Medicine pricing interventions – the South African experience

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Abstract

All countries face the challenge of finite health resources, and therefore the need to limit expenditure on medicines. Post-apartheid South Africa developed a National Drug Policy in 1996, which signaled a multi-faceted series of interventions to reduce medicines prices and also improve prescribing and dispensing practices. Implementing this policy has not been without challenges, including legal challenges by the pharmaceutical manufacturers, medical practitioners and pharmacists. While a policy of mandatory offer of generic substitution has been implemented successfully, improving the quality of medicines use in the private sector has not been as easily addressed. A single exit price mechanism for all medicines in the private sector has been introduced, with regulated maximal annual increases. However, the greatest difficulty has been encountered in determining a reasonable and enforceable dispensing fee. This element of the pricing intervention remains highly contested. South Africa’s experience has also highlighted the need for clear legal drafting when attempting medicine pricing interventions. Other elements which still need addressing are the selection of medicines in the private sector, an enforceable code of marketing practice, and a more transparent way of indicating which medicines can be substituted, based on suitable bioequivalence and other data. South Africa’s National Drug Policy is expected to be reviewed in the near future, and these issues will need urgent attention if the country is to realize its goal of introducing a National Health Insurance system.

Keywords: Medicine pricing, South Africa, policy reforms.

Introduction

Post-apartheid health policy discourse in South Africa has been dominated by the drive to improve equity in the health system as a whole, as well as to improve access to healthcare services for those citizens previously disadvantaged by racially-discriminatory policies and practices. In the immediate aftermath of the 1994 elections, new Ministers in the Government of National Unity embarked on wide-ranging policy reviews. The first post-apartheid Minister of Health, Dr Nkosazana Dlamini-Zuma, created 11 such policy review committees, one of which was tasked with developing a National Drug Policy. The process followed in the development and early implementation of this policy has been extensively reviewed. The National Drug Policy was approved by the Cabinet and published in 1996.

This paper addresses just one element of the policy—that directed at reducing the prices of medicines.

Policy background

The issue of medicines prices had been addressed previously by the apartheid government on a number of occasions. Commissions of Inquiry were constituted in 1961, 1978 and 1985 to investigate the high costs of healthcare, including the costs of medicines. The responses by government to the recommendations from these three investigations – the Snyman, Steenkamp and Browne Commissions – are particularly instructive. All three Commissions identified patent legislation as contributing to high prices. The Snyman Commission (1961) recommended that the Minister of Health be empowered to issue compulsory licences for medicines. This was not implemented. The Steenkamp Commission (1978), a decade and a half later, also recommended that compulsory licences be used, as provided for in local patent legislation. None has ever been issued by a South African government. All three also identified generic medicines as important cost-savings mechanisms, and both the Snyman (1961) and Browne (1985) Commissions recommended that generic substitution be used. This only became legal in 2003, almost two decades later. The Snyman Commission (1978) identified excessive promotion of all types of medicines as contributing to high expenditure, and recommended prohibition of the practice of free gifts and ‘bonusing’ of medicines to pharmacists, medical practitioners and dentists. An enforceable code of marketing practice is not yet in place. Almost the only recommendation that was implemented in full was that made by the Browne Commission (1985) to establish a public sector tender process for the procurement of medicines.

‘Bonusing’ refers to the practice of giving free stock or reduced prices linked to volume purchases. A typical example would be a “buy 10 and get 2 free” offer.
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The lesson learned from these decades of attention to medicines prices is simple – interventions are easily identified, but difficult to implement. The reasons for such difficulties varied from resistance from vested interests (both from manufacturers and healthcare professionals) to the political exigencies of the time (such as the sanctions imposed on apartheid South Africa in the 1980s).

Although some work had been done within progressive health circles and the African National Congress party prior to the change of government (and also by the apartheid Department of National Health and Population Development, in the early 1990s), the policy process undertaken in 1994-1996 was rushed and incomplete. The greatest challenges were encountered during implementation of the new policy. The 2002 review by the Centre for Health Policy concluded: “The challenge of implementation is less a matter of following blue-prints and recipes than of “learning by doing”. This involves a high degree of organisational reflexivity – the ability to learn from experience. In the instances where the South African drug policy established processes that met these requirements, such as during the writing of the policy and the essential drugs list, outcomes were successful. Where these processes were not sustained, gains were not maintained or followed through. On the whole, the drug policy process in South Africa showed a high awareness of the actor environment, but only partial recognition of the fact that policy implementation is inherently a process of constant negotiation and renegotiation. Over time, the opportunities for negotiation have tended to diminish rather than expand. If future policy implementation is to be successful, mechanisms for organisational learning need to become far more institutionalised. Within government, this implies ensuring ongoing mechanisms to combine top-down, national with bottom-up, district and provincial planning. Also important are regular review and evaluation, creating opportunities for external actors to regularly interface with policy and legislative processes, and opening up public debate on measures that are likely to be controversial and elicit reaction from players with strong interests.” South Africa’s experience with implementing a medicines pricing intervention clearly demonstrates these points.

The policy options

Medicines are accepted as not being ordinary articles of trade, as their market is imperfect. Specifically, there is a three-tiered demand structure – with the prescribers 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 also limited competition between suppliers, especially in the case of patented products. The information available to prescribers and consumers is often selective, unbalanced or incomplete. Medicines also have both positive and negative externalities. As a result, almost all governments regard medicines as “meritorious” goods, worthy of government intervention.

Intervening to reduce expenditure on medicines requires attention both to prices and to volumes. The policy options open to any government have been summarized as follows:

- Producer price control measures – these include direct price controls, reference pricing systems, the practice of equity pricing, as well as generic-friendly policies
- Distribution chain cost controls – these include controls over mark-ups, fixed professional fees, limits or removal of value-added tax
- Bulk purchase measures – these include the use of tender and negotiation strategies, as well as regional initiatives
- International trade agreement relief measures – these include compulsory licensing and parallel importing
- Demand side measures – these include measures to ensure rational medicine use, as well as such tactics as co-payments that may limit demand by patients.

No single intervention is sufficient. For example, while generic substitution may reduce expenditure, this can be limited by prescribers choosing to prescribe patented medicines for which no generic versions exist.

The medicine pricing intervention – content and process

The policy committee charged with developing the National Drug Policy (NDP) was tasked “to develop a pricing plan for drugs used in South Africa in the public and private sectors”. While the subsequent detail has been characterised as vague – “the policy instruments included in the NDP seem to vacillate between intervention and what has been termed “monitored freedom”” – the policy does seem to aim at addressing several points simultaneously. The proposed pricing intervention was described as such:

- “A Pricing Committee with clearly defined functions to monitor and regulate drug prices will be established within the Ministry of Health. Committee members will include health economists, pharmaco-economists, representatives from the Department of Finance, the Department of Trade and Industry, the Procurement Unit of the Department of Health, the Department of State Expenditure, and consumer representatives. There will be total transparency in the pricing structure of pharmaceutical manufacturers, wholesalers, providers of services, such as dispensers of drugs, as well as private clinics and hospitals. A non-discriminatory pricing system will be introduced and, if necessary, enforced. The wholesale and retail percentage mark-up system will be replaced with a pricing system based on a fixed professional fee.”

However, the overall policy stance incorporated other elements, and can be summarized as follows:

- 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 within the private sector
• 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.

Implementing some of these recommendations required changes to legislation. South Africa's medicines law, the Medicines and Related Substances Act (Act 101 of 1965), was amended in 1997, with the introduction of two inter-related sections. The first of these (section 18A) banned “bonusing” ii and the second (section 22G) created a “pricing Committee”. It also provided for a “transparent pricing system”, which would include a “single exit price” (SEP). It stated that “such price shall be the only price at which manufacturers shall sell medicines … to any person other than the State”, but that pharmacists and licensed dispensing practitioners (nurses and medical practitioners) would be allowed to charge a “dispensing fee”. These provisions only came into effect in 2003, once legal challenge to the legislation by the multinational pharmaceutical industry had been withdrawn.

As the details were not in the primary legislation, these had to be provided in the form of Regulations, issued by the Minister of Health (then Dr Manto Tshabalala-Msimang). The process of implementing has not yet been completed, because of repeated legal challenges. The necessary Regulations were published for comment in mid-January 2004, allowing barely enough time for the required 3-month comment period before the final versions were issued. This happened on 30 April 2004, and the scheme was intended to come into effect on 2 May 2004. Instead of the fixed professional fee envisaged in the policy, a capped fee (26% to a maximum of R26 per item iii) was prescribed. The single exit price was defined as the weighted average of 2003 prices offered to the private sector, thus locking in all volume discounts that had been offered before. An annual maximum percentage increase in single exit prices was to be published by the Minister thereafter. The prospect of a reference pricing system, or at least a one-off benchmarking exercise, was also signaled, but not described in detail.

The challenge to this intervention came from pharmacists in the community and private hospital arenas, and not from the pharmaceutical industry. The latter had succeeded in altering a draft regulation which sought to impose an immediate 50% cut in the factory gate price. As noted, the single exit price was initially cost-neutral, with the promise of annual review. Initially, two linked cases were heard by a full bench in the Cape High Court, and rejected by the majority (reported as New Clicks South Africa (Pty) Ltd v Tshabalala-Msimang and Another; Pharmaceutical Society of South Africa and Others v Minister of Health and Another 2005. (3) SA 231 (C)). The majority dismissed the challenges on all counts, and awarded costs to the State. In striking contrast, the dissenting judge found the Regulations to be contradictory (and in conflict with other legislation), and the dispensing fee based on “no more than a thumb suck”. Immediately, the parties to the action sought leave to appeal this judgment. After more legal tribulations, the Supreme Court of Appeal came to a unanimous decision (reported as Pharmaceutical Society of South Africa v Minister of Health and Another; New Clicks South Africa (Pty) Ltd and Others v Minister of Health and Another 2005. (3) SA 238; 2005 (6) BCLR 576 (SCA), overturning the Cape High Court decision with costs. The entire set of Regulations was declared “invalid and of no force and effect”. They also found fault with the enabling Act, stating that “It will be extremely difficult, if not impossible, to draft sensible regulations unless the Act is amended” (at paragraph 95). This decision was immediately countered by the Minister of Health, who appealed to the Constitutional Court. The resultant findings (reported as Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others CCT59/04 2005 (2) SA 311 (CC) were complex, with a number of minority judgments in relation to certain points. In essence, the right of the State to intervene was upheld, but the Minister of Health was instructed to re-determine an appropriate dispensing fee for pharmacists. Importantly, the Chief Justice found that, while some evidence had been provided that the dispensing fee would result in damage to the viability of pharmacies (and in particular, rural pharmacies and courier pharmacies), the onus was on the Minister (as advised by the Pricing Committee) to show that their scheme would not have this effect: “Absent such explanation, there is sufficient evidence on record to show that the dispensing fee is inappropriate”.

After the judgment, revised Regulations were issued, as instructed, and a process of determining a new dispensing fee was commenced. The revised fee was proposed to operate as follows:
• where the single exit price (SEP) was less than R75, the pharmacist would be allowed to charge up to R7 plus 28% of the SEP
• for an SEP between R75 and R150, the dispensing fee would be R23 plus 7% of the SEP
• for an SEP between R150 and R250, the dispensing fee would be R26 plus 5% of the SEP
• for an SEP of R250 or more, the dispensing fee would be R31 plus 3% of the SEP

ii Section 18A reads “No person shall supply any medicine according to a bonus system, rebate system or any other incentive scheme.”
iii At the time of writing US$1 is approximately worth R8
all these fees would include value-added tax (14% in South Africa).

When announced, this fee was again found to be unacceptable by the pharmacists, and a renewed court challenge ensued in the Pretoria High Court. In an attempt to settle this matter, the Minister of Health published a new draft set of dispensing fees in June 2009. The details were as follows:

- where the SEP was less than R100, the dispensing fee would not exceed R6 plus 36% of the SEP
- for an SEP between R100 and R250, the dispensing fee would be R32 plus 10% of the SEP
- for an SEP between R250 and R1000, the dispensing fee would be R45 plus 5% of the SEP
- for an SEP of R1000 and more, the dispensing fee would be R65 plus 3% of the SEP
- all these fees would include value-added tax.

A similar contestation with dispensing practitioners has also been settled out of court, following a legal challenge.

Finality on this issue has not yet been reached, and assessing the impact of the proposed dispensing fee on the viability of different pharmacies, operating in very different communities, is extremely difficult. Modeling the effect on a “model” pharmacy of average size and average costs is possible, but may still pose problems. In principle, the fee needs to compensate the pharmacist for her/his professional service, while also covering the costs of maintaining an inventory of medicines and providing a suitable return on investment. The fee also has to be applicable to and practical for both community and private hospital pharmacies.

In a parallel development, the South African Pharmacy Council has published draft rules on which non-distributive services pharmacists can charge for, and what the basis of those fees should be. These include cognitive services as well as compounding services, and diagnostic tests. These fees have taken into account the methodology used by the National Health Reference Price List, a mechanism to exert pressure on the costs of all non-medicine healthcare services.

The extent to which the various pricing interventions have exerted downward pressure on medicines prices (and/or on medicines expenditure) in South Africa’s private sector is challenging to depict. About 16% of South Africans are privately insured (are members or beneficiaries of a medical scheme). The Council for Medical Schemes Report 2007-2008 noted that expenditure on medicines dispensed by pharmacists and providers other than hospitals was R9.4 billion in 2007, accounting for 16.7% of scheme benefits7. Expressed in constant 2007 prices, medicines expenditure in this sector peaked in 2001, declined sharply until 2005, but was seen to be increasing again, albeit at a slower rate than had been seen between 1997 and 2001. The timing of these changes is interesting: generic substitution became legal in 2003, and the single exit price intervention was introduced in 2004, with schemes varying in how they paid dispensing fees thereafter. Medical schemes make use of intermediaries (administrators), and the reports of one of these (Mediscor) provide some insight into the changes seen over time. The Mediscor Medicines Review 2007 noted that “the use of generics is increasing steadily … from 43% in 2005 to 46% in 2006 and to 47% in 2007”. However, it also noted that “the average item cost for generic equivalents increased with 28% from 2005 to 2007”. This administrator felt that the “increase in medicine expenditure between 2006 and 2007 is mainly driven by an increase in the average cost per claimed item (10.2%)” and that the “impact of new chemical entities with blockbuster potential and new generic equivalents for products that came off patent are clearly demonstrated”.

Comparisons with private sector markets in other countries are possible, but strewn with methodological pitfalls. In 2008, it was reported that OECD countries spent an average of USD PPP 401 per person on pharmaceuticals in 20055. However, these figures were skewed by the high expenditure in one country: “Per capita pharmaceutical expenditures were much higher in the United States (USD PPP 792) than they were in the next highest spending country, Canada, which spent USD 589 per capita”. Other OECD countries were not as variable in expenditure on medicines: “The modest degree of deviation from the average is notable–half of all OECD countries have spending that deviates by less than 20% of the average – although three countries are outliers in this respect. At the other extreme, Mexico spent only USD PPP 144 per capita, about USD PPP 100 less per capita than Poland, the next lowest-spending country, and just 18% of the US spending level.” Notably, it showed that “Prescribed medicines consumed outside the hospital setting account for the bulk of pharmaceutical expenditure”. The following summary statements are worth considering: “In the vast majority of OECD countries, universal coverage schemes act as a combination pharmaceutical subsidy and de facto price regulation mechanism that is in effect for subsidised products (whether or not on-patent) nation-wide. This is the case, for example, in Sweden and Switzerland, where pharmaceutical firms submit their proposed ex-manufacturer prices to the pricing and reimbursement authority for consideration with supporting documentation. Once approved, the product is subsidised by the coverage scheme, but the manufacturer may not raise the price without approval; most OECD countries place restrictions on manufacturers’ ability to increase prices. Products that are not proposed or approved for reimbursement, including most OTC products, may be sold to consumers in the country at any price. The US government employs de facto price regulation in the case of federal purchasers (e.g., the Veterans Health Administration) and in the Medicaid social assistance programme—which provide coverage for about 20% of the US population. These schemes limit the prices manufacturers can charge, using the prices obtained by competing private plans as a benchmark.”
Conclusions

South Africa’s NDP is now overdue for re-evaluation and review. That process has recently started. The country has, however, attempted a number of interventions in relation to medicines expenditure, and its progress can be summarized as follows, by reference to the available options:

- Producer price control measures – while a policy or mandatory offer of generic substitution is in place, the single exit price (SEP) provides transparency at that level, and also limits annual increases to a set maximum
- Distribution chain cost controls – a single flat professional fee proved impossible, and finding a suitable dispensing fee has proven challenging; value-added tax remains in place
- Bulk purchase measures - the use of tender strategies, taking account of volume discounts, is limited to the public sector; no regional initiatives have yet been attempted
- International trade agreement relief measures – while the means to issue compulsory licences and the legal means to allow parallel importation are in place, these have not been used
- Demand side measures – while co-payments are routinely used in the private sector, there is evidence that prescribing of newly launched, expensive medicines may be reducing the impact of savings from generics.

The South African experience has demonstrated that clear legal drafting is a key element in the implementation of any intervention. The South African experience in the pricing case has also shown that, where policy implementation is challenged in the courts, there is a need for policy interventions to pass the test of reasonableness, based on the outcomes expected. The level of data required to satisfy a court is not easily predicted, but may be considerable.

Some elements remain unimplemented. Not only is a dispensing fee not yet in place and enforceable, but the ways in which wholesalers and distributors share in the SEP remain non-transparent. It has been suggested that further savings can be made by more closely aligning private sector medicines selection with the evidence based national Standard Treatment Guidelines/Essential Drugs Lists. An enforceable code of marketing practice is also still recommended. Increasing generic utilisation could also be strengthened if the Medicines Control Council moved from the non-substitutable “negative” list to a transparent Orange Book-like “positive” list. Finally, even though a benchmarking exercise has been repeatedly signaled, this has not yet been implemented. In time, as South Africa moves towards its goal of a National Health Insurance system, a more traditional reference pricing system, underpinned by rigorous pharmacoeconomic evaluation, may be possible. In order to do so, all actors in the medicines policy space will have to engage with the problem of medicine prices, and together find a way forward.

References