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Policies to Control Prices of Medicines: Does the South African Experience Have Lessons for Other African Countries?

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Introduction

Despite the heightened interest in the African pharmaceutical market, there are constraints and challenges that continue to affect access to medicines. One of the key constraints is the high prices of medicines. In the private sector, wholesale and retail mark-ups have been found to range from 2% to 380% and from 10% to 552%, respectively (Cameron et al., 2011). A later study found wholesaler mark-ups between 25% and 50% (IMS Health, 2014a; 2014b), and retail mark-ups between 25% and 500% (Rosen and Rickwood, 2014). Local manufacturers and importers alike have expressed concern over the high mark-ups in the distribution chain, as the exorbitant prices are believed to limit patients' access and sales.

African governments are all grappling with the issue of high medicine prices. Coupled with the increasing momentum for developing local pharmaceutical industries, the issue of medicine prices and how to contain them will come into sharp focus for policy makers. African policy makers are also acutely aware of measures employed by other countries around the world to contain runaway health care costs, and specifically pharmaceutical expenditure. Although price controls are important policy instruments, they are very controversial. The South African experience with pharmaceutical price controls may therefore be a useful case study to inform other African countries' interventions.

This chapter presents the South African experience with the single exit price (SEP) regulations which were enacted to deal with these distortions and to replace the mark-up-based retail pricing systems with fixed professional fees in order ultimately to reduce the price to patient.

Pharmaceutical price control options

Governments have moved to control prices, first, because the innovative pharmaceutical industry has historically been dominated by monopolies, creating the tendency to price products at a premium. Medicines are also different from any other consumer goods in that patient is often price-insensitive, given that the doctor prescribes and a third party pays for the drugs. Furthermore, many consumers and health care professionals equate a higher-priced product with quality, and conversely see a lower-priced product as inferior, resulting in the ready acceptance to prescribe, dispense or ask for high-priced products. The challenge for governments therefore is how to institute proper controls to ensure that medicines are priced fairly and that access is not constrained by high prices.

The literature on pharmaceutical price controls identifies three distinct ways in which expenditure can be controlled: direct controls on the prices of medicines across various levels in the distribution chain; through demand-side measures including financial and reimbursement systems; and finally by influencing demand through the implementation of demand-side measures.

Price controls at the level of the manufacturer

The most difficult step in price controls is arriving at a reasonable or fair price for a medicine. The literature on price controls and the tools employed are mostly from high-income countries. These include the cost-plus method, profit caps, comparative pricing, direct price negotiations and pharmaco-economic evaluations, or a combination of these tools. The cost-plus pricing model is difficult to employ in a country where most suppliers are subsidiaries of international companies or importers of products from other markets. In this scenario, experience shows that it is very difficult to obtain accurate and reliable data to arrive at a determination of real costs and profits.

The second method of price controls, using profit caps, is employed in, for example, the United Kingdom through the Pharmaceutical Price Regulation Scheme (PPRS), whereby the government negotiates a reasonable profit with companies for products sold to the National Health

Service. This method too faces difficulties with arriving at accurate costs and profits when dealing especially with subsidiaries of international companies and importers.

The third method is comparative pricing, comparing prices of products in other markets with local market prices. Complexities include varying dosage forms, strengths and trade names, and the fact that the margins and mark-ups allowed to players in the chain differ across territories. The Netherlands, for example, sets maximum permissible prices using the average wholesale price of similar products in a basket of countries including Belgium, Germany, France and the United Kingdom. It is reported that upon its introduction in 1996, Dutch pharmaceutical prices dropped by an average 20% (Rietveld and Haaijer-Ruskamp, 2002).

The fourth commonly used tool involves direct price negotiations between buyers and pharmaceutical companies. In France, the government directly controls prices through negotiations before a product is launched. Finally, pharmaco-economic evaluations are used by regulators to attempt to arrive at a fair price, taking into consideration the societal costs of the disease and the costs of other treatments. Through economic modelling, the direct and indirect benefits of the drug are calculated and compared with alternative therapies. Pharmaco-economic evaluations are used extensively in the UK, Netherlands, Canada and Australia, among other markets (see also Chapter 13).

Price controls at the wholesale and pharmacy level

Wholesaler margins are controlled through setting either a maximum margin or a maximum price at which wholesalers can sell on to retail pharmacy. Margins in retail pharmacy can be controlled by setting a fixed percentage mark-up to the wholesale price of each medicine, by setting a maximum over all mark-up, or finally by tiered mark-ups where the percentage mark-up reduces as the price of the product increases. The fixed-margin system is widely used in Europe, with margins for prescription drugs normally around 30%, whilst over-the-counter products are freed from price controls. Although margins are fixed, wholesalers may still be able to negotiate discounts and thus increase their profits. The tiered structure is intended to create disincentives for dispensing more expensive products.

Some countries, including China, have a system of price controls that differentiates between imported and locally produced products (Bao, 2000). The Chinese system also differentiates based on drug classes: basic therapeutic and preventive drugs acquired in large volumes, class 1

anti-psychotics, anaesthetic agents, contraceptives and other special classes.

Other measures to influence prices

There are other demand-side measures that can influence prices and expenditure. These include positive and negative lists, reference prices, co-payments, parallel importation, and generic substitution, as well as education of health care professionals and the public. A negative list of products that are not reimbursed forces companies to lower prices in order to gain a listing on the positive list. Similarly, reference prices, which are used to benchmark products in the same therapeutic category that are assigned a certain price cap, and related demand-side measures such as co-payments, are meant to force patients to opt for the cheaper medicines. Generic substitution and closely related educational measures to educate health care professionals and patients about the quality and benefits of generic medicine are other demand-side measures that have been employed to lower medicine expenditure.

The basis of the South African price control regime

Implications of the two-tier South African health care system

When the first democratic government in South Africa came into power in April 1994, it inherited a two-tier health care system (private and public) reflective of the country's divided history. These two tiers have widely differing resources and access medicines via different channels. The private health care tier is a well-resourced private insurance-based world-class platform which serves an estimated 15% of the population (Council for Medical Schemes, 2014). The private pharmaceutical market is valued at \$4.1 billion (IMS Health, 2014b) and is supplied with medicines by about 130 manufacturers and importers supplying 5,000 product lines.

The second tier, the public sector health care system, serves the remaining 85% of the population. It is under-resourced, with chronic staff shortages, a quadruple burden of disease and systemic lack of funding. Public sector supplies are obtained through tenders administered by the Central Procurement Unit of the Department of Health. It is supplied with 2,400 product lines by an estimated 90 manufacturers and importers, at an estimated value of \$1 billion a year in 2014.¹

Besides these deep divisions, the democratic government faced spiralling health care costs and an increasingly exclusionary health care

system, in which those who served the poor and marginalized were paying more for medicines than those in the affluent areas who were more likely to benefit from price and volume discounts, rebates, bonuses and other incentives. The pricing of medicines had historically been left to market forces, so companies were free to price their products as they wished, to offer bonuses and deals, discounts and rebates, and to discriminate among clients on the basis of volume of purchases and other considerations. The government therefore decided to intervene to correct the distortions.

Despite the large literature on pharmaceutical price controls in highly developed markets with well-developed health insurance schemes and universal coverage (Rietveld and Haaijer-Ruskamp, 2002), there was little from the developing world with similar health care systems to South Africa with a significant portion of patients without health care insurance and with considerable out-of-pocket expenditure on health care and medicines.

The government was also aware of developments internationally, where high medicines prices were receiving global attention from governments and consumers alike. Further, they were acutely aware that price controls have to be enacted in such a way that they still create headroom for market forces to work to exert further downward pressure on pricing. In trying to come up with mechanisms to control prices, the government looked to emulate countries that had successfully introduced controls and managed to reduce, contain and sustain medicine expenditure.

A further challenge faced by South Africa was the huge fragmentation of the distribution channel, unlike the Western world where there are a few distributors and wholesalers controlling the entire distribution chain, and hence enjoying economies of scale. So the choice of policy options to contain drug costs would have to take into consideration the country's unique health care structure.

The South African rationale for price controls

The government believed that medicines were public utility goods, and not mere commodities, and that it could no longer allow a situation where companies priced their products as they pleased. This was reinforced by their view that the prevailing drug prices in South Africa were inflated artificially through the elaborate system of bonuses, discounts, rebates and other perverse incentives systems that led to the dispensing of more expensive drugs, and irrational use of drugs. These perverse incentives, the state alleged, added an additional 50% to the final cost

of the drug. The Department of Health claimed that South Africa was among the world's top five most expensive medicine markets.

The Department of Health's position was strongly challenged by the Pharmaceutical Manufacturers Association (PMA) of South Africa, who held the claims were devoid of truth and based on an unfair comparison. The PMA held that the Department of Health was trying to influence the public and create the impression that the pharmaceutical industry was responsible for the high medicine costs, in order to introduce measures to control the industry. To circumvent this, the PMA approached the office of the Public Protector to make a determination whether the statements made by the Department of Health, perceived as laying the groundwork for price controls, were factual.

A key contention was that the Department had compared prices of products sold in the South African retail sector with prices of multi-source products sold by a prominent global NGO, the International Dispensary Association, which supplies developing countries with generics bought internationally in bulk. The PMA's position was that the department was using an untenable comparison to justify the introduction of medicine registration and pricing reform in South Africa, whilst ignoring the fact that patient prices were often double the ex-manufacturer prices, and that various studies had indicated that South African prices were on par with international prices.

Despite the PMA's efforts to block the reforms, the government made clear that they would immediately take measures to correct the disparities and distortions. In this regard, a number of key government policies – legislative and regulatory provisions – were enacted. The next section reviews the constitutional mandate that led to the interventions.

Constitutional enablers of the National Drug Policy

On 8 May 1996, the democratically elected parliament adopted the new Constitution of the Republic of South Africa.² This enshrined a Bill of Rights. Section 27 underpinned the legislative and regulatory processes that would follow in reforming the health sector; it read:

Section 27 (1) (a); everyone has the right to have access to healthcare services, including reproductive health.

Section 27 (2): the state must take all reasonable legislative and other measures within its available resources, to achieve the progressive realisation of each of these rights.

Informed by this provision in the constitution, and acutely aware of the urgency to address the imbalances of the past, to create a new and equitable health care system with universal access to affordable quality health care for all, and ensure the progressive realization of Section 27, the government introduced a number of policy papers which would drive far-reaching regulatory and legislative reforms. The most important was the National Drug Policy (NDP) of 1996. The NDP had far-reaching implications, laying the basis for the Single Exit Price (SEP) regulations discussed below.

National Drug Policy

The NDP (Department of Health, 1996) was aimed broadly at increasing access to safe, affordable quality medicines for all South Africans, and laid the foundation for all the subsequent legislative and regulative revisions and amendments. Specifically, the NDP's objective was '[t]o promote the availability of safe and effective drugs at the lowest possible cost'. The NDP intended to rationalize the pricing structure of drugs and included the following to realize that aim:

- the appointment of a Pricing Committee;
- introducing total transparency in the pricing structure of pharmaceutical manufacturers, wholesalers and dispensers of drugs;
- introducing a non-discriminatory pricing system;
- replacing the wholesale and retail percentage-based mark-up system with a fixed professional fee;
- regulating price increases.

The far-reaching aims of the NDP found expression in the amendment to the Medicines and Related Substances Control Act 101 of 1965. The new Act 90 of 1997 introduced, among others, sections dealing with bonuses and samples (18 A and B), the ethical marketing of pharmaceuticals (18C), generic substitution (22F) and the creation of the Pricing Committee and enactment of the single exit price regulations (22G).

The Medicines and Related Substances Act

Before the introduction of the SEP regulations, the South African pharmaceutical market was dominated by innovator brands, with very little generic penetration. Medicines were promoted directly to doctors and pharmacists, who often received samples, bonuses and many other incentives to drive the prescription or dispensing of particular drugs. These practices led to doctors often prescribing more expensive drugs.

The amended Medicines Act made provisions for the parallel importation of medicines into South Africa by others other than the patent holder (15C), the prohibition of bonusing, rebates and any other incentive scheme (18A), prohibition of sampling of medicines (18B), mandatory generic substitution (22F) and the formation of a Pricing Committee and the clauses governing its mandate³ (22G), namely that:

- (1) The Minister shall appoint such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.
- (2) The minister may, on the recommendation of the Pricing Committee make regulations
 - (a) on the introduction of a transparent pricing system for all medicines and scheduled substances sold in the republic
 - (b) on an appropriate dispensing fee to be charged by a pharmacists or person licensed in terms of Section 22 C (1) (a).
- (3) The transparent pricing system contemplated in sub-section (2) (a) shall include a single exit price which shall be the only price at which manufacturers shall sell medicines and scheduled substances to any person other than the state.

The provisions contained in the amendment to the Medicines and Related Substances Control Act 101 of 1965 were immediately challenged in court by the Pharmaceutical Manufacturers Association of South Africa (PMA), who felt that the Department had overreached itself in drafting the act. Although the PMA withdrew its court challenge in 2001 following an international outcry and mounting international and civil society pressure, the regulations pertaining to a Transparent Pricing System for Medicines and Scheduled Substances⁴ only came into effect on 2 May 2004.

The Single Exit Price regulations

South Africa's attempt to control prices at wholesale level has elements of a fixed professional fee but with a fixed maximum, based on a tiered scale that considers the price of the product. At retail pharmacy level, the professional fees are also fixed, on a tiered system that endeavours to promote the dispensing of cheaper products. Over-the-counter products are exempted from controls, but pharmacists cannot benefit from discounts as they do in Europe.

The SEP was defined by the regulations as a composite of the manufacturer's exit price, plus the distribution or logistics fee and a 14% value

added tax (VAT). The SEP thereby derived would be the one and only price at which wholesalers, pharmacies and other people allowed to dispense in terms of Section 22C (1) (a) could sell the medicine in South Africa, irrespective of the volumes purchased. The SEP would control pricing throughout the pharmaceutical value chain, setting dispensing fees for pharmacists and logistics fees for wholesalers and distributors.

The final price to the end user would include the SEP and the professional (dispensing fee) for the service rendered. Whilst companies would have the freedom to set initial prices, the pricing committee would decide on an annual price increase in accordance with a methodology in the SEP regulations.

Whilst the introduction of the SEP was widely criticized and seen as an anti-private-sector move by the new democratic government, the high prices of medicines had received attention previously from government commissions under the National Party. The three previous commissions – the Snyman Commission (1962), the Steenkamp Commission (1978) and the Browne Commission (1985) – had also made recommendations including curbing excessive medicine promotions, generic substitution, issuing of compulsory licences, calling for the state to participate in the supply of medicines through a tender system and for the state to investigate the introduction of price controls.

Setting the regulations

The Minister of Health appointed a pricing committee with representation from the Departments of Trade and Industry and Finance and the Competition Commission. The committee had pharmacists, lawyers, health economists, pharmaco-economists, academics and consumer representatives, but no industry representation. Their mandate was to establish a new regime of total transparency in the pricing structure of all prescription medicines and over-the-counter products. The committee would also set up regulations for logistics and dispensing fees, international benchmarking of pharmaceuticals and pharmaco-economic evaluation of medicines.

The government stated that, when fully implemented, it expected the SEP regulations to reduce the prices of medicines by 40–70%. In line with the regulations, effective 2 August 2004 and for a year thereafter, the price of medicines would not be higher than 50% of the 'Blue Book' manufacturer net price.⁵ The Blue Book was a well-known industry publication that supplied the pharmaceutical industry and health care sector with independent and accurate price lists. The government held that the manufacturer net price listed in the Blue Book was inflated to

cater for the complex systems of bonuses, rebates and other incentives at play in the industry, in order to allow the retail chains to acquire drugs at below 50% of the listed Blue Book price.

The SEP regulation 8 allowed for a manufacturer to set their single exit price, which could only be raised once on an annual basis, whilst temporary price reductions were allowed as often as the manufacturer wanted to make them for competitive reasons. The SEP could be increased only once a year based on a predetermined formula⁶ that incorporated, among others, the Consumer Price Index (CPI) and Producer Price Index (PPI) for the preceding year; changes in the rates of foreign exchange and purchasing power parity; and the need to ensure the availability, affordability and quality of medicines. The currencies considered are the US Dollar and the Euro, as most South African pharmaceutical companies purchase products and inputs of production from abroad with these two currencies.

The final increase as per formula is calculated as follows:

$$\begin{aligned} \text{API Formula} &= 70\% \text{ CPI (historical)} + 15\% \text{ (Rand/Dollar variance)} \\ &+ 15\% \text{ (Rand/Euro variance)} \end{aligned}$$

The exchange rate split of 15% US\$ and 15% Euro was based on data provided by the Department of Trade and Industry and data on pharmaceutical imports.

Although this formula has been applied from the beginning, the actual price increases granted by the MoH have displayed a degree of discretion, and the timing has often been delayed, in some cases by up to five months.

Manufacturers can also apply for increases above the formula-based increases, to assist manufacturers and importers to compensate for exchange-rate-related increases in the prices of production inputs or finished products imported from principals overseas. The exceptional circumstances under which the minister would authorize such an increase were adverse financial, operational and other consequences for the manufacturer; adverse effects on the availability of the medicine in South Africa should the increase not be granted; the nature of the disease the medicine was registered for; resultant adverse effects on public health; and lastly, to ensure that the constitutional obligations were not abrogated.

Finally, the Director General of the Department of Health could inform the public if she or he felt that the single exit price of a medicine was unreasonable. Manufacturers and importers were required to inform

the Director General six months before the registration of a medicine the intended SEP, the countries where the product was sold and how much it was selling for, the costs of manufacturing, and the marketing and selling costs of the product.

At inception, the regulations stipulated the maximum professional fees that could be added to the single exit price by various players in the distribution chain.

Controversies and challenges

The SEP regulations were immediately challenged in court by various organizations. The pharmacy groups contended that the fees were not sufficient for them to survive, and that the stipulated professional fees threatened the survival of many independent pharmacies. Further, the Pharmaceutical Society of South Africa (PSSA), a large retail pharmacy chain, New Click (Pty) Ltd, and others argued that the Department had overreached itself in promulgating the regulations. The Cape High Court found in favour of the state and dismissed the case, although the dissenting judgment⁷ held that it was difficult to understand how the SEP was arrived at; that the logistics fee regulations were contradictory and at odds with other legislation; and that the dispensing fee had been based 'on no more than a thumb suck' and a simplistic 'one size fits all' approach. The PSSA, New Clicks and others appealed the Cape High Court ruling, and the case went to the Supreme Court of Appeal where the Cape High Court decision was overturned.

The Supreme Court of Appeal, in overturning the decision of the Cape High Court, made this finding⁸:

The order of the court below is set aside and replaced with the following order in each application:

- (a) The 'Regulations relating to a Transparent Pricing System for Medicines and Scheduled Substances' as published in GN R553 on 30 April 2004 are declared invalid and of no force and effect.

The state in turn appealed, and the case went all the way to the Constitutional Court, which ruled that the Department had indeed acted within the law, but ordered the Department to go back to the drawing board and review the professional fees.

The Department of Health adjusted the proposed dispensing fee to 26% of SEP to a maximum of R26. This proposal was immediately

rejected by the Pharmaceutical Society of South Africa, once again on the grounds that it was insufficient and would cause unnecessary hardship to their members and eventual closure of pharmacies. The PSSA proposed a tiered dispensing fee system with average fees of R37, a proposal that found no favour with the Department of Health.

Following these court challenges and negotiations between the various parties, the dispensing fee and the logistic fees have gone through various iterations, and have now been finalized. The June dispensing fee was first published in March 2006, and was immediately rejected by pharmacists. This was then replaced with a new proposal of June 2009. More discussions and consultations followed, and the last iteration was published in June 2014 (Table 11.1). The table shows the complex calculations of the permitted fee for each band of the SEP, at the various revision dates.

The proposed dispensing fees were revised upwards over time as pharmacists complained that their business would be unsustainable (Table 11.1). The lowest tier has stayed below R100 (US\$8.50) and the fixed fee was reduced, but the dispensing fee has been revised upwards with the adjustment of the percentage of the total medicine price. In the top tier of products above R799.85 (US\$67.80), the fee has also been adjusted upwards through a revision of both the fixed component and the percentage of the medicine price

Logistics fee

Prior to publication of the logistics fee regulation, wholesalers and manufacturers negotiated the logistics fee independently, and there were reports of widely varying logistics fees, with some companies paying in the high double digits. Innovator companies with patent-protected products that wholesalers were desperate to stock would often pay in the low single digits, whilst some did not pay any logistics fees at all. This position put the generic pharmaceutical industry at a distinct disadvantage, as wholesalers would often squeeze generic companies for bigger logistics fees to make up for the loss with innovator companies. The government finally moved to regulate the logistics fee, and in March 2011 published the first draft regulations for Logistics Fees (LF). The second iteration was published in September 2012 following negotiations and discussions with providers of logistical services. The fee involves four tiers, with a LF of 8% of the ex-manufacturer price excluding VAT + R3 (\$0.25) for items less than R100 (US\$ 8.50), and a LF of R54 (US\$4.58) for items exceeding R1,000.00 (US\$84)

Table 11.1 Pharmacy dispensing fee: fee in rands (R) plus permitted mark-up (%), by band of SEP in rands (R) and date of publication of schedule

Date of publication of fee schedule		06/2009	12/2010	09/2013	06/2014
SEP < R77.00	SEP < R100.00	SEP < R75.00	SEP < R81.00	SEP < R81.00	SEP not > R 85.70
R7.00 + 28% of SEP	R6.00 + 36% of SEP	R6.00 + 46% of SEP	R6.30 + 46% of SEP	R6.30 + 46% of SEP	R 6.95 + 46% of SEP
SEP = R75.00 < R 150.00	SEP = R100.00 < R 250.00	SEP = R75.00 < R 200.00	SEP = R81.00 < R 216.00	SEP = R81.00 < R 216.00	SEP R 85.70 < R228.53
R 23 + 7% of SEP	R 32 + 10% of SEP	R 15.75 + 33% of SEP	R 16 + 33% of SEP	R 16 + 33% of SEP	R18.55 + 33% of SEP
SEP > R150.00 < R250.00	SEP > R150.00 < R1000.00	SEP > R200.00 < R700.00	SEP > R216.00 < R756.00	SEP > R216.00 < R756.00	SEP > 228.53 < R799.85
R 26 + 5% of SEP	R 45 + 5% of SEP	R 51 + 15% of SEP	R 55 + 15% of SEP	R 55 + 15% of SEP	R59.00 + 15% of SEP
SEP > R 250.00	SEP > R 1000.00	SEP > R 700.00	SEP > R 756.00	SEP > R 756.00	SEP > R799.85
R 31 + 3% of SEP	R 65 + 3% of SEP	R 121 + 5% of SEP	R 131 + 5% of SEP	R 131 + 5% of SEP	R 140 + 5% of sep

Source: Government Gazettes, various years, extracted by author.

Despite representations from wholesalers and support from the generics industry for the logistics fee to include a minimum fee and a fixed cap, the department rejected that application on the grounds that having a fixed minimum would be anti-competitive. It published the final logistics fee with only a fixed cap. Manufacturers and importers would be free to negotiate a fee up to the capped level with wholesalers. The regulations also stipulated that where the current logistics fee exceeds the current caps, manufactures and providers of logistical services must negotiate to reduce the fee within 60 days of publication of final logistics fees. The regulations, however, allowed the minister to authorize a manufacturer or importer to increase the logistics fee in exceptional circumstances.

Experience with the Single Exit Price regulations to date

Price increases under the regulations

Table 11.2 below captures the experience with the SEP to date. It shows the quantum as determined by the SEP methodology and the eventual increase granted by the Minister.

It is clear from the table that the minister has not always adhered to the formula, and has exercised discretion in granting increases – a sore point for the industry.

Although the industry has complained about the low increases from inception, experience shows that since the introduction of the SEP, they have not always taken the full increase granted. In fact, temporary price reductions have been taken frequently within the period of an

Table 11.2 SEP increases since the implementation of the SEP (%)

Year	SEP calculation as per methodology (%)	SEP granted by the Minister (%)	Variance
2004/05 & 2006/07	2.60	5.20	N/A
2008	8.40	6.50	-1.90
2009	12.12	13.2	+1.08
2010	9.90	7.40	-2.50
2011	-2.10	0.00	N/A
2012	6.90	2.14	-4.76
2013	8.20	5.80	-2.40
2014	8.90	5.80	-3.10

Source: National Department of Health, Pharmaceutical Task Group, author analysis.

SEP increase. This has largely been for competitive reasons, and at times motivated by the need to sell short dated stock before it expires.

A further justifiable complaint is that the Department of Health delays the increases, so companies lose out. For example, in 2010, there was a five-month delay between the increase and the time that companies could take the increase. These delays occurred as a consequence of the 'application' process introduced, and decisions to accept applications only from 1 April. Given the 30-day approval process, the earliest companies can take an increase is 1 May, which leaves companies with just seven months to enjoy the price increase. Besides these delays, there were also frequent rejections due to such matters as formatting issues on the SEP increase application template, Department of Health database discrepancies and missing documentation.

SEP impact on prices

The experience of South Africa with price controls demonstrates that, contrary to popular opinion, the Department of Health conceptualized a regime based on global practice and tried to blend a number of instruments with a good historical record of effectiveness in other countries.

In terms of controls at the manufacturer level, in attempting to arrive at a fair ex-manufacturer price, and considering the complexities of setting a fair price in a predominantly import based industry, the government settled arbitrarily on 50% of the Blue Book price on the basis that prices were inflated by the same figure to make up for the incentives, bonuses, sampling and other perversities in the system. The price negotiation component between companies and government has only been recently employed for state procurement, where besides published reference prices, the Central Procurement Unit can and does directly negotiate prices with manufactures, especially if they are not too far from the reference prices listed. At the same time, elements of comparative pricing were built into the regulations through the International Benchmarking provisions wherein South African prices would be compared to a basket of prices in five countries including Canada, Australia, New Zealand and Spain. Similarly, pharmaco-economic evaluations were also built into the regulations, although these and comparative pricing through benchmarking have yet to be finalized.

When it comes to other measures to control prices, South Africa has not adopted positive and negative lists, whilst experience with demand-side measures such as reference prices, co-payments, and generic substitution and education of health care professionals and the public is mixed. Private health care insurance schemes all have reference pricing

systems in place, and accompanying co-payments if patients elect to use more expensive products outside the formulary and reference prices. Government enacted provisions for mandatory generic substitution, and although this and other measures have seen generic usage increase from the mid-20% in 2002 to around 60% by volume (IMS Health, 2014a), there is still scope for more growth. To this extent, the government can do more to educate patients about the safety, quality and efficacy of generic medicines, as well as the benefits for patients and health systems. This is an area that still requires much work.

There is general acceptance that the introduction of the SEP regime has resulted in a downward impact on the prices of medicines. The graph in Figure 11.1 is drawn from data from the Council of Medical Schemes, which publishes an annual report detailing, among other things, total health care expenditure in the private sector, and looks at the contribution of the various players.

The Department of Health reported savings of 19%, made up of 25–50% for generic medicine prices and 12% for originator medicines.⁹ IMS Health reported an average drop in medicine prices of 24% between June 2003 and June 2006 (Vokes, 2007) since the introduction of the SEP. Similarly, Emsley and Booyesen (2004) reported that the introduction of the SEP had resulted in a reduction of 36.7% in the prices of quetiapine and 13% for haloperidol. Admittedly, that paper was published a few months after the introduction of the SEP, so it is

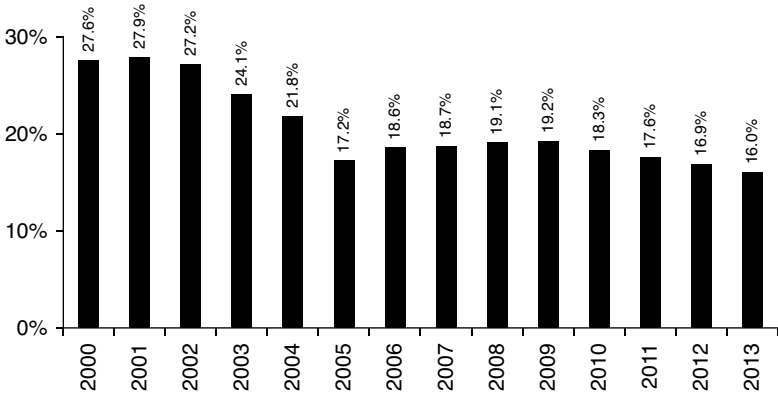


Figure 11.1 Medicine contribution to total private health care costs

Source: Drawn by the author from data from Council for Medical Schemes (2014).

not clear if the reductions have been sustained. Further evidence of the impact of SEP on prices was reported by Steyn et al. (2007), who demonstrated that the SEP regime had reduced the average cost of anti-diabetic medicines by around 29.6%. Finally, the biggest private health insurance company, Discovery Medical Aid, reported: 'Because of the single exit price legislation, these drug price reductions benefit all users in the private healthcare system. Conservative estimates suggest total annual savings of about R 319 million per year are achieved for the scheme in medicine expenditure' (DHMS, 2012).

The media and other parties have also reported extensively on the impact of these price regulations. For example, the *Mail and Guardian*, South Africa's leading weekly newspaper, reported on 26 February 2008: 'The introduction of medicine pricing regulations a few years ago resulted in a 20% drop in prices, and savings of over R 2.3 billion on medicines'.

Other reports and theses, especially looking at the impact of the SEP on the pharmacy profession, and occasionally on the patient, do however offer a different view of the impact. They describe a profession decimated by the regulations, with multiple closures of pharmacies, especially in rural areas. Although critically important and requiring further critical academic enquiry, they are outside the scope of this chapter. There is also anecdotal evidence that the early gains made may be slowly eroding as the contribution of medicines to overall health care costs continues to creep up, albeit slowly. Whether this is purely a factor of the SEP policies starting to fall short, or because of increased medicines usage, or the impact of pseudo-generics which tend to crowd out true generics and inflate prices, or other factors, requires further study.

SEP impact on manufacturers and access to medicines

It is accepted internationally that the entry of generics significantly widens access to medicines, and the size (volume) of the market often expands after patent expiry. The impact of the SEP regime on access to medicines is an area that still requires further investigation.

The reference prices are normally set with the first generic entrants and often undergo revisions with further entry. In certain instances, the revisions have been quite dramatic, leading to wholesale price decreases, further lowering the price of the drug and indirectly promoting access. The case of simvastatin is instructive. Simvastatin is highly genericized, with the first generic product launched in 2002 by Adcock Ingram. Adcock remained the clear market leader despite other generic alternatives. In 2009, Michol, a new simvastatin generic entrant, came in at a

very low SEP, and as a consequence the prices of a pack of 30 simvastatin tablets dropped from over R120 to around R25. Arguably, the effect of this would have been to increase access by patients, especially those who pay out of pocket for package deals that include consultation fees and medicines from family practitioners.

The impact of the SEP has also come through in capping prices through private medical schemes' reference pricing systems. All the private medical insurance schemes have their own reference pricing systems to set the maximum price a scheme will pay for a generic drug. The effect has been to force newly launched generics to price below the reference price, and in some instances to compel the innovator to drop their prices or face the risk of their products facing co-payments. Similarly, if, for competitive reasons, a generic manufacturer drops prices drastically and sets a new reference price, other companies are forced to follow suit or face the prospect of co-payments, which will deter patients.

Impact on manufacturers

Manufacturers have complained that the SEP regime has put the sector under pressure, as the SEP increases are insufficient to offset the effect of the weaker Rand, coupled with wage and utilities inflation. This leads to reduced earnings and threatens the commercial viability of some product lines. Given that most companies import both the active pharmaceutical ingredients and other raw materials from overseas, the weakening of the Rand in a price-controlled environment leads to significantly higher cost of goods sold, without the recourse to increase prices to offset that. This is particularly so because although the regulations have a mechanism for extraordinary prices increases, companies complain that the process is onerous, hugely bureaucratic and difficult to access. These pressures have led to some manufacturers discussing discontinuation of some products. Recently, it was reported that Fresenius Kabi had withdrawn one product, Voluven, from the market, although the company stated that the withdrawal was not related to cost pressures (Bateman, 2014).

Delays are also a major problem for manufacturers. When a company applies for an SEP for a new product, or informs the Department of an SEP price adjustment, the Department 'approves' and then notifies price vendors such as Medikredit. The product is then allocated a NAPPI (billing) code, after which it can be sold on the South African market. Companies complain that delays in assessing the SEP applications and informing vendors delays market access for new products, and in the case especially of first-to-market generics, restricts and denies patients access to cheaper products. Although the regulations envisaged that the

SEP would be agreed within 48 hours of notifying the Department of Health, the process has evolved to one of 'approval', and delays of up to a month are not uncommon.

The potential closure of independent community pharmacies in rural and remote areas, mentioned above, may clearly reduce access. The Pharmaceutical Society of South Africa opposed the SEP regulations and the dispensing fees on the basis that they threatened the viability of independent community pharmacy. Since the early court challenges, there have been widespread reports that some community pharmacies did go into bankruptcy. The Pharmaceutical Society of South Africa reports that many small town and rural pharmacies have closed (PSSA, 2014) negatively affecting access. Dodd (2007) demonstrated that independent pharmacies saw net profits fall, that the price controls could push some pharmacies into bankruptcy and that closure of pharmacies in remote and rural areas would render the distribution of medicines economically unviable and thus affect access.

Some contend, furthermore, that the SEP regime has the unintended consequence of keeping prices higher than they would otherwise have been. They argue that late entrants often find it impossible to offer discounts on the prevailing prices, given that medical schemes will still reimburse up to the level of the reference price, so there is no incentive for pharmacists to offer the lower-priced product. This is compounded by the fact that the dispensing fee is calculated as a percentage of the price of the drug, inadvertently incentivizing pharmacists to dispense the highest-priced generic as long as it is within the reference price band.

Finally, it is argued that the SEP regime creates a disincentive for new entrants to offer lower entry prices. Some experts believe that because companies know that they will struggle to get price increases (Medical Chronical, 2012) sufficient to offset inflationary pressures and Rand weakness, among other challenges, they deliberately set high prices from the outset, possibly reducing access. The proponents of this view note that medicine prices in South Africa are artificially inflated, and higher in comparison to the same products in other countries.

Conclusion: are there lessons for other African countries?

South Africa embarked on the SEP path exactly a decade ago, informed by the realization that, as public utility goods, medicine prices could not be left to the vagaries of the market. In that time, there has been much acrimony, public disagreements in the media and other public spaces

between the main protagonists. Throughout all of this, the Department of Health, backed by the government and the ruling party, as well as public health and patient advocates, held firm. There have been threats of court cases, and many actual court cases, which have invariably led to iterations of the dispensing and logistics fees. What has emerged, though, is that through proper consultation and a willingness to open up and present the evidence base for positions held on various issues, it is possible to move towards negotiated positions. The first critical lesson for those who would want to embark on the price regulation route, therefore, is the absolute necessity of having clear and unambiguous political support for reform. Without this, there is no hope for success.

The second key lesson from South Africa's journey with price regulations is the necessity of involving all key stakeholders in the process very early on. Governments and policy makers must take the private sector into their confidence and clearly and firmly explain the rationale for their decisions, ensuring that all views and all aspects are taken into consideration beforehand. Arguably, if the South African Department of Health had embarked on an exercise with the pharmacy profession, escorted by reputable independent and honest brokers, to arrive at a reasonable and evidence-based dispensing fee, there would have been no need for court cases, nor for the time spent in the last couple of years on endless consultations and the various iterations of the dispensing fee.

Third, it is imperative to collect the evidence base to guide policy decisions to be taken before embarking on a price reform process. This means making a full and thorough assessment of the entire distribution chain and finding the factors at play with each of the stakeholders. In the South African example, the R26/26% dispensing regime was no danger to the big retail chains, but threatened the survival of the small community pharmacy.

Fourth, it is imperative to make both the interpretation and implementation of any regulatory processes as simple as possible. The complexity that crept into the South African SEP regime and the bureaucratization of the process only served to make the pricing regime more unpopular. A measure of predictability and certainty around the application and approval process, the time periods for taking the increases and so forth would have lessened the tension between industry and the regulators.

Finally, although the SEP regime seems to have had a positive impact on prices, it is clear that supply-side measures on their own have only limited impact. It is thus critical for those governments that intend to regulate prices to devote equal attention to the demand side. This can be

done, among other methods, through massive patient education about the benefits of generic medicines, the incentivization of health care professionals to prescribe or dispense the cheapest products – above and beyond the dispensing fee – and the need to adopt generic prescribing across the board.

Notes

1. National Department of Health, South Africa – Tender analysis by author, from data accessed in December 2014 at <http://www.doh.gov.za/mpc3.php>.
2. The Constitution of the Republic of South African – ‘Everyone has the right to have access to – a) health care services, including reproductive health care’. Section 27 (1) (b) of the Constitution further mandates the state to, ‘take reasonable legislative and other measures, within its available resources to achieve the progressive realisation of the right’.
3. The Medicines and Related Substances Control Act 101 of 1965 as amended.
4. Department of Health. Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances. GG No R 553 30 April 2004.
5. Department of Health. Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances. GG No R 553 30 April 2004.
6. National Department of Health – Regulations relating to a transparent pricing system for medicines and scheduled substances made in terms of Section 22G of the Medicines and Related Substances Act, 1965 (Act No 101 of 1965).
7. *New Clicks South Africa (Pty) Ltd v Tshabalala-Msimang and Another NNO; Pharmaceutical Society of South Africa and Others v Tshabalala-Msimang and Another*.
8. The Supreme Court of Appeal of South Africa – In the matter between The Pharmaceutical Society of South Africa AND Others and the Minister of Health and ANOTHER, New Clicks South Africa (Pty) Ltd and Dr Manto Tshabalala-Msimang and ANOTHER, Case No 542/04 & 543/04.
9. A presentation by the Department of Health on Medicine price regulation – the South African experience (2009).



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