

South African Health Review 2000 Briefing Summary



Drug pricing

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Drug Pricing

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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 and 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.

Introduction

Pursuing equity as a policy goal implies improving access to quality health care. Access may be constrained by many factors, both geographic and economic. Economic factors are usually related to the costs of services.

Out-of-pocket expenditure¹ on drugs is high in many countries, and has been quoted at:

- ◆ 65% of total drug expenditure in sub-Saharan Africa
- ◆ 81% in Asia and
- ◆ Less than 40% in established market economies.

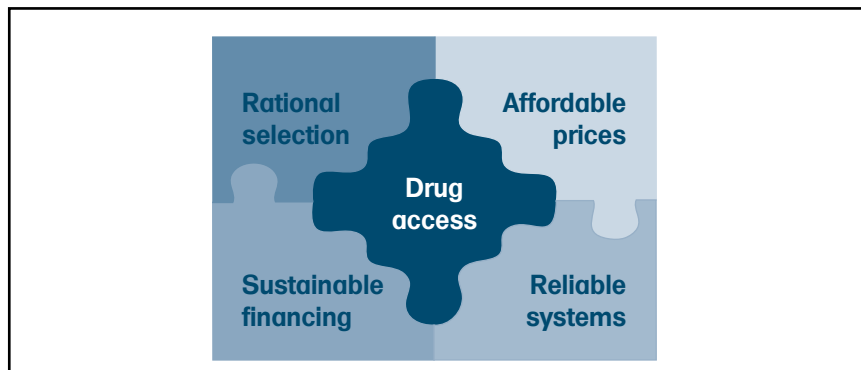
Generally:

- ◆ The rise in drug expenditure over time exceeds that for other health expenditures
- ◆ Drug prices influence access. For, example, The Panos Institute, says that “the main reason why anti-retrovirals are not widely available in the developing world is the price of the drugs.”
- ◆ The cost of drugs is one of the factors that determines the drugs inclusion in the Essential Drugs Lists.

However, as shown in Figure 1, cost alone does not determine access. It should also be noted that expenditure is a result of both unit price and volume of consumption.

1 “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).

Figure 1: Interlocking contributions to drug access (source: WHO/EDM staff)



South African expenditure and prices

Public sector drug costs are second only to personnel costs and in the private sector drugs are the single biggest cost driver. In 1998:

- ❖ Medicines accounted for 27.0% of the money paid out by medical aid schemes
- ❖ In addition 28.5% of payments made to private hospitals, were for drugs
- ❖ Private doctors were responsible for 15% of drug sales
- ❖ Per capita expenditure on drugs in the public sector was R59 as compared with between R641 and R800 in the private sector.

The cost of drugs in South Africa is a contested issue. This is part of a greater struggle that pits the health and economic interests of the South against those of global free trade.

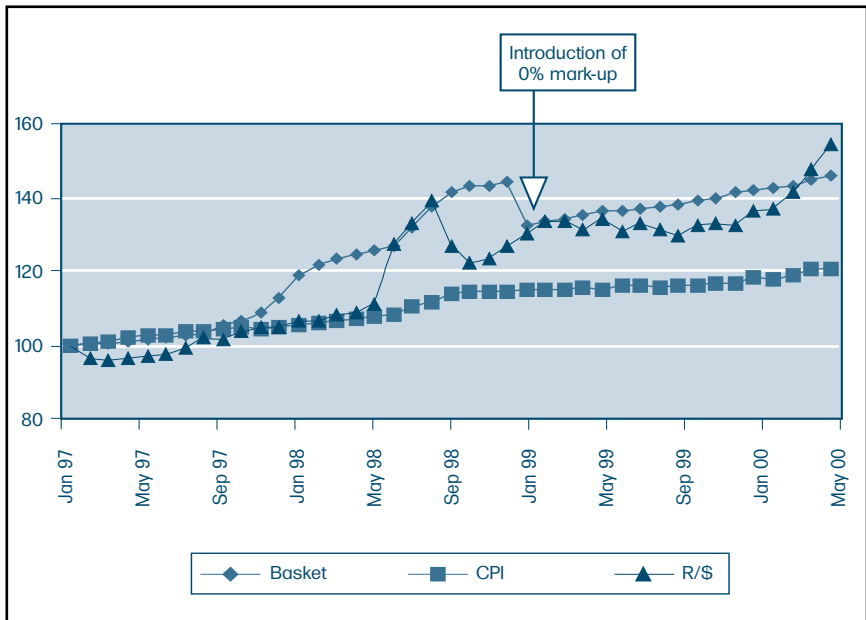
The Hospital Association of South Africa monitored prices of a basket of 1 000 drugs between January 1997 and May 2000 and found that the cost of drugs increased substantially more than many items. From a starting point of 100 for each variable:

- ❖ The all products basket reached 145.9

- ◆ The Consumer Price Index was only 120.4
- ◆ The Rand/US dollar exchange rate weakened to 154.1.

The close tracking of the drug prices and the exchange rate 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

The global pharmaceutical industry

Global sales are predominantly in industrialised regions:

- ◆ 46.7% in North America
- ◆ 24.8% in Europe and
- ◆ 11.3% in Japan

- ◆ 1.3% in sub-Saharan Africa
- ◆ 1.8% in the Indian sub-continent.

One single firm may dominate the sales in an area such as cardiovascular drugs or in the management of a particular disease such as ulcers or HIV/AIDS. Such firms may, within that particular area, wield considerable influence.

- ◆ The top 3 products in a particular therapeutic sub-market may account for up to 60% of sales
- ◆ In South Africa 4 firms account for 92% of local company sales in the private pharmacy market.

All products, including medicines manufactured abroad, need local finishing to comply with local registration, labelling and quality control requirements. This makes local subsidiaries liable to (and for):

- ◆ “Transfer pricing” practices, where the raw material prices are inflated to ensure optimal profits at the global level
- ◆ Local marketing and sales forces, resulting in marketing costs being nearly double those of research and development (R&D). High R&D costs contribute to the high costs of innovator drugs.

High profits made by the pharmaceutical industry contribute to high drug costs.

- ◆ In the last 10 years, the pharmaceutical companies have 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
- ◆ 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%.

Drugs’ prices have less to do with manufacturing and development costs, but 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).

Price surveys

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. However, caution regarding these studies needs to be exercised, as:

- ◆ Price comparisons are controversial and fraught with methodological difficulties
- ◆ Studies usually have cautionary notes, such as “the price information presented is not exhaustive and should only be considered as an indication of the variation in prices between countries ...”
- ◆ Despite these concerns, it has been noted that policymakers continue to act on studies that display weaknesses in one or more areas of methodology.

Within-country comparisons, while not devoid of challenges, are somewhat easier but differences usually exist between sectors.

- ◆ In South Africa, major differences exist between private sector prices and State tender prices. Claims are made that the difference is on average 10-fold
- ◆ Lower prices offered to the State are sometimes blamed for higher than usual prices in the private sector, constituting some form of cross-subsidisation (although there are no accurate data to support this)
- ◆ There also exist discriminatory pricing practices between different purchasers in the private sector, confirmed by the Competition Board investigation in 1992.

The South African policy trajectory

Local policy is encapsulated in the 1996 National Drug Policy and seeks to “ensure the availability and accessibility of essential drugs to all citizens” by aiming to:

- ❖ “Lower the cost of drugs in both the private and public sectors”
- ❖ “Promote the rational use of drugs”
- ❖ “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 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 including generic substitution
- ❖ Improve rational drug use, including establishing Pharmacy and Therapeutics Committees (PTCs) in all hospitals
- ❖ Control of pharmaceutical marketing practices
- ❖ Export of local products to neighbouring countries was also to be encouraged.

Policy options

Price control is more common in developed than in developing countries, even though price sensitivity might be greater in countries with poorer social security systems.

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)
- ❖ 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).

Producer price control measures

Direct Price control:

- ❖ Would contravene South Africa's national trade and industrial practices
- ❖ Is complicated and cumbersome and easily by passed by transfer pricing (inflation of the prices of imported raw materials)
- ❖ Is open to political interference.

Reference pricing:

- ❖ Is a more transparent system
- ❖ Involves 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.

Equity pricing:

- ❖ Manufacturers agree to subsidise lower prices in developing countries by levying higher prices in wealthier countries
- ❖ Equity pricing is the basis for the UNAIDS negotiations with major AIDS drugs manufacturers, and also underlies offers of drug donations to developing nations
- ❖ Donations are difficult to accept when accompanied by additional demands, as was the case with the Pfizer offer of fluconazole to South Africa in early 2000.

Promotion of generic medicines:

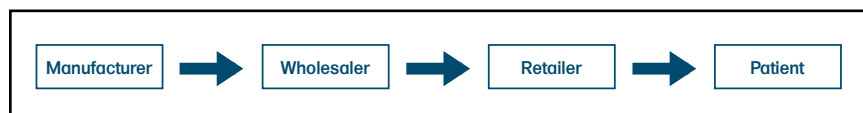
- ❖ Unpopular with the research-based industry, but usually effective
- ❖ Stimulate competition and promote the development of local manufacturing concerns. For example, in Brazil anti-retrovirals dropped in price by only 9% from 1996 to 2000, compared to an average of 79% for drugs that faced generic competition.

Distribution chain cost controls

Figure 3 illustrates the typical distribution route for pharmaceuticals in the private sector.

- ❖ At each step a percentage mark-up is applied, but this is often accompanied by a discount
- ❖ The actual mark-up might therefore be lower than the theoretical mark up
- ❖ Most patients do not pay directly for their medicines, medical aid pay on their behalf, resulting in 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 medical aids.

Figure 3: Traditional distribution chain for medicines (the “retailer” is either a pharmacist in a retail pharmacy or private hospital or a dispensing doctor)



Mark-up chain results in an 81% mark-up from manufacturer to patient.

An example of the impact of the mark-up chain to the price of a drug

Consider a product leaving the manufacturer at a nominal R100.00. The product would then 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%.

Actual percentage contributions of each stage, for each of the two discount scenarios described above, to the final cost are presented 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

- ❖ Manufacturer's exit prices account for the highest proportion of drug costs, around 40% being constituted by the distribution chain costs
- ❖ It is also worth noting that there has been significant vertical integration in South Africa, where 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.

South African private hospitals have:

- ❖ A 0% mark-up policy on wholesale list price
- ❖ Use their collective buying power to extract 20% rebates from manufacturers, therefore, end-up making a profit on medicines despite levying no mark-up.

Current proposals include:

- ❖ Replacing mark-ups with a fixed professional fee of R20.00 per item
- ❖ No discount to the medical aid
- ❖ VAT to be levied as before.

Possible impact of the proposal:

- ❖ Current low cost items might actually increase in price, due to the applied fee of R20.00, regardless of the cost of the medicine
- ❖ By removing the profit motive, pharmacists will earn the same amount, regardless of whether s/he dispenses an expensive branded product or a cheaper generic.

Bulk purchase measures

The State already uses the most basic measure – competitive bidding (tender) – as the major mechanism to ensure maximal price leverage.

- ❖ Competitive bidding has not led to affordable prices
- ❖ Tenders are only open to locally-registered firms, better prices might be obtained on the international market
- ❖ Some local tender prices were more than double the median price in the 1999 International Drug Price Indicator Guide.

A growing demand is for regional bulk purchasing arrangements, particularly with other member states of the Southern African Development Community (SADC).

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. 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).

Achieving this will not be easy as international pharmaceuticals oppose these measures and patent rights have been strengthened in recent years by new international trade agreements. Of particular importance is the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which gives drug companies 20 years' patent protection on their inventions.

Demand side measures

Forcing rational prescribing behaviours on prescribers has rarely been successful without considerable "buy-in" by those prescribers. This remains a key area of implementation though, and requires strengthening in South Africa.

Conclusions and recommendations

The drug environment is highly complex and dominated by varying interests representing different stakeholders. In its attempt to improve access to drugs in South Africa, the NDP is faced with immense challenges. There are those who believe that it is necessary to prioritise 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)²
- ❖ 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.

Crucial to the success of these options will be the:

- ❖ Strengthening of the national departments tasked with overseeing the implementation of the NDP
- ❖ Inspectorate functions of the MCC.

Strengthening the entire system will ensure that potential pitfalls are minimised or avoided and will demonstrate that exposure to inferior quality or even counterfeit drugs is not an inevitable consequence of the policy choices outlined in this chapter.

2 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.