SOUTH AFRICA
Implementation of reforms under the National Drug Policy

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Prior to the democratic transition in 1994, health services in South Africa were provided in a fragmented manner as they were primarily informed, and enforced, by the racially-inspired policy of “separate development” – usually referred to as apartheid. In 2009, a paper on the history of the South African health system described the deep roots of the fragmentation as follows: “A notable feature of the history of health services in South Africa has been fragmentation, both within the public health sector and between the public and private sectors. At an early stage, health facilities were racially segregated, and curative and preventive services were separated (by the Public Health Amendment Act of 1897)” (1). The structural basis of the fragmentation of health services was thus entrenched in law for almost a century before the transition to democracy in 1994.

In alignment with the racial laws, health services in the public sector during the apartheid era were provided separately to different ethnic groups. Separate health facilities were provided for Black Africans, whites, those of mixed race (so-called “coloured”) and those descended from South Asian (usually Indian) immigrants. Not only were these facilities separate in physical terms, but they were also funded differentially and managed separately. Reflecting the prevailing orthodoxy, as opposed to any racist theory, health services were also divided between predominately curative services managed and provided by provincial authorities and services designated as preventive and promotive which were managed and provided by the National Department of Health (previously called the National Department of Health and Population Development). The definition of preventive and promotive services was, however, idiosyncratic, as it included psychiatric services as well as the provision of family planning.

Under the application of grand apartheid, the South African government created a series of tribal “bantustans” (also referred to as “homelands”) for Black African ethnic groups. Some of these attained a degree of independence from South Africa though this was not formally recognized by any other state. The supposedly independent bantustans of Bophuthatswana, Ciskei, Transkei and Venda operated their own departments of health in parallel to South African structures. The remaining bantustans varied in the extent to which provision of health services was separate from or integrated with services offered by the surrounding provinces. Prior to 1994, South Africa was divided into four provinces – the Cape Province, Natal, Orange Free State and Transvaal. Each operated its own provincial department of health, responsible for curative services. In the larger urban centres, city health departments also operated primary health care facilities and provided a range of preventive, promotive and curative services. As Coovadia et al. summarized: “The apartheid system further entrenched fragmentation of health care when the bantustans were created, each with its own health department. The bantustans (and their government departments) acted separately from each other, like quasi-independent powers, with control carefully manipulated by Pretoria. By the end of the apartheid era, there were 14 separate health departments in South Africa, health services were focused on the hospital sector, and primary-level services were underdeveloped” (1).

This level of fragmentation had direct and far-reaching implications on the provision of medicines. The selection of medicines in the public sector was decided separately by each of the provincial departments of health for predominately curative services, by the National Department of Health and Population Development for preventive and promotive services, and by each of the bantustans. If each of these separate medicine selection processes had been based on evidence, the impact on efficiency would have been minimized. An evidence-based selection of essential medicines would have resulted in a smaller list, avoiding...
unnecessary duplication and in turn enabling more effective procurement, distribution and use of those medicines. The selection processes were, however, weak and reflected the biases of individual prescribers and academics. The procurement lists were increasingly illogical, duplicative and, hence, inefficient.

Each of the four predemocracy provinces operated its own pharmaceutical depot (central store), with the Cape Province maintaining two such facilities. Medicines procured by the provinces were generally delivered to the depots and then distributed to health facilities. For white patients only, ambulatory care medicines prescribed by district surgeons were provided from private-sector pharmacies and paid for by the provincial Department of Health. These services were predominantly accessed by white pensioners who lacked private health insurance. From the end of World War II until 1988, medicines for the National Department of Health and Population Development and the bantustans were procured by the Medical Base Depot operated by the South African Defence Force. The medicines were distributed via a series of subdepots located in major centres to hospitals and other facilities.

The extent to which racial divisions informed health-care funding was also described by Coovadia et al: “Health services in the bantustans were systematically underfunded—by 1986/87, public sector health-care spending per head ranged from R 23 (about $ 11) in Lebowa to R 91 (about US$ 45) in Ciskei (bantustans) and from R 150 (about US$ 75) in Transvaal to around R 200 (about US$ 100) in Natal province and the Cape province” (1). This had a major impact on the degree to which access to medicines could be funded by the different departments of health and the facilities they operated, and thus on the range of medicines available.

The challenges facing the South African health system were summarized in 2009 as follows: “South Africa exemplifies a country that has undergone a protracted and polarised health transition, which is shown by the persistence of infectious diseases, high maternal and child mortality, and the rise of non-communicable diseases. This confluence of several transitions (health, demographic, and epidemiological) needs to be understood in the context of the country’s development pathway; South Africa has been substantially shaped by its colonial and apartheid past that divided society by race, class, and sex” (2). The same factors that shaped the health system thus shaped access to medicines. Medicines were financed in ways that reflected racial privilege or discrimination, the were selected by weak and fragmented health authorities, and they were procured, distributed and used in ways that were not designed to maximize efficiency but rather reflected the prejudices and polarized history of the country.

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1 In this quotation, R = South African Rand (or ZAR).
The major post-apartheid health policy reforms addressed key social determinants of health and access to health services. They had relatively little direct impact on access to, and the use of, medicines but illustrate the policy environment in which pharmaceutical policy was being developed. Table 1 shows the major policy changes in the post-apartheid period.

### Table 1. Major post-apartheid health-related policy changes

<table>
<thead>
<tr>
<th>Year</th>
<th>Nature of policy shift</th>
<th>Implications for access to and use of medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>1996</td>
<td>Introduction of free care for children younger than 6 years and pregnant women</td>
<td>Removed user fee barriers at the point of care; later extended to free primary health care for all who are not beneficiaries of medical schemes (private health insurance)</td>
</tr>
<tr>
<td>1996</td>
<td>Passage of the Choice on Termination of Pregnancy Act, which legalised abortion</td>
<td>No direct impact on medicines issues, but posed a challenge for selection, as misoprostol was not registered for this indication; increased access to abortion, and led to marginal declines in septic abortions and stabilisation in maternal mortality from septic abortions</td>
</tr>
<tr>
<td>1999</td>
<td>Tobacco Products Control Amendment Act prohibited smoking in public places, restricted tobacco product promotion, and enhanced taxation</td>
<td>No direct impact on medicines issues; contributed to a substantial reduction in smoking</td>
</tr>
<tr>
<td>2000</td>
<td>Firearms Control Act restricted access to firearms</td>
<td>No direct impact on medicines issues; resulted in a reduction in gun-related homicides</td>
</tr>
<tr>
<td>2001</td>
<td>Free Basic Water Strategy defined water as a social and developmental good and basic human right</td>
<td>No direct impact on medicines issues, but significant impact on social determinants of health</td>
</tr>
<tr>
<td>2002</td>
<td>Mental Health Care Act legislated against discrimination against mental health-care users</td>
<td>No direct impact on medicines issues</td>
</tr>
<tr>
<td>2004</td>
<td>National Health Act legislated for a national health system incorporating public and private sectors and the provision of equitable health-care services and for the establishment of the district health system to implement primary health care throughout South Africa</td>
<td>Confirmed the extension of free care throughout the public sector for the uninsured</td>
</tr>
</tbody>
</table>

Adapted from Coovadia et al. (1)

The new democratic post-apartheid constitution entrenched the rights to health and social security, requiring the state to ensure their progressive realization. However, it included the important caveat that the state must act within the constraints of available resources. This is in stark contrast to the unfettered right in the constitutions of other countries that has enabled the use of litigation to gain access to essential medicines (3).
2.1 Health systems restructuring

The fragmentation of the public sector was addressed through the creation of a unitary health system, constructed as spheres of government (national, provincial, local) in accordance with the constitution. This was first outlined in the White Paper on the Transformation of the Health System in South Africa in 1997 which stated “We have set ourselves the task of developing a unified health system capable of delivering quality health care to all our citizens efficiently and in a caring environment” (4). Accordingly, there is a National Department of Health (NDOH), there are nine provincial departments of health coordinated through a National Health Council, and a range of municipal health services are delivered by local authorities. The relationships between the spheres of government are defined in the constitution and are also detailed in the National Health Act (Act 61 of 2003) (5, 6).

The reforms, however, did not simply replace the 14 health departments with a single, unitary, National Department of Health. The system remained complex with implications for the provision of medicines in the public and private sectors. The division remained between the public sector with an estimated annual per capita health expenditure of ZAR 2667 (approx. US$ 390) in 2011, and the private sector with an estimated per capita expenditure of ZAR 11 048 (approx. US$ 1600) (7). The public sector is largely funded by the state and caters to the uninsured; the private sector is funded largely from insurance premiums and out-of-pocket payments and caters mostly (but not exclusively) to the members of medical schemes. In 2012, out of an estimated South African population of 50.7 million, 8.7 million persons were insured in 93 different schemes – 25 of them open and 68 restricted to employees of specific sectors or companies (8). Importantly, 98.3% of all members of private medical schemes were subject to some form of managed health care.

2.2 National Drug Policy

In relation to medicines, the 1997 White Paper included, as an addendum, the 1996 National Drug Policy for South Africa (Table 2) (9).

<table>
<thead>
<tr>
<th>Overall thrust</th>
<th>Specific objectives</th>
</tr>
</thead>
</table>
| Health objectives | - to ensure the availability and accessibility of essential drugs to all citizens  
- to ensure the safety, efficacy and quality of drugs  
- to ensure good dispensing and prescribing practices  
- to promote the rational use of drugs by prescribers, dispensers and patients through provision of the necessary training, education and information  
- to promote the concept of individual responsibility for health, preventive care and informed decision-making |
| Economic objectives | - to lower the cost of drugs in both the private and public sectors  
- to promote the cost-effective and rational use of drugs  
- to establish a complementary partnership between Government bodies and private providers in the pharmaceutical sector  
- to optimize the use of scarce resources through cooperation with international and regional agencies |
| National development objectives | - to improve the knowledge, efficiency and management skills of pharmaceutical personnel  
- to reorientate medical, paramedical and pharmaceutical education towards the principles underlying the National Drug Policy  
- to support the development of the local pharmaceutical industry and the local production of essential drugs  
- to promote the acquisition, documentation and sharing of knowledge and experience through the establishment of advisory groups in rational drug use, pharmacoeconomics and other areas of the pharmaceutical sector |


2 ZAR = South African Rand.
The post-apartheid health reforms improved the access to and equity of health services. However, the reforms did not address some key causes of inefficiencies in the health system, especially those related to access to essential medicines and technologies.
3 TACKLING INEFFECTIVENESS IN THE PUBLIC SECTOR

The key inefficiencies in the provision of medicines faced by the public health-care sector in 1994 were the fragmented processes for the selection of medicines by 14 departments of health, the racially-defined financing of health services, including medicines, the fragmented procurement processes (although with some elements of coordination), the loss of access to distribution facilities as a result of new provincial boundaries, and the lack of influence over the rational use of medicines by health professionals and patients. The procurement list for medicines was overpriced and bloated with non-essential drugs.

3.1 Selection to guide procurement and use

Prior to the democratic transition, the list of medicines considered to be “on code” in the various provinces had expanded considerably. In 1994, the “essential” medicines list contained some 2600 items, including a significant number of duplicate drugs of the same pharmacological classes. Reforms in the public sector therefore required attention to all phases of the medicines supply cycle (selection, procurement, distribution, use), as well as to the enabling factors (rational selection, sustainable financing, affordable prices, health and supply systems). In contrast to the bloated “on code” list at the time of the democratic transition, a far more restricted list of 337 medicines (in 422 dosage forms) in 1998 compared well with the 1999 WHO Model List of Essential Medicines (307 items in 547 dosage forms). A more restricted list provides greater bargaining power in relation to prices.

The first objective of the South African National Drug Policy was “to ensure the availability and accessibility of essential drugs to all citizens”. This was recognized even as the process of developing the policy was underway. Accordingly, one of the first initiatives in the public sector after the 1994 democratic transition was the establishment of an Essential Drugs Programme in the National Department of Health to address not only the selection of essential medicines but also their rational and safe use. The Minister of Health appointed a National Essential Drugs List Committee in 1995. Members included pharmacists, general practitioners, medical specialists, pharmacologists and public health experts. They were tasked initially to focus on primary-level care. In consultation with stakeholders, the committee generated standard treatment guidelines and a list of essential medicines. It based its work on established WHO criteria, but it was also among the vanguard of national institutions using standard treatment guidelines as the starting point for the development of an essential medicines list.

Key principles of the selection of medicines for inclusion in the list were:
- a focus on those medicines that meet the needs of the majority of the population;
- reliance on sufficient evidence of effectiveness;
- selection of products with demonstrated quality;
- the use of generic names only (also referred to as international nonproprietary names or INNs);
- a commitment to support reliable local suppliers; and, in general,
- a preference for single-agent products, except where fixed-dose combinations were shown to increase patient adherence.

The first edition of Standard treatment guidelines and essential medicines list for primary health care (the first “green book”) was printed and distributed in April 1996, just months after the launch of the National Drug Policy. The process of development of the guidelines and the list was therefore truncated and had to rely on previous efforts, notably in the then Northern Province. Following criticism of the process, a revision was immediately...
begun with more extensive stakeholder engagement. Nine provincial essential drugs programme coordinators were appointed to promote the new essential medicines concept among health workers. The process was complicated by the simultaneous introduction of free health care for children under 6 years and for pregnant women, and by some clinics moving from a restricted number of services towards comprehensive primary health care. These moves resulted in a marked increase in patient demand, with resultant staff overload and increased demand on medicine stocks. It also coincided with the reorganization of the provincial medicines supply systems.

3.2 Rationalizing procurement and distribution
Immediately after the democratic transition, the five pharmaceutical depots that operated in the four apartheid-era provinces continued to be responsible for the supply of medicines to the facilities of the Department of National Health and Population Development and of the bantustans. After 1994, each of the nine new provinces were required to set up their own public-sector pharmaceutical depot. The Orange Free State, Gauteng, KwaZulu-Natal and Western Cape provinces continued to operate the existing provincial depots in Bloemfontein, Johannesburg, Durban and Cape Town. The Eastern Cape could use the former subdepot in Port Elizabeth and also inherited a facility at Mthatha in the former Transkei. Initially, the Northern Cape Province continued to rely on the Western Cape depot. In the newly-created Mpumalanga province, Northern Province (later renamed Limpopo), and the North West province, new depots were created and were initially outsourced to private-sector operators on a prime distributor model. The immediate impact was one of disruption, but there was also the potential to create more effective distribution systems located closer to health facilities. There were also attempts to increase the involvement of depot-based personnel in demand management at facility level, notably in Limpopo. These efforts were complicated to some extent by the introduction of new regional and district boundaries within provinces. The commitment to a district health system was initially signalled in the White Paper of 1997, but its implementation was delayed until the passage of the National Health Act in 2003. It is still a work in progress.

For the procurement of medicines, the public sector had operated the rudiments of a coordinated limited competitive tender system since 1985 under the auspices of the Committee on the Procurement of Medical Supplies. Tenders were invited only for locally registered medicines. The constitution of 1996 introduced a new form of fiscal federalism, allocating state revenues to provinces on the basis of demographic and social indicators. The provincial treasuries thereby became the main source of funds for the provincial departments of health. This limited the ability of the NDOH both to direct medicines selection and procurement at provincial level to impose a strict national essential medicines list.

3.3 Evidence of implementation
Since the publication of the Standard treatment guidelines and essential medicines list for primary health care in 1996 South Africa has continued to build and strengthen a standardized and methodological approach to the selection of essential medicines, based primarily on the development of comprehensive standard treatment guidelines. A further nine editions were published, four of them based on revisions of the primary health care guidelines, three for adult hospital care and two for paediatric hospital care. Recently a list of medicines for use at the tertiary/quaternary or academic level of health facilities was issued, albeit without the accompanying treatment guidelines.

Between 1996 and 2008, the number of medicines for primary health care increased from 156 to 198, while the number of medicines in the standard treatment guidelines for adult hospital care decreased from 372 to 366 (12). This expansion reflects the growth in sophistication of the primary health care services and not a loss of focus on rational selection. In recent years, the selection process for medicines has become more participatory. Draft standard treatment guidelines and essential medicines lists are reviewed by stakeholders outside of the National Essential Medicine List Committee – including universities, provincial and hospital pharmacy and therapeutics committees, and clinical societies. Since the first publication of the Standard treatment guidelines and essential medicines list for primary health care, the National Essential Medicine List Committee received between 41 and 108 evidence-based contributions for each revision. A total of 348 professionals provided written submissions. Conflict-of-interest policies were strengthened and a reviewer’s manual was introduced after the 2012 review. The national selection process is now tightly managed but has become bureaucratized, resulting in long delays in issuing revised versions of the standard treatment guidelines and essential medicines list.
Overall, there is evidence of a robust process for the selection of medicines to be included in the essential medicines list. It is, however, important to note that the provinces currently have no legal restrictions on their ability to procure medicines funded from their share of the national budget. Only those medicines that are to be procured with funds allocated by the NDOH in the form of conditional grants are required, by virtue of the conditions of those grants, to be in accordance with national decisions. The extent to which provinces are compliant with the National Essential Medicine List Committee’s selections and utilize national tenders is entirely dependent on the influence of the National Minister of Health and the National Health Council, which is made up of political and civil service leaders from the national and provincial levels. The provinces are legally entitled to vary their selections and in some cases still do so. This is particularly important for very expensive medicines used in tertiary and quaternary care.

The opportunity to issue regulations for the selection of essential medicines and medical devices is provided by the National Health Act (Act 61 of 2003) but has yet to be exploited. Such regulations could address the applicability of the decisions of the National Essential Medicine List Committee for the provinces and could provide a roadmap for their application under the planned national health insurance scheme, further closing the gap between the public and private sectors.

The selection of essential medicines is, however, only the first step in the medicines management cycle. It is a crucial enabling factor. If applied correctly, it can improve the chances of effective procurement. Following the establishment of the Committee on the Procurement of Medical Supplies in 1985, the procurement of medicines in the South African public sector employed a limited competitive bidding process, generally conducted at national level with the assistance of the National Treasury. The fiscal federalism of the 1996 constitution further entrenched the autonomy of the provinces and threatened to reverse the efficiency gains expected from the nationally-determined essential medicines lists. Provincial pharmacy and therapeutics committees continued to make selections and to include medicines on the procurement lists. In some cases, provinces chose different medicines from the same pharmacological class without evidence-based reasons (Box 1). Although provincial pharmacy and therapeutics committees were meant to be established in all provinces, they varied in their capacity and performance. Some have been stable and have effectively executed their mandate for selecting medicines, but others have had to be revived.

**Box 1. Procurement of essential medicines**

Initially, the most commonly used agent was perindopril, which was available only from the innovator and in a "cloned" form from the same manufacturer. Based on the view that a cost-minimization approach was warranted in the absence of evidence of clinical benefit from any one example from this class, two provinces (KwaZulu-Natal and Western Cape) changed to the less expensive enalapril, which was available in various generic forms. However, other provinces have continued to procure perindopril, incurring additional costs, and both ACEIs are available on tender. There are also differences in the way in which tertiary/quaternary medicines, many of which are very expensive, have been selected in those provinces that offer such services (notably the Western Cape, Gauteng, Free State and KwaZulu-Natal).

An essential medicines list based on standard treatment guidelines should provide a clear guide to procurement. Pooling procurement at national level should result in lower prices by leveraging volume and increasing competition. The first step in achieving this should be a robust quality specification process with access to pharmaceutical intelligence in the form of reference or indicative prices. This should then be followed by an informed quantification process based on the burden of disease, or at least on accurate data about historical demand. Poor quantification of demand has often been a major reason for failure to gain the most from a competitive tender. A central pharmaceutical data warehouse, which would improve access to historical demand data, was planned but was never implemented. This was in part related to the outsourcing of the management of provincial depots to private operators using proprietary procurement and supply management software. Issues of interoperability across systems and providers have not yet been solved. Data cannot therefore be readily shared, limiting the ability of the NDOH to manage procurement effectively at national level.
There is no formally published evidence that indicates whether the development of the standard treatment guidelines and essential medicines lists has improved the efficiency of procurement of medicines in the public sector. However, a number of actions are expected to result in better prices. Recently, the NDOH introduced changes to the procurement system for medicines, reducing the involvement of the National Treasury. The use of indicative prices was credited with more advantageous prices for the procurement of antiretroviral drugs. The same approach was applied in a number of recent tenders, including one for procurement of tuberculosis medicines. A far more centralized and NDOH-controlled process has been implemented for both the procurement and the distribution of third-line antiretroviral medicines for HIV infection.

Standard treatment guidelines and essential medicines lists should also guide the rational use of medicines. Ownership of the process and the guidelines is important, as is a deliberate and closely monitored dissemination and implementation strategy for health facilities, health professionals, students of health sciences and the public. In 2003, the process was described as far from ideal: “Although the lists were widely distributed, implementation was described as patchy and considerable challenges remained, including the apparent dislocation between the Essential Drug List (EDL) committee and the structures responsible for the design of programmes and training material” (10). The review noted that “the committees were, in effect, dissolved once the books were published; maintenance of the lists was therefore neglected, and guidelines produced by national vertical programmes increasingly deviated from the selection made by the EDL committee.” Evidence to the contrary, at least in terms of the primary care facilities, was provided in two impact studies conducted by the NDOH. The mean number of items per prescription decreased from 2.5 in 1998 to 2.2 in 2003. Other changes in indicators are presented in Figure 1 (13).

**Figure 1. Results of the impact study by the South African Essential Drugs Programme**

Some of the indicators for rational use of medicines (such as the use of injections and prescribing of medicines on, or not on, the essential medicines list) showed considerable improvement over the period of the evaluation, but little improvement was observed for others (such as the practice of issuing generic prescriptions). On a smaller scale, Cassimjee & Suleman conducted a cross-sectional randomized study of 100 prescriptions for hypertension in each of 21 health facilities in the eThekwini district in 2007 (14). Each prescription was assessed against modified WHO indicators to determine compliance with standard treatment guidelines. The study found that the mean compliance with the guidelines was 22%. The highest compliance score of 66% was attained by a primary health care facility. The low mean compliance with standard treatment guidelines was due mainly to the absence of a diagnosis recorded on the prescription, and the widespread use of poly-pharmacy, adding a new medicine for each symptom without consideration of drug–disease and drug–drug interactions.

Overall, the introduction of the Essential Drugs Programme resulted in increased access to essential medicines in the public sector, but this increase was related more to a determined policy of constructing new primary health care clinics, upgrading hospitals and decreasing financial barriers to access, than to the functioning of the pharmaceutical system. The availability of essential medicines at sampled facilities is used as an indicator of access, but access is also affected by the degree to which patients and carers are able to access health-care services.

Structural interventions related to the management of medicines were made mainly at the level of the NDOH, but not all have been sustained. Although a chief directorate for the Essential Drugs Programme was created in 1996, the position remained unfilled for long periods. There is a persistent gap between the “models” provided by the national documents, such as the various standard treatment guidelines and essential medicines lists, and the reality in the provinces and health facilities. Critically, South Africa lacks a clear monitoring and evaluation system that is able to track which medicines are available and how they are being used across the country, taking into account the differences both between and within provinces.

The national health information system provides only information about the availability of selected essential medicines. There have been persistent problems with data quality even for this minimalist indicator. The “district health barometer” reports produced by the Health Systems Trust on the basis of public-sector data have to date not reported on this indicator. There are also persistent information gaps between province and national levels in relation to the overall supply, management and use of essential medicines and health technologies. Quantification of needs from provinces remains a problem, affecting national tenders and the planning cycles of suppliers and manufacturers. The financial management of provinces is variable, with some provinces unable to pay suppliers on time, resulting in the halting of services and repeated stock-outs. The Stop Stockouts report released by the Stop Stock Outs Project in late 2013 raised concerns. In telephone interviews with staff of 3826 public sector facilities, 21% reported a stock-out of HIV or TB medicines in the three months prior to the survey. This percentage varied considerably between provinces, from 4% to 54% (15). South Africa also experienced shortages of medicines due to manufacturers’ failures to meet demand or decisions to withdraw products from the market (16,17).
At the time of the democratic transition, health-care services in the private sector in South Africa were largely funded through health insurance, primarily by one of many “medical schemes”. A proportion of health-care services were purchased out of pocket, including by the uninsured. Medical schemes in South Africa were largely closed organizations in which membership depended on employment in a particular firm or industry. The number of schemes was therefore large, with significant fracturing of the risk pools. In addition, medical schemes in South Africa were able to set premiums on the basis of individual risk, including consideration of prior medical history. Classical health insurance, aimed at providing cover for major surgical interventions or hospitalizations was also available, and remains so. The South African Health Review of 1997 raised concerns about medical schemes as follows: “The private sector is currently facing a number of challenges, including the pressure of rising costs and the changing make-up of the insured population. These challenges threaten to upset the traditional balance in the South African medical scheme industry. Instead of broadening access to the resources of the private sector, they could result in the shifting of private sector patients onto the already over-stretched public sector” (18).

The Medical Schemes Act (Act 131) of 1998 consolidated previous laws dealing with medical schemes and, together with subsequent regulations, introduced some important reforms, namely:

- defining the business of a medical scheme in such a way as to clearly differentiate it from health insurance and making all schemes subject to the control of the Medical Schemes Council;
- prescribing minimum levels of reserves for schemes;
- limiting the ability of schemes to restrict coverage for pre-existing medical conditions;
- providing for the designation of prescribed minimum benefits to be offered by all schemes (currently these constitute a range of in-hospital treatments, as well as a list of 25 chronic conditions treated in ambulatory settings for which the minimum treatments are specified in the form of treatment algorithms);
- enabling the creation of managed health care, and setting standards for such programmes (examples include the use of designated service providers and the application of treatment protocols and formularies).

Of specific relevance to the supply of essential medicines and technologies, Regulation 151 of the Medical Schemes Act required that “if managed health care entails the use of a formulary or restricted list of drugs (a) such formulary or restricted list must be developed on the basis of evidence-based medicine, taking into account considerations of cost effectiveness and affordability; (b) the medical scheme and the managed health care organisation must provide such formulary or restricted list to health care providers, beneficiaries and members of the public, upon request; and (c) provision must be made for appropriate substitution of drugs where a formulary drug has been ineffective or causes or would cause adverse reaction in a beneficiary, without penalty to that beneficiary”.

The treatment algorithms for prescribed minimum-benefit ambulatory conditions were last amended in 2009 and do not have an explicit link with the standard treatment guidelines and essential medicines lists issued since 1996 by the NDOH. The 1996 National Drug Policy stipulated a national essential medicines list but left the private sector the option that “the list may also be used as a model for medical aid schemes”.

The ability of the medical schemes to influence expenditures on essential medicines and technologies was limited. In addition, each scheme was responsible for its own selection of medicines and the enforcement of

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3 While a medical scheme provides reimbursement of costs incurred for the provision of health care, an insurance policy provides a fixed payment on the basis of a prespecified event such as a diagnosis or hospitalization.
rational use, unrelated to any interventions in the public sector. A ban on generic substitution in force until 2002 limited the ability of the medical schemes to promote the use of generic medicines. They were able to exert their influence by employing the maximum medical aid price (MMAP) scheme, operated by the Pharmaceutical Society of South Africa (19). This scheme established a maximum price for reimbursement by the medical scheme which was in general aligned with the price of the generic drug. If the patient or the prescriber insisted on the branded version, the difference in price was levied as a co-payment. The private health-care sector, however, was under stress. “The health sector in general is subject to a greater degree of cost escalation than most other economic sectors. Among the reasons for this are the ageing of the population, which requires greater expenditure on health services, and the development and use of increasingly expensive technologies. In South Africa these factors have been aggravated by the increases in the prices of imported goods, such as medicines and equipment, due to the fall in the value of the Rand in the 1980s” (20).

The challenges facing the private health sector in the early post-apartheid years were made evident by the lack of growth in the proportion of the population covered by medical schemes, reductions of the benefits available for medical scheme members, increasing use of out-of-pocket co-payments, and extensive use of risk-rating and premium increases. An indirect effect of efforts by the medical schemes to contain costs was an increase in the dispensing of medicines by medical practitioners as a means of supplementing their income to compensate for reductions in fee-for-service charges imposed by the schemes.

4.1 Medicine pricing interventions
The 1996 National Drug Policy (Box 2) sought to improve access to essential medicines for all, and to lower the costs of medicines in both the public and the private sectors. In order “to promote the availability of safe and effective drugs at the lowest possible cost”, the policy proposed “monitoring and negotiating drug prices and ... rationalising the drug pricing system in the public and private sectors, and ... promoting the use of generic drugs” (9).

Measures to enable the implementation of both the pricing and the generic substitution components of the National Drug Policy were included in the Medicines and Related Substances Amendment Act (Act 90 of 1997), which was passed by Parliament at the end of 1997. However, in early 1998 the Act was prevented from being promulgated by court action initiated by the Pharmaceutical Manufacturers’ Association and 39 of its member companies in early 1998. That block was removed only when the complainants withdrew their case in 2001. There were further delays until the Act and subsequent amendments were finally promulgated in May 2003.

**Box 2. Policy directives of the National Drug Policy**

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.
Price increases will be regulated.
Where the State deems that the retail prices of certain pharmaceuticals are unacceptable and that these pharmaceuticals are essential to the well being of any sector of the population, the State will make them available to the private sector at acquisition cost plus the transaction costs involved.
The availability of generic, essential drugs will be encouraged through the implementation of incentives that favour generic drugs and their production in the country.
The policy will aim at achieving generic prescribing in both the public and private sectors. Until this aim is achieved, generic substitution will be allowed, through legislation, in the public and the private sector. It will be incumbent on the pharmacist, prior to dispensing a prescription, to inform the patient on the benefits of generic substitution and to ensure that substitution takes place with the patient’s full understanding and consent.
Patients have the right to make informed decisions concerning their own health, including a choice for generic drugs.
A regularly updated list of products that cannot be substituted will be prepared and disseminated by the MCC.
In the meantime, much effort was expended on the preparation of alternative legislation – the South African Medicines and Medical Devices Regulatory Authority Act (Act 132 of 1998) – which was brought into effect prematurely and was subsequently repealed. Although this legislation had limited impact on access to and cost of essential medicines in the private sector, it is relevant in view of current efforts to establish a new South African Health Products Regulatory Authority which would also regulate medical devices.

In relation to generic substitution, the amendments to the Medicines and Related Substances Act, the changes to the General Regulations published in terms of that Act in 2003, and the subsequent guidelines issued by the Medicines Control Council, introduced the following:

- a clear definition of interchangeable multi-source medicines, with appropriate standards to determine the therapeutic equivalence of such products, based on appropriate data (including bioequivalence testing, where necessary);
- a non-substitutable list, which was amended over time and since 2010 lists only biosimilar products as being non-substitutable;
- the requirement that all dispensers (whether pharmacists or licensed dispensing prescribers) offer generic substitution, where possible, to all patients;
- the establishment of safeguards that allow patients to refuse substitution and prescribers to express the desire not to allow substitution (but with requirements that are sufficiently onerous to prevent abuse of this right).

A final change was introduced in 2002 requiring dispensers to take reasonable steps to inform the prescriber in the event of a substitution. It is unclear to what extent pharmacists comply with this provision which was adopted as a compromise to a request for pre-authorization of substitutions.

In the absence of a publicly-accessible medicines register, it is difficult to provide accurate data on the growth of the generic medicines market since 2003 – i.e. in terms of the number of products registered by the Medicines Control Council. However, the vast majority of new products registered by the Medicines Control Council are generic medicines and not new chemical entities. Duplicate registrations are common, with many registered medicines not being actively marketed. Generic substitution, together with the wide application of internal reference pricing mechanisms, is resulting in increasing generic utilization. However, given the considerable number of medical schemes that still operate and the number of medical scheme administrators that compete for this aspect of their operation, there is a lack of publicly-accessible information about the extent of generic penetration. One medical scheme administrator (Mediscor) has placed data of this nature in the public domain (Figure 2). In 2011 Mediscor was responsible for managing the claims of 32 medical schemes, covering 1.6 million insured clients.

![Figure 2. Prescriptions reimbursed by Mediscor](source: Mediscor, 2012 (21).)
This degree of generic penetration, which now exceeds 50% of all prescriptions dispensed in the schemes administered by Mediscor can be benchmarked against global figures reported by IMS Health in 2013 (22). In 2012, the Mediscor expenditures on generic medicines accounted for 36% of all medicine expenditures. This is equal to the proportional global expenditures on generic drugs projected by IMS Health in 2017. However, it is considerably lower than the 63% projected for typical countries with emerging markets.

A further provision of the 1997 Medicines and Related Substances Amendment Act created the Pricing Committee as an advisory body to the Minister of Health. This made possible the introduction of a number of important reforms in the private-sector market, namely:

- the introduction of a single exit price for all prescription medicines (i.e. a fixed ex-factory price for medicines sold to all purchasers other than the State);
- restrictions on the logistics fees that manufacturers can add to the ex-factory price when selling to wholesalers and distributors (no additional mark-ups for logistics can be charged to pharmacies, hospitals or dispensing practitioners);
- a regulated maximum increase in the single exit price, determined annually and published by the Minister of Health;
- regulated maximum dispensing fees for pharmacists and licensed dispensing practitioners that are reviewed annually;
- a ban on off-invoice bonuses, rebates and various other marketing incentives (and their definition in regulations);
- a ban on the supply of free samples of medicines to anyone;
- the publication, albeit in a voluntary format (since 2013), of guidelines for the submission of pharmaco-economic evaluations of new medicines, justifying their initial single exit prices.

The launch of the single exit price mechanism was expected to be controversial, as there were reports of a proposed 50% cut in private-sector prices (23). This did not happen; a cost-neutral introductory mechanism was chosen instead. When the pricing interventions became operative in May 2004, the initial single exit prices were set at the weighted average of 2003 prices, after taking into account all discounts and rebates allowed to purchasers in that year. The introduction of regulated maximum dispensing fees was far more controversial, with a series of court challenges and eventually a decision by the Constitutional Court that led to a redesign of the initial fee structure for pharmacists. Subsequent adjustments to those fees, and to the fees charged by licensed dispensing practitioners, have also been controversial but have not been held up by court action. An element of pricing intervention that has not yet been brought into effect is planned external reference pricing (referred to locally as international benchmarking), which would compare South African prices for patented medicines with prices in four countries. The logistics fee remains another contested issue as it is not transparent, and the ability of smaller, full-line independent wholesalers to negotiate with manufacturers and distributors is limited. Subsequent draft regulations dealing specifically with logistics fees were published for comment in 2012 but have not been finalized. Draft regulations to strengthen the ban on all forms of incentive schemes were published in 2014. Such practices have proven to be persistent, despite the clear policy intent to prohibit perverse incentives.

The annual maximum increases in the single exit price that were stipulated by the Minister since the intervention was first launched in 2005 varied from a minimum of 0% in 2011 to a maximum of 13.2% in 2009. The most recent increase (2014) was set at 5.82% (24). The amount of increase is determined each year through stakeholder consultations.

4.2 Evidence of implementation

In 2004, before the interventions came into effect, Health Action International together with WHO conducted a pricing survey of medicines in public- and private-sector facilities in Gauteng Province (25). The survey showed that, in private-sector pharmacies and private hospitals, proprietary brand products were 25-26 times more expensive than the median price quoted by the International Drug Price Indicator Guide produced by Management Sciences for Health. The lowest-priced generics were about 6.5 times more expensive. The

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document by Management Sciences for Health presents "a spectrum of prices from pharmaceutical suppliers, international development organisations, and government agencies". It is widely used as a reference by procurement agencies. On the basis of prices quoted in procurement tenders, the public sector paid on average 1.6 times the median price quoted in the indicator guide for both high-priced proprietary and low-priced generic drugs.

The impact of drug pricing policies over time can be indirectly assessed in terms of the contribution of the cost of medicines to total medical scheme expenditures, as reported in the annual reports of the Council for Medical Schemes (8). In marked contrast to the sustained increase in expenditure by private hospitals and medical specialists, expenditures on all other health professionals (general practitioners, dental specialists, dentists and other supplementary and allied health professionals) and providers (such as provincial hospitals) have remained relatively constant. Expenditures on medicines declined after 2001, with a more accentuated decline after 2003 following adjustment for inflation. This coincided with increased prescriptions of generic medicines after the mandatory offer of substitution was introduced. However, by 2009, expenditure in constant Rands had rebounded to the same level as 2001 and has continued to increase. Table 3 shows the percentage of expenditure on medicines in the private insured sector (which reflects marked changes in overall spending), and expenditure per beneficiary per year on medicines during 2002-2013. It is evident that medicine expenditure per beneficiary remained relatively constant during the early years of implementation of medicine pricing policies (both a mandatory offer of generic substitution and the single exit price mechanism).

### Table 3. Medicine expenditure in the private-sector medical scheme (insured) environment

<table>
<thead>
<tr>
<th>Year</th>
<th>% Expenditure on medicines</th>
<th>Medicine expenditure per beneficiary (annual) in South African Rand (unadjusted for inflation)</th>
<th>Annual maximum single exit price adjustments (%)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>23.5</td>
<td>1 206.39</td>
<td>–</td>
</tr>
<tr>
<td>2003</td>
<td>22.3</td>
<td>1 241.93</td>
<td>–</td>
</tr>
<tr>
<td>2004</td>
<td>19.2</td>
<td>1 156.79</td>
<td>–</td>
</tr>
<tr>
<td>2005</td>
<td>15.7</td>
<td>1 053.31</td>
<td>–</td>
</tr>
<tr>
<td>2006</td>
<td>16.9</td>
<td>1 220.65</td>
<td>–</td>
</tr>
<tr>
<td>2007</td>
<td>16.7</td>
<td>1 257.01</td>
<td>5.2</td>
</tr>
<tr>
<td>2008</td>
<td>17.3</td>
<td>1 422.25</td>
<td>6.5</td>
</tr>
<tr>
<td>2009</td>
<td>17.4</td>
<td>1 648.38</td>
<td>13.2</td>
</tr>
<tr>
<td>2010</td>
<td>17.0</td>
<td>1 683.56</td>
<td>7.4</td>
</tr>
<tr>
<td>2011</td>
<td>16.3</td>
<td>1 782.70</td>
<td>0</td>
</tr>
<tr>
<td>2012</td>
<td>15.8</td>
<td>1 877.99</td>
<td>2.14</td>
</tr>
<tr>
<td>2013</td>
<td>16.0</td>
<td>2 050.98</td>
<td>5.8</td>
</tr>
</tbody>
</table>


Note: *The single exit price mechanism was announced in 2004 but was implemented only in 2006 and therefore adjustments came into effect as from 2007. Mandatory offer of generic substitution was implemented from 2003.

The largest of the medical scheme administrators estimated that the introduction of the single exit price mechanism had saved the scheme about 319 million Rand per year in medicine expenditure since 2004 (26). The rate of increase in expenditure on medicines in the private sector is, nonetheless, far less than the rate of increase in the costs of private hospitals and medical specialists. The private sector must, nevertheless, face demands for new and expensive medicines, as can be seen in the more recent expenditure data in Table 3. This prompted the release of guidelines for pharmaco-economic evaluations in 2013, although submission of such evaluations is voluntary until further notice. It is therefore unclear what effect, if any, this provision is having on the market (27).
South Africa’s National Drug Policy lacked a clear strategy for dissemination, implementation and training but has benefitted from a strong process for the selection of essential medicines, with potential impacts on procurement and use. However, some challenging issues remain. The impact of the minimalist approach to regulating the selection of medicines for tertiary/quaternary care remains to be assessed.

A further challenge has been fiscal federalism and the autonomy of provincial health departments. The respective roles of the National Essential Medicine List Committee and the provincial pharmacy and therapeutics committees should be more clearly defined. The legal provisions for such clarity can be issued with relatively little effort. Importantly, it will be necessary to engage provincial pharmacy and therapeutics committees in the neglected field of promoting and monitoring the rational use of medicines.

Consumer behaviour and interest in the reforms under the National Drug Policy constitute another challenge. A study by Patel et al. in 2010 found that consumers used the price of service as a proxy indicator for quality, thus ultimately influencing their perception of the quality of medicines (28). If something was less expensive than the original product, or could even be obtained free of charge, it was perceived to be of inferior quality. This perception influenced behaviours and undermined trust in the health services. Patient involvement through education, information and improved communication is key to ensuring that there is a shared understanding of the objectives of the National Drug Policy.

South Africa introduced significant policy interventions in the private sector to address many of the ills afflicting health insurance systems – such as adverse selection practices. Further challenges will need to be addressed, however, as South Africa introduces universal health coverage in the form of a National Health Insurance system. The intent is to overcome the anomaly of a privileged private sector surrounded by an under-funded and under-resourced public sector. The pricing and managed care interventions that kept expenditure on medicines in the private sector somewhat under control over the last decade may not be sufficient in this new context. Some interventions, such as reference pricing and pharmaco-economic evaluations, have yet to be implemented. They hold the key to future efficiency gains. Simple application of selection of a limited list which guides pooled procurement to the new National Health Insurance system will not be possible. However, the principles of evidence-based selection can assist in the development of reimbursement policies for National Health Insurance. Much has been achieved, but more needs to be done.

Overall, the following key lessons can be learned from the South African experience:

- Access to essential medicines and health commodities cannot be addressed in isolation from the sociopolitical and economic context of the country. In the case of South Africa, the complex transition from apartheid to democracy must be taken into consideration. Although the racially-based fragmentation of the apartheid era was addressed, a quasi-federal system has posed new challenges of coordination.

- The implementation of national policies requires focus and patience, regular monitoring and updating. The South African experience, while providing evidence of considerable political will, has also been a salutary lesson of the consequences of failure to update policies to take account of changing circumstances.
- Monitoring and evaluation must be included and supported in the implementation of national policies. In the absence of strong systems that are routinely applied, periodic cross-sectional surveys provide inadequate evidence of outcomes and impact.

- Sustainable financing must be part of implementation; otherwise initial momentum is lost with competing priorities. This is particularly true as a health system attempts to introduce universal health coverage.

- Transparency in selection, procurement and regulation of pharmaceuticals is essential for keeping all stakeholders on board. This is a central tenet of good governance.

- Essential medicines lists should be clearly and explicitly based on the best available evidence and constantly updated, with medicines being both added and deleted from the list.

- Although challenging, the development of essential medicines lists on the basis of clear and comprehensive standard treatment guidelines is critical. However, the ability to apply this methodology to tertiary and quaternary services has yet to be demonstrated.

South Africa has achieved global recognition for policy reforms to enhance access to care. This was particularly true during the 1998-2001 attempt by transnational pharmaceutical manufacturers to delay or prevent the implementation of amendments to South African medicines legislation. However, the efforts to enhance access to medicines and to address the entrenched inefficiencies of the apartheid-era fragmentation of the health system cannot be reduced to simple dichotomies. Access to generic HIV medicines may be an easily-identified “poster child” for the media, but the realities of the policy trajectory in South Africa are more complex and more illuminating. They provide important lessons for many other countries embarking on efforts to improve the efficiency of their health systems.
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