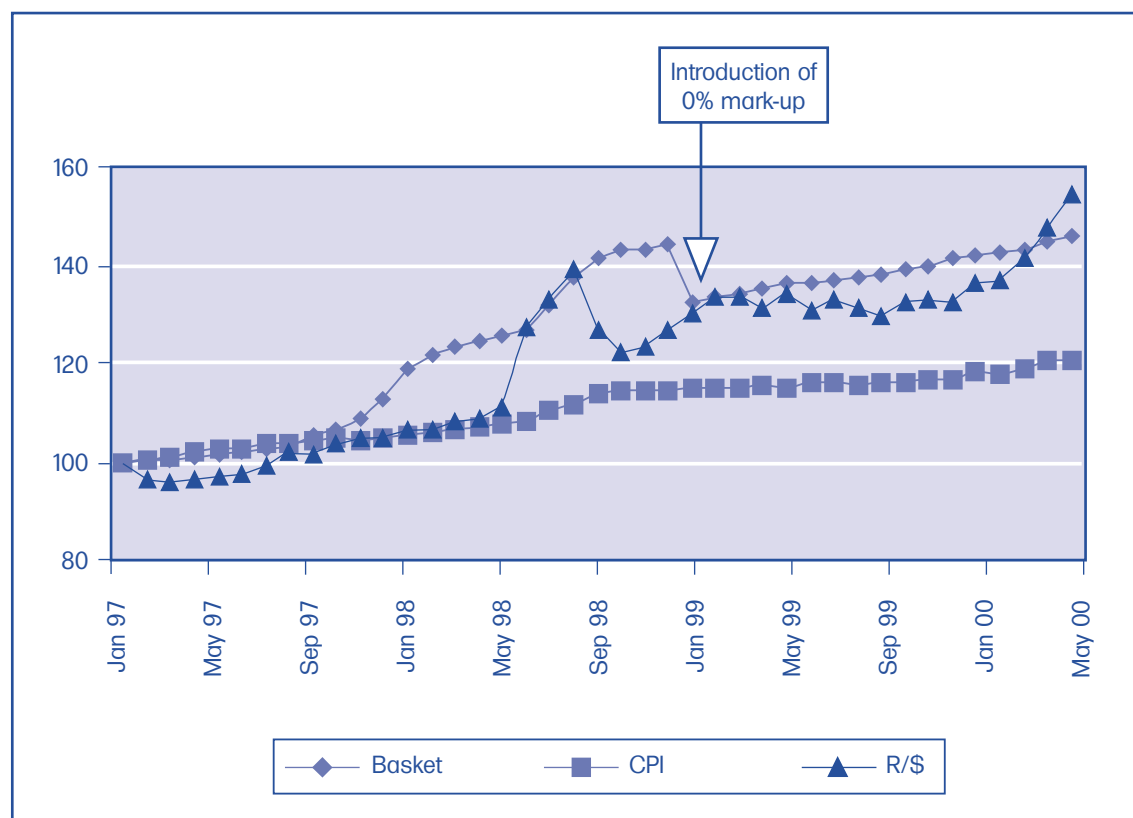
value of drug sales is anticipated to be R8.25 billion. Public sector sales are expected to make up 24%, which translates to R59.36 per person not belonging to a medical aid scheme. In contrast, the per capita expenditure on prescription drugs in the private sector would be R800.29 (excluding sales of over-the-counter (OTC) medicines, which are expected to constitute only 6% of the total value). This includes sales via private pharmacies, private hospitals and dispensing doctors. If, as is sometimes claimed, the dispensing doctors (who are responsible for 15% of drug sales) were servicing only indigent patients on behalf of the State, the private sector per capita expenditure would still be R641.69, which translates to more than 10 times the amount spent per person in the public sector.

The cost of drugs in South Africa relative to other markets has long been a contested issue. In 1997 government statements on the matter were the subject of a complaint by the PMA to the Public Protector. The first of these alleged “offending statements” was that “South Africa rated in the top five most expensive countries in the world for medicine”. The final ruling by the Public Protector (aided in his inquiry by four independent experts) is perhaps indicative of the complexity of the subject. He stated that it was “not possible to say that the Minister of Health was able or unable to prove or substantiate the statement”.¹¹ However, he went on to record his view that “pharmaceutical profits are substantial in this country; that the cost and price of pharmaceuticals in South Africa is high; and ... the amount spent on medicine, is nearly double to triple that of other major countries”. This area of policy has also been seen as part of a greater struggle, one that pits the health and economic interests of the South against those of global free trade.^{4, 12}

The National Department of Health does not routinely collate price comparisons over time. However, in preparation for the 2000 tender adjudication round, a comparison was made for a selected basket of high expenditure items. For 31 of the 36 items, prices for the same pack sizes could be compared between 1997 and 1999. The median price change was an increase of 7.8% per annum. While the largest increase was 93.2% pa, the item with the greatest price decrease dropped by 7.5% pa. For the 22 items for which a 2000 price was already available, the median change from 1997 was an increase of 7.4% pa. The largest increase was 62.1% pa, and the item with the greatest price decrease had dropped by an average of 13.9% pa.

The Hospital Association of South Africa has closely monitored the prices of a basket of 1 000 high cost/high volume items, which have been compared to the prevailing consumer price index (CPI), and tracked against the Rand-US dollar exchange rate. Against a January 1997 index of 100 for each parameter, the all products basket reached 145.9 in May 2000, whereas the CPI was only 120.4. The rand had weakened to 154.1 by the same point. The close tracking of the exchange rate and the basket price is shown in Figure 2.

Figure 2: Prices of a basket of 1 000 drugs used in private hospitals, plotted against the consumer price index (CPI) and Rand/US dollar exchange rate



Source: Hospital Association of South Africa

It should be stated clearly though that expenditure is a result of both unit price and volume of consumption. Countries with recognised low prices may not be able to keep prescribing levels under control (e.g. Italy, France).^{13, 14, 15} The United Kingdom, with the highest prices in Europe, manages to keep drug expenditure to about 10% of total health care costs. Australia is recognised as the exception, which has managed to both curtail prices and improve on the rationality of drug use.

The global pharmaceutical industry

The global pharmaceutical industry is predominantly located in the industrialised North. Its global sales in 2002 are expected to be \$406 billion.¹⁶ Sales are predominantly in industrialised regions (46.7% in North America, 24.8% in Europe and 11.3% in Japan). Despite their numerical preponderance and disease burden, all the countries of sub-Saharan Africa are expected to account for only 1.3% of sales and the Indian sub-continent 1.8%.

The global industry is often viewed as being dominated by a small number of extremely powerful corporations. While it is true that about 10 large research-based firms account for just over a third of global sales, none has a dominant position.¹⁵ Although it has been claimed that there is considerable market share turbulence, all the firms in the top 15 in 1992 were already in the top 20 in 1981. Recent years have seen increasing mergers and acquisitions. Recent deals include the merger of Glaxo-Wellcome (ranked number 1 in 1993) and SmithKline Beecham (ranked 8th), and that of Rhone Poulenc Rorer (14th) with Hoechst

(3rd). Research-based firms have also sought to acquire or enter joint ventures with generic manufacturers. About 80% of generic drugs in the US are manufactured by research-based firms. However, it is within therapeutic sub-markets that there is considerable concentration. In other words, a firm may dominate the sales in an area such as cardiovascular drugs or in the management of a particular disease such as ulcers. The top 3 products in a particular sub-market may account for up to 60% of sales. This is also true within South Africa, where 4 firms account for 92% of local company sales in the private pharmacy market.⁹ Such firms may, within that particular area, wield considerable influence.

Since manufacture of the raw materials is highly concentrated in the countries of origin of the major firms, but local finishing is common, there is considerable intra-firm trade. Local finishing is often necessary to comply with local registration, labelling and quality control requirements. This makes local subsidiaries liable to “transfer pricing” practices, where the raw material prices are inflated to ensure optimal profits at the global level.¹⁷ This also means that local marketing and sales forces are required, resulting in marketing costs being nearly double those of research and development (R&D). High R&D costs are often assumed to be responsible for the high costs of innovator drugs. An analysis of the top 12 drug manufacturers in America in 1999 showed that the median percentage of revenue dedicated to R&D was 12.4%, whereas a median of 37.3% was dedicated to marketing and administrative costs.¹⁸

Yet another reason used to question the necessity for high drug costs is the high profits made by the pharmaceutical industry. For the past 10 years, the pharmaceutical industry has been the most profitable in America, with median profit rates more than treble those of other leading companies. Chief executive officers of the top 10 firms averaged \$10 million each in salaries in 1999, with stock options averaging another \$10 million each.¹⁹ Profits for the 12 Fortune 500 drug companies in 1999 were 18.2% of revenue, compared to a median for all Fortune 500 industries of only 5.1%.¹⁸

Drugs’ prices are therefore considered to a large extent to be managed by their manufacturers, rather than by the market. They have less to do with the manufacturing and development costs of the particular product, and more to do with the characteristics of the market in which they are placed (including average incomes, types of social security, exchange rate fluctuations, competitor price levels and future research and development costs).¹⁷

Price surveys

As was demonstrated in the PMA vs Minister of Health spat over price comparisons, this entire area is fraught with methodological difficulties. Among the issues shown to have considerable effects on the results of surveys that attempt to compare prices over time or between countries are:²⁰

- ◆ Sample selection (it may be necessary to include generics and OTC drugs that might substitute for the branded items being compared; also the choice of countries)
- ◆ Units of measurement for price and volume (often pack sizes vary considerably, and direct comparisons between bulk and patient-ready packs cannot be made on the basis of unit dose prices)
- ◆ The relative weight given to consumption patterns in the different settings
- ◆ The use of exchange rates or purchasing power parities for currency conversions.

Despite these concerns, it has been noted that policymakers continue to act on studies that display weaknesses in one or more area of methodology.²¹ A study that sought to compare South African prices with those in known high price countries (USA, UK, Germany, Denmark, Netherlands) is still used by the PMA.²² Price comparisons continue to make headlines, such as the recent study that showed that East Africans pay more for AIDS-related drugs than do Europeans or North Americans.²³ Studies might however include a cautionary note, as in the case of the recent Médecins Sans Frontières (MSF) study, which stated “the price information presented in this report is not exhaustive and should only be considered as an indication of the variation in prices between countries for given drugs”.⁷ There is also a need for an internationally acceptable reference pricing system. The current International Drug Price Indicator Guide produced by Management Sciences for Health has been attacked from various quarters.²⁴ While it is not, as has been alleged in this country, a listing of “charity prices”, it does suffer from a lack of data on the quality of the suppliers listed. It is in fact a listing of prices from supply organisations that service non-profit humanitarian projects (such as ECHO International Health Services), but also those that supply governments (International Dispensary Association, United Nations Children’s Fund Supply Division) and government bulk-purchase structures themselves (Eastern Caribbean Drug Service and Costa Rica Social Security). A recent joint publication of the United Nations Programme on HIV/AIDS-United Nations Children’s Fund-World Health Organisation (UNAIDS-UNICEF-WHO) has sought to gather price information on AIDS-related drugs.²⁵ This is an on-going project. The provision of such information was also the subject of a May 2000 resolution adopted at the World Health Assembly.²⁶

Within-country comparisons, while not devoid of challenges, are somewhat easier. In South Africa, there are considerable differences between private sector prices and those offered on State tender. Claims are made that the difference is on average 10-fold. It has also been alleged that the lower prices offered to the State are responsible for higher than usual prices in the private sector, in other words that higher private sector prices are used to offset revenue losses and that this constitutes cross-subsidisation. However, there are no accurate data to support either contention.^{9,22} There is also evidence of discriminatory pricing practices between different purchasers in the private sector. An in-depth Competition Board investigation in 1992 concluded that such discriminatory practices existed, that they constituted a “restrictive practice”, and that this was not in the public interest.²⁷ Some of these practices, such as the selling of stock by dispensing practitioners to so-called “short-line” wholesalers,^b would also have been dealt with by Medicines and Related Substances Control Amendment Act (Act 90 of 1997).²⁸ The Act will prohibit wholesalers from buying drugs from anyone other than a manufacturer or importer. However, this type of in-country market segmentation is not unique to South Africa, and has also been demonstrated in the United States.^{19,29}

b A “short-line” wholesaler is one that stocks only a restricted range of goods, rather than a comprehensive selection as is the case with a traditional or “full-line” wholesaler.

The South African policy trajectory

Local policy is encapsulated in the 1996 National Drug Policy.⁵⁰ As early as mid 1994, the then newly constituted Drug Policy Committee was tasked to “develop a pricing plan for drugs in South Africa in the public and private sectors”. The resulting drug policy therefore sought to “ensure the availability and accessibility of essential drugs to all citizens”. While it sought, as a purely economic objective, to “lower the cost of drugs in both the private and public sectors”, it also aimed to “promote the rational use of drugs”, thus targeting both parts of the expenditure equation. As a national development objective, it aimed to “support the development of the local pharmaceutical industry and the local production of essential drugs”.

Specific cost containment measures that were signaled in 1996 were:

- ◆ A pricing committee, to “monitor and regulate drug prices”
- ◆ Total transparency in the pricing structure (at all points of the distribution chain)
- ◆ A non-discriminatory pricing system
- ◆ Replacing the wholesale and retail mark-up system with one based on a fixed professional fee
- ◆ A database to monitor costs compared with other developing and developed countries
- ◆ Regulation of price increases
- ◆ Provision, in certain circumstances, of public sector stock to the private sector (e.g. supplying lower cost drugs bought by the State to private sector clinics in order to address a priority disease)
- ◆ Promotion of generics (multi-source pharmaceutical products, generally cheaper than the originator’s branded products), including generic substitution, while maintaining a negative list (a list of drugs that could not be substituted by the pharmacist at the patient’s request, but where the prescribed brand would have to be supplied)
- ◆ Measures to improve rational drug use, including establishing Pharmacy and Therapeutics Committees (PTCs) in all hospitals
- ◆ Control of pharmaceutical marketing practices.

Under the heading of “procurement and distribution”, mention was also made of international tendering, of competitive negotiation for state supplies and price preferences for local manufacturers. Export of local products to neighbouring countries was also to be fostered.

Many of these measures required legislative action. This was first attempted in the Medicines and Related Substances Control Amendment Act (Act 90 of 1997). The subsequent court action by PMA-aligned manufacturers has been covered in detail in previous editions of the Health Review.⁵¹ Measures such as generic substitution and parallel importation remain hostage to that court action. The return affidavit from the complainants was received in July 2000, and indications are that a court date will be set soon.

Policy options

Medicines are not ordinary articles of trade. Specifically, their demand and supply characteristics do not follow classic market principles.^{1, 3, 17} Firstly, there is a three-tiered demand structure – with the prescribers (physicians and others) as the actual demanders,

the patients as the consumers and the health care system frequently the payer (both in the public and private sectors). There is often limited competition between suppliers, especially in the case of patented products. Medicines also have both positive and negative externalities (e.g. effectively treating an infectious disease such as tuberculosis not only benefits that patient but has the additional positive “external” value of reducing the spread of the infection to other people in the community; conversely, not having the drug available increases the risk of spread and will also discourage patients from seeking help from a health facility). Information available to prescribers and consumers is often selective, unbalanced or incomplete, further demonstrating the supply-driven nature of trade in medicines. Finally, market forces rarely reflect true social costs and benefits, and cannot meet social objectives such as equity. The factors mentioned above, together with the apparent inability of the industry to develop and provide needed drugs for tropical diseases in poor countries have been called “market failure”. Drugs can therefore be considered to be “meritorious” goods, worthy of government intervention.

This contention is not however shared by the pharmaceutical industry. Industry groups claim that “the market is working”, and that interventionist policies “don’t work, may actually increase health-care expenditures, and stifle innovation”.³² A June 1999 position paper by a European grouping called for “market pricing for all medicines”, “less dependence on national social security systems”, “more private/insured purchase”, and “competitive purchasing systems operating in a price-deregulated environment”.³³ There were also veiled calls for direct-to-consumer advertising (DTCA) of prescription drugs. In an area marked by interventionist stances and largely socialised health care systems, this amounts to a call to adopt US standards. However, a recent policy analysis of DTCA options for South Africa has suggested retaining a European rather than US standard.³⁴

The options open to governments that do choose to intervene can be characterised in a number of ways. They can be either direct (primarily legal measures that have an immediate effect on suppliers or consumers) or indirect (usually market-related measures, which entail financial implications for the various actors).² They may either target prices themselves (supply side measures such as price controls, positive or negative lists,^c promotion of generics) or consumption (demand side measures such as exclusion from positive lists, reclassification to OTC status, introduction of patient co-payments, caps on pharmaceutical budgets). Policy options have been described as resulting in either a total control situation (as in Ecuador and Honduras), a mixed system (as in Canada), a situation of monitored freedom (as in Brazil) or total freedom (as in the US).¹⁷ Significantly, resorts to price control are more common in developed than in developing countries, even though price sensitivity might be greater in countries with poorer social security systems.¹

While the South African policy commitment to some form of intervention is clear, the exact mechanics of the proposed system have yet to be revealed. Policy instruments available to any government can be described as either:

- ◆ Producer price control measures (direct price controls, reference pricing systems, equity pricing, generic policies)
- ◆ Distribution chain cost controls (mark-ups and fixed professional fees, value-added tax)

c A positive list includes those items that will be supplied or reimbursed, a negative lists in contrast indicates those items that will not be available to the patient.

- ◆ Bulk purchase measures (tender and negotiation strategies, regional initiatives)
- ◆ International trade agreement relief measures (compulsory licensing, parallel importing)
- ◆ Demand side measures (rational drug use, co-payments).

Each of these is examined in some depth. Since most experience with these measures has been documented outside of South Africa, the examples quoted are not always local. However, where possible local data or potential applications are identified.

Producer price control measures

The imposition of direct price control would seem to be in conflict with South Africa's national trade and industrial practices, which are influenced to a large extent by global trends. The balance of evidence from other countries would seem to indicate that such practices, while commonly used, are complicated and cumbersome.^{1, 15, 17, 35} They are easily circumvented by transfer pricing (inflation of the prices of imported raw materials), are open to political interference, and rely to a great extent on difficult to obtain industry transparency. For example, the Ecuadorean policy involved a production cost plus 20% margin for locally-produced goods, and a landed cost (CIF or "cost, insurance and freight") plus operating costs plus 20% margin for imported goods. Production costs are not often easily determined, while the use of a "landed costs plus" system is open to manipulation by transfer pricing.

A more transparent system is that of reference pricing. Internal reference pricing systems involve a national authority setting local prices for a drug by comparison with similar drugs on the national market (e.g. deciding that a new anti-hypertensive drug will be similar in price to other drugs already available to treat hypertension). External reference pricing systems use the prices of drugs sold in other countries as well, as part of the comparison. An example is the best available price (BAP) system for social security refunds in Canada. It is also a key component of the successful Australian system. In South Africa, a form of this system is already in effect in the private sector, where many medical aids use a maximum medical aid price (MMAP) system for drugs that are no longer controlled by a patent and are therefore available from many sources. Patients who wish to receive a branded version that costs more than the MMAP have to pay the difference in price themselves (an example of a patient co-payment). However, it is not clear that any such system is applied when adjudicating State tenders. The experience in the Netherlands and Germany has been that reference pricing is not effective, and is out-flanked by changes in prescribing habits. It may just shift the load to the patient, by way of the additional co-payments that are necessary.^{2, 15, 36} Innovator drugs are usually not covered by reference price systems, as no comparator products exist. If applied internationally, this might result in convergence of prices at higher levels, hurting current low price countries.

An idea that enjoys some current favour in activist circles is that of equity pricing, where manufacturers agree to subsidise lower prices in developing countries by levying higher prices in wealthier countries. The Panos Institute has identified two potential problems with this approach.⁴ Firstly, prices might not drop sufficiently. Secondly, consumers in the North might insist on either lower prices or the right to import drugs from low price countries. Legislative attempts to allow such parallel trade are already underway in the US. Equity pricing is the basis for the UNAIDS negotiations with major AIDS drugs manufacturers, and also underlies offers of drug donations to developing nations. Neither approach is without problems. Donations in particular are difficult to accept when accompanied by demands

for additional (and costly) monitoring or other systems costs and restrictions, as was the case with the Pfizer offer of fluconazole to South Africa in early 2000. Negotiations on this offer are ongoing.

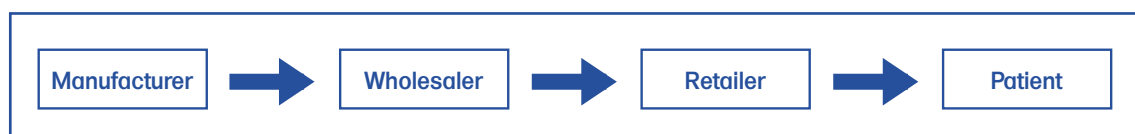
Efforts to promote the production and use of generic medicines, while unpopular with the research-based industry, are effective. They not only stimulate competition, but also promote the development of local manufacturing concerns.³⁷ Two policy instruments are however lacking in South Africa. The first is an unambiguous legal framework for generic substitution (which is already practised in the public sector, and is often necessary in order to comply with MMAP restrictions in the private sector). The second is the enactment of so-called “Bolar” provisions that will allow prospective generic manufacturers to complete scientific and regulatory processes before the expiry of the patent, allowing for quick entry of the generic product onto the market and fair competition with both the originator product and any “generic” versions made by that company or its subsidiaries. Such provisions are not in conflict with international trade agreements.³⁵ Naturally, this practice is not welcomed by industry groups.³⁸ Perhaps the most dramatic evidence of the impact of generic competition on drug prices has been provided by Brazil. Anti-retrovirals that were only available from innovator companies (i.e. the original developers of the drugs, who held the patents) reduced in price by only 9% from 1996 to 2000. In comparison, the prices of those that did face such competition dropped an average of 79% over the same period.³⁹

Distribution chain cost controls

PMA contentions are that South Africa’s distribution chain costs are among the highest in the world, adding more than 100% to the manufacturer’s factory gate price.^{9, 22} This is vehemently denied by the Pharmaceutical Society of South Africa (PSSA).⁴⁰ Direct control over mark-ups has been abandoned by government, but is still exercised indirectly by the reimbursement policies of the medical aid industry.

The traditional distribution route for pharmaceuticals in the private sector is as illustrated in Figure 3. At each step a percentage mark-up is applied, but this is also often accompanied by a discount. The actual mark-up might therefore be lower than theoretical figure. However, each stage starts from a presumed price resulting from application of the theoretical mark-up by the previous actor. In most cases, patients do not pay directly for their medicines. That payment is rendered by the medical aid, which is therefore a third party to the transaction between the seller (pharmacist or doctor) and the supposed buyer (the patient). The mark-ups are to a large extent the result of acceptance of the system by the payers, the medical aids. This acceptance is formalised in the Pharmaceutical Scale of Benefit published by the Board of Healthcare Funders (BHF), which is a voluntary association of medical aids. Most medical aids make use of intermediaries (medical aid administrators) to manage the payments for claims submitted by their members.

Figure 3: Traditional distribution chain for medicines



Note: the “retailer” is either a pharmacist in a retail pharmacy or private hospital or a dispensing doctor

The start of the process is the manufacturer's selling price, also called the factory gate or exit price. Theoretically the pharmaceutical wholesalers add a mark-up of 21.2%. However this is brought down by the practice of giving retail clients discounts, either on bulk purchases or as reward for loyalty (based on the total of that client's purchases over a period of time). These discounts average 10-11%. The retail pharmacy sector adds a 50% mark-up on the theoretical wholesale exit price (the manufacturer's price plus the 21.2% mark-up). This results in a maximum 81% mark-up from manufacturer to patient. Additional dispensing fees (R1.20 per item), broken bulk (10%), container and copy fees add negligible amounts to the final bill. However, third party payers demand discounts from the retailer, varying from 20% (which is the norm for acute medication) to 30% (for chronic medication). This can be confirmed by looking at the average cost difference between gross amounts claimed and net values paid by medical aid administrators. In 1999, this difference amounted to an average of 23.8% for one such administrator.⁴¹

In order to understand the net result of these mark-ups and discounts, it is easier to consider a product leaving the manufacturer at a nominal R100.00. This product would therefore be sold by the wholesaler at R121.20, but the discount offered would on average reduce the actual cost to the retailer to R109.80. The retail pharmacist would then add the 50% mark-up to the theoretical purchase price of R121.20, selling the product at R181.80. In turn, the retail pharmacist would be required to discount this price to either R165.25 (20%) or R145.08 (30%) depending on whether it was claimed against the patient's acute or chronic benefit. Value added tax would be levied at 14%.

If the actual amounts retained by each actor in this chain (after applying discounts) are expressed as percentage contributions to a final amount (100%), for each of the two discount scenarios described above, then the "contribution" of each step to the final cost can be seen. These figures are provided in Table 2.

Table 2: Relative contributions to the final selling price of a medicine to the private sector patient in South Africa

Discount scenario	Manufacturer exit price (%)	Wholesale mark-up (%)	Retail pharmacy mark-up (%)	VAT (%)
20% (acute medicines)	60.5	5.5	21.7	12.3
30% (chronic medicines)	68.9	6.3	12.5	12.3

The greatest proportion of drug costs is accounted for by the manufacturer's exit price, with less than 40% being constituted by the entire distribution chain costs. A 1994 study in nine European countries showed that the manufacturer's contribution to the final price of a prescription item (including VAT) varied from 47.1 to 69.8%.⁴² Put another way, pharmacy gross profit margins are between 14.5% and 24.8%. In most European countries, degressive margins are applied (lower mark-ups are allowed for more expensive items).² Retail pharmacy margins vary in similar ranges to those in South Africa, with some countries having higher margins. Wholesale margins vary from 4 to 18%. VAT rates vary considerably, from 0% on prescription items to as much as 25%. It is also worth noting that there has been significant vertical integration in South Africa. As much as 55% of wholesale trade now goes through direct distributors owned by consortia of manufacturers. This is the subject of an imminent antitrust suit in the High Court, brought by the traditional "full-line" wholesalers.

The situation in South African private hospitals is different, where a 0% mark-up on wholesale list price is levied. Private hospital pharmacies have however been able to use their collective buying power to extract rebates from manufacturers of up to 20%. In effect therefore, they make a profit on medicines despite levying no mark-up. When the 0% mark-up was introduced, an agreement was reached between the hospitals and the medical aids that prices should not rise more than 20% between December 1998 and April 2000. They had in fact only risen by 13.2% over that time period, as can be seen in Figure 2. Nonetheless, a steady increase in private sector drug prices is evident from these data.

The NDP objective of replacing mark-ups with a fixed professional fee has not been realised, despite intense negotiations between the PSSA and BHF. Current proposals include a professional fee of R20.00 per item, plus the disclosed non-discriminatory net unit exit price from the manufacturer, plus inventory related costs (5%) and practice costs (R4.00). No discount would be given to the medical aid, and VAT would be levied as before. However, as this fee would be applied regardless of the cost of the medicine, current very low cost items might actually increase in price. The logic behind the policy is that removing the profit motive will mean that the pharmacist earns the same amount, regardless of whether s/he dispenses an expensive branded product or a cheaper generic.

One effective cost containment measure that is in place is that for anti-retrovirals under the "Aid for AIDS" programme operated by Medscheme. Such drugs are paid for by the medical aids at factory gate prices plus R50.00, without any mark-ups at either wholesale or retail level.^d However, this does not apply to other AIDS-related drug needs, such as drugs for opportunistic infections and palliative care.

Bulk purchase measures

The State already uses the most basic measure – competitive bidding (tender) - as the major mechanism to ensure maximal price leverage. However tenders are only open to locally-registered firms. It is possible that better prices might be obtained on the international market. This does have implications for the reach of the Medicines Control Council. Manufacturers abroad must either be cleared by the inspectorate for Good Manufacturing Practice (GMP) standards, both before and during the tender period, or foreign regulatory systems or international certification schemes must be relied upon to guarantee the quality of goods purchased.

Recent indications are that competitive bidding alone is not assuring the State of sufficiently competitive prices. A number of products were identified where the price offered by a local tenderer was more than double the median price in the 1999 International Drug Price Indicator Guide. Post-tender negotiations have been successfully used to further reduce prices in some instances.

A growing demand is for regional bulk purchasing arrangements, particularly with other member states of the Southern African Development Community (SADC). These are crucial if African countries are to overcome their historical disadvantage in negotiating power with the global pharmaceutical market. Such arrangements can also be used to bolster local production. Africa still imports more than 90% of its pharmaceutical needs, and the African share of global production value has slipped from 1.3% in 1975 to 0.7% in 1995.⁴⁵ Three successful regional schemes have been assessed.⁴⁴ Bulk purchasing by countries of the *Union*

d Medscheme Integrated Care Division, personal communication

Maghreb Arabe (Libya, Mauritania, Tunisia, Algeria, and Morocco) achieved price reductions ranging from 15-20%. The six-nation Gulf Cooperation Council (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates) achieved savings averaging 30%, compared to purchasing by individual countries. A trial by the African Association of Central Medical Stores for Essential Drugs (ACAME) in 1998 involved 5 essential drugs procured by three countries (Guinea, Mali, and Niger), compared to bulk purchasing tenders. The costs obtained by the bulk scheme were 7-27% lower than the individual countries had been able to obtain for the previous 3 years. Perhaps the most telling evidence of the power of collective bargaining comes from the recent MSF price comparison study. Wishing to place AIDS drug price reduction offers to African countries of 80-90% in perspective, MSF notes that far greater reductions have been obtained by international agencies.⁷ The Pan American Health Organization (PAHO) supplies vaccines at discounts of between 86% (*Haemophilis influenzae* type B) and 99% (oral polio vaccine) compared to US public sector (Centers for Disease Control) prices. The United Nations Population Fund (UNFPA) is able to supply contraceptives at between 97% (injectables) and 99% (condoms and oral contraceptives) discounts compared to US wholesale prices.

International trade agreement relief measures

A fundamental way to address prices would be to weaken the monopoly-like powers afforded the manufacturers by the patent system. The issue was covered in some detail in the Drug Policy chapter of the 1999 Health Review.⁵¹ In essence this would involve either or both of the following measures:

- ◆ Compulsory licensing (giving a local firm the right to make a copy of an expensive patented drug at a lower price, while compensating the patent holder)
- ◆ Parallel importation (buying drugs from countries where prices are already lower, and so trading in parallel with the local seller of the same drugs).

Patent rights have been strengthened in recent years by new international trade agreements, in particular the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). For example, by 2006 all signatories to the Agreement (which means all members of the World Trade Organisation) must give drug companies 20 years' patent protection on their inventions. Much attention has therefore been focussed on attempts to soften the potential access-denying impacts of these agreements. The WHO and other commentators have produced guidelines on the safeguards available to nation states under the TRIPS agreement.^{35, 45} Opposing views on such measures can best be captured by two statements made at the 1998 Revised Drug Strategy meeting in Geneva. Dr Zafar Mirza of the Association for Rational Use of Medication in Pakistan stated that "a patent is not an absolute right nor an end in itself; public health is an end in itself". In contrast, Mr Harvey Bale of the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA) held that "there are no winners in a game whose goal is to find loopholes in this [patent] protection – except for those who would drain society of opportunities and skills by copying rather than inventing".

Included in the relief measures outlined by the WHO, and in line with the international agreements, is the right to issue compulsory licenses. This right may be used where a patent holder (the manufacturer who first registered the invention, or drug in question) can be shown to be abusing its monopoly position, or in cases of national emergency. Such licenses may only be used predominantly for "supply of the domestic market", but both entire imports and partial exports are permissible. This could allow South African decisions to be made to

the additional benefit of our SADC neighbours. In other words, a compulsory license issued in South Africa could be used to allow importation of the drug that was the subject of the license from a manufacturer outside of South Africa (entire import). However, while the TRIPS agreement only allows this strategy to be used to mainly satisfy our own needs for the drug, there is some flexibility allowed. Some of the stock procured under the license, by local manufacture or importation, could in turn be exported. Such flexibility is important if South Africa is to export needed drugs to neighbouring countries, which perhaps lack the infrastructure to engage in manufacture under compulsory licenses. South Africa has recourse to the 1978 Patents Act, which includes a compulsory license provision. The Medicines Amendment Act (Act 90 of 1997) was an attempt to introduce health-specific measures to exploit the safeguards provided by TRIPS. However, it remains blocked by a court case preventing its promulgation. Most commentators agree that the wording of section 15C, as included in that Act, is flawed. Section 15C allows the Minister to alter the rights of a patent holder without involving a judicial process, as is the case under the Patents Act.

Parallel importation is based on the principle of exhaustion of rights - a patent holder's rights are said to be "exhausted" once the product is first placed on the market, allowing the purchaser to resell the product without offending the intellectual property rights of that patent holder. Specific mention is necessary in national law of where rights are considered to be exhausted, so that parallel trade can occur within that area. Industry groups have contended that even where regional exhaustion of rights does occur, as in the European Union, price reductions to the consumer have been modest.⁴⁶ It is alleged that profits are generally retained by the parallel importer. This might not be the case where the State is the importer, but might blunt the impact of parallel trade in the private sector. An industry-linked researcher, Patricia Danzon, warns that parallel trade and price regulation based on international comparisons might lead to price convergence at higher levels.⁴⁷ In other words, where pressures are brought to bear on manufacturers (either by publishing comparisons of prices in different countries or by moving products from high price to low price countries) the tendency will be to counter such measures by pricing such products in a narrower range that might be closer to that currently paid in the higher priced countries.

While US Trade Representative efforts to force developing nations to abandon moves to implement relief measures might have been stayed by President Clinton's Executive order in May 2000,⁴⁸ this has yet to be translated into effective utilisation of these measures by such countries. Political announcements in South Africa have yet to be actioned, although some movement is expected soon. Many developing nations assume that innovator products are patented in their countries. It is important to note that international patents do not exist. Patents are only issued in terms of national law or regional agreements. Some countries and regions have mistakenly enacted patent measures in excess of the minima set by the World Trade Organization (WTO). This is particularly true of the West African signatories to the revised Bangui Agreement.⁴⁹ South African health authorities have also not made a systematic search for unpatented products, which might be available cheaper from generic manufacturers such as those in Brazil and Thailand. Interestingly, while compulsory licenses are opposed by the pharmaceutical industry, they have considerable experience in voluntary licensing practices. This is a major feature of the global pharmaceutical industry, to a greater extent than is seen in other manufacturing sectors.¹⁴ Cross-licensing between firms that have shared R&D costs is also common. This experience can be put to good use in technology transfers between major multinationals and local manufacturers, without unduly impacting upon global returns on investment.

Demand side measures

Efforts to improve the rationality of drug prescribing and use have been covered extensively in previous Health Reviews, and are therefore not repeated here. However, it is worth noting that coercive rules to force rational prescribing behaviours on prescribers have rarely been successful without considerable “buy-in” by those prescribers.⁵⁰ This remains a neglected area in both the private and public sectors in South Africa.

Conclusions and recommendations

Chile faces similar challenges to South Africa, with very similar stratification between a private sector serving some 20% of the population and an overburdened and under-resourced public sector servicing the remaining 80%.⁵¹ A report on their policy choices concludes that “it is not clear that the process of privatization of health care or the financing of health services, and the complete liberalisation of drug prices, are the best ways to achieve equitable and rational coverage in respect of drugs in Chile. The state urgently needs to devise mechanisms to exercise its normative functions in regard to drugs in order to prevent the present freedom from degenerating into anarchy”. Both a WHO review on health reform and drug financing¹ and the Austrian Health Institute review of market controls in Europe² point to a “pendulum” effect. As governments act on an unfavourable situation by either tightening state control or relying on market instruments, so the local situation reacts, initiating a swing in the opposite direction. The challenge is therefore to minimise the amplitude of the swings, by finding an adequate but flexible mix of interventions. That different countries may be at different parts of the pendulum’s swing might go some way to explain the apparent paradox that while developing countries are generally moving towards market-driven policies, developed nations are increasingly resorting to direct interventions. The policy instruments included in the NDP seem to vacillate between intervention and what has been termed “monitored freedom”. This latter course has not been shown to be particularly effective.¹⁷ There are also potential conflicts with overall trade policies. Some may also be in conflict with one another. For example, higher levels of price control may inhibit the development of a generic market.

What is clearly needed is action on some of the NDP steps that closely match those suggested by the WHO as general advice to all countries:

- ◆ More detailed data on price trends in both the private and public sectors
- ◆ More analysis of the impacts of policy decisions, with emphasis on indicators of equity, affordability and availability
- ◆ Finality on those policy choices which seem to hold clear advantages (such as fixed professional fees and non-discriminatory exit pricing based on volume)^e
- ◆ Finality on the legal struggle to introduce generic substitution, to regulate marketing practices and to exploit the safeguards provided by the TRIPS Agreement
- ◆ Consideration of regional options, including bulk purchasing across the SADC region.

^e A single exit price is not recommended. Instead, the policy seeks to ensure that all purchasers can obtain the same discounts if they buy similar quantities. This would prevent some of the perverse incentives introduced by current discriminatory pricing practice, such as the selling of medicines to pharmacies by dispensing doctors who have secured preferential prices.

Crucial to the success of these options will be strengthening of the national departments responsible, the Directorate: Pharmaceutical Programmes and Planning (and in particular the sub-directorate of Medical Stores and Systems, which provides the secretariat to COMED) and the Directorate: Medicines Administration (the secretariat to the Medicines Control Council). Significant strengthening of the inspectorate functions of the MCC will also be necessary if the potential pitfalls of parallel trade and compulsory licensing are to be avoided. Strengthening the entire system will ensure that the populace is not exposed to counterfeit and sub-standard medicines and will demonstrate that such exposure is not an inevitable consequence of the policy choices outlined in this chapter. In this regard, South Africa remains a test case, one watched closely by the international community.



