Medicines Selection and Procurement in South Africa

The main objective of South Africa’s National Drug Policy (NDP), adopted in 1996, was to support equitable access to medicines by addressing a full range of components: legislation, selection, pricing, procurement and supply, human resources and traditional medicines as well as cooperation with regional and international organisations. The objective of this chapter is to review the medicines selection and procurement components of the NDP. Medicines selection in both the public and private sectors in South Africa has undergone significant transformation in the past 16 years. The implementation of the national Essential Medicines List and supporting structures in the form of provincial and facility-based Pharmacy and Therapeutics Committees has introduced levels of rigour in assessment of medicine selection but still needs improvement.

The procurement of medicines is also in the process of reform, with proposals for establishing a centralised procurement unit, referred to as the “Central Procurement Agency”. The relocation of medicines tender processes from the National Treasury to the National Department of Health appears to have had some impact in reducing the cost of medicines and improving access and availability. The potential role of state-owned manufacturing of pharmaceuticals is also discussed.
Introduction

It has been 16 years since South Africa’s National Drug Policy (NDP) was officially announced and adopted. The NDP sought to reform the health sector in a way that would bring about an improvement in medicines access and use in both the public and private health sectors. Figure 1 shows the three main objectives of the NDP, each with its specific set of sub-objectives.

The World Health Organization (WHO) identifies two key prerequisites for the successful implementation of an NDP. The first is to have a system for monitoring and evaluation. This is a constructive management tool that enables a continuous assessment of progress and helps in the decision making. The second is that the NDP should be periodically evaluated. Such evaluations should form an integral part of the pharmaceutical master plan (a prioritised implementation plan for the policy), with the necessary resources allocated from the start. Independent consultants or professionals from other countries or from the WHO may be invited to complement a national evaluation team.

Although the original policy document committed to conducting regular evaluations of the NDP, no official, comprehensive review of the South African NDP and its impact has been conducted since its adoption in 1996. However, some assessments have been carried out. Provincial surveys on the NDP were conducted by the National Department of Health (NDoH) between 1996 and 1998 in seven of South Africa’s (SA’s) nine provinces. These surveys were conducted to establish baselines for future monitoring of progress in terms of the implementation of selected aspects of the NDP. While medicines availability was found to be just over 85% both in the hospitals and primary health care (PHC) clinics in the provinces surveyed, awareness of the NDP was found to be quite low (below 40% on average). Follow-up surveys were carried out in all the nine provinces and six metros of SA in 2003, with the aim of determining the impact of the NDP at PHC level. The availability of medicines was again found to be high (on average, 82% of a basket of key medicines). However, significant challenges were noted in terms of stock control (for instance, 50% of stock records were inaccurate) and rational medicines use (in 7% of facilities, 50% or fewer patients knew how to take their medicines). A marked increase in the proportion of patients prescribed an antibiotic was noted, up from an average of 25% in the 1996 to 1998 baseline surveys to 47% in 2003. However, some progress was noted in the percentage of patients that received an injection (down from 11% to 5%).

In 2005, the Human Sciences Research Council (HSRC) sought to evaluate the impact of the NDP on the availability of medicines in the public and private sectors of two provinces (Limpopo and Western Cape). The HSRC concluded that some notable progress had been achieved. However, considerable input, in terms of improved infrastructure and training of healthcare workers, would be required to improve procurement and distribution practices. All the public sector hospitals visited had a copy of the national Standard Treatment Guidelines (STGs), and this resource was also found in 77% of private general practitioners’ practices and 43% of private pharmacies, even though it was not officially applicable in such settings. This survey again found high levels of antibiotic prescribing in all settings.

Perhaps the most comprehensive assessments of progress in the public sector’s pharmaceutical services are the 2005/6 series of audits requested by the NDoH and conducted by Rational

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**Figure 1: Objectives of the NDP**

### Health Objectives
- Ensure availability and accessibility of essential medicines to all citizens.
- Ensure the safety, efficacy and quality of medicines.
- Ensure good dispensing and prescribing practices.
- Promote the rational use of medicines by prescribers, dispensers and patients through provision of the necessary training, education and information.
- Promote the concept of individual responsibility for health, preventive care and informed decision making.

### Economic Objectives
- Lower the cost of medicines in both the private and public sectors.
- Promote the cost-effective and rational use of medicines.
- Establish a complementary partnership between government bodies and private providers in the pharmaceutical sector.
- Optimise the use of scarce resources through cooperation with international and regional agencies.

### National Development Objectives
- Improve the knowledge, efficiency and management skills of pharmaceutical personnel.
- Reorientate medical, paramedical and pharmaceutical education towards the principles underlying the NDP.
- Support the development of the local pharmaceutical industry and the local production of essential medicines.
- Promote the acquisition, documentation and sharing of knowledge and experience through the establishment of advisory groups in rational medicine use, pharmacoconomics and other areas of the pharmaceutical sector.

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Pharmaceutical Management Plus (RPM Plus), a USAID-funded programme managed by Management Sciences for Health (MSH). The purpose of the audits was to assess and measure the extent to which pharmaceutical services in the public sector complied with the Medicines and Related Substances Act (Act 101 of 1965) and the Pharmacy Act (Act 53 of 1974), to recommend ways of attaining such compliance, and to estimate what it would cost to bring public sector facilities to the required levels of compliance. However, the results of these audits have never been placed in the public domain, thereby making them inaccessible to other researchers or policy makers outside of the Department of Health.

Since 1997, chapters in various editions of the South African Health Review have been devoted to aspects of pharmaceutical services and to the implementation of the NDP, such as medicines pricing in the private sector and policy and legislation. Most recently, in the 2007 edition, Taylor discussed the rationing of medicines and healthcare technology and reviewed the impact of various legislative reforms, such as the dispensing fee and the single exit price (SEP), on the cost and utilisation of technologies. A review of health legislation and policy in 2010/11 describes the effect of various measures, which include the SEP and the logistics fee, aimed at regulating medicine prices in the private sector.

Undoubtedly, much has happened in the country’s healthcare system and there is a need for a comprehensive review of the NDP. The decision to embark on a national health insurance (NHI) system has to be the most compelling reason for such a review to be undertaken.

The focus of this chapter is on the medicines selection and procurement aspects of the NDP. Medicines selection is discussed in the context of reforms that would be necessary as the country gradually moves towards NHI. The chapter also assesses recent developments in medicines procurement in the public sector, notably the impact of reforms in the tender system. Finally, the chapter discusses the merits of a state role in the manufacturing of active pharmaceutical ingredients (APIs) as an option for reducing medicines expenditure.

Medicines selection

Medicines selection is a key factor in the successful implementation of access to equitable health care. Medicines selection should be based on the principles of health technology assessment (HTA) and include assessment of the evidence-base for the medicine choice and pharmaco-economic evaluations. Decisions around the selection of a medicine for inclusion on a formulary or medicines list should also take into account issues such as access and implementation. The funding of medicines is subject to further conditions such as budget impact (to the funder) and affordability (by the patient). In the private healthcare sector in SA, the funding of medicines is subject to complex medical scheme rules and policies regarding the type of health plan and the benefits that a member has selected. This is discussed in more detail below.

Medicines selection in the private sector

Medicine formularies and guidelines

Generally, clinical decisions regarding the selection of medicines for formularies are made within each medical scheme, as implemented by medical scheme administrators. The level and breadth of expertise utilised in the selection process can range from a single medical advisor to teams of evaluators made up of pharmacists, nurses, medical practitioners and other experts in public health or health economics.

The selection of medicines for private sector formularies is dependent on the type or class of medicine. For high-volume, low-cost medicines such as statins or angiotensin-converting-enzyme (ACE) inhibitors the selection is generally based on price. However, high-cost medicines are considered for selection, these are subject to a more thorough evaluation, which includes clinical efficacy and effectiveness, cost-effectiveness and budget impact.

Selection of medicines under prescribed minimum benefits

Prescribed minimum benefits (PMBs) are defined to ensure a minimum benefit for all beneficiaries and are considered to be comprehensive and thorough. They cover nearly 270 conditions: for each condition, the minimum service level is comparable to that provided in the public sector. Medical schemes are allowed to manage their benefits and control costs with measures such as:

- designating service providers for PMB services;
- employing a formulary and associated management tools such as a pre-authorisation (i.e. patients must fulfil certain requirements as laid down by the medical scheme prior to authorisation for funding being issued) and protocols;
- establishing risk-sharing arrangements with different types of providers; and
- contracting with specified hospitals or hospital groups to provide services.

The Regulations to the Medical Schemes Act (Act 131 of 1998) also specify that schemes must pay for the diagnosis, medical management and medications of a specified list of common chronic conditions, estimated to cover about 75% of the chronic conditions seen in primary practice. The initial 25 chronic disease list (CDL) conditions, as drawn up in 2003, included, among others, asthma, cardiac failure, chronic obstructive pulmonary disease, diabetes, epilepsy, hyperlipidaemia, hypertension, Parkinson disease, schizophrenia and rheumatoid arthritis. The medical treatment options for each CDL condition were laid out in therapeutic algorithms, which were developed by the Council for Medical Schemes in 2003. The list was subsequently increased to 27 conditions, with the addition of the requirement that medical schemes provide at least the antiretroviral (ARV) treatment provided in the state (after 2004), and with the addition of the Bipolar Mood Disorders (BMD) Therapeutic Algorithm in 2009. However, the remainder of the algorithms have not been updated since they were published in 2003. The list of these medicines, in effect, constitutes a PMB formulary of medicines that must be funded for all patients, regardless of whether they have a Medical Savings Account or remaining funds in their plan type.
A review of the medicines listed in the CDLs in 2009 showed that all but three of the CDLs had generic alternatives to the medicines listed at the time of the study. The PMB formulary, however, does not necessarily specify particular medicines and may only prescribe a class of medicines (e.g. ACE inhibitors). Each medical scheme is allowed to use a selection process to create its own PMB formulary on the basis of principles of evidence-based medicine, cost-effectiveness and affordability. Often this is subject to negotiation with the pharmaceutical manufacturers on the price of the proposed medicine. In this way, substantial SEP reductions can be achieved for selected medicines for the whole of the private sector market.

However, certain medical schemes believe that being compelled to pay in full for the treatment of PMBs could negatively affect their sustainability. The Board of Healthcare Funders, to which most of the country’s medical schemes are affiliated, lost a court case in November 2011 against the Council for Medical Schemes, in which it attempted to get the court to place a limit on how much the schemes should pay for PMBs. The Minister of Health is reportedly in discussions with the Competition Commission over suitable mechanisms for addressing the issue of setting tariffs in the private healthcare sector.

Medicines selection in the public sector

The WHO advocates that procurement should take place against a list of essential medicines. The selection of medicines that are available for procurement in the public healthcare sector in SA takes place through the National Essential Medicines List Committee (NEMLC) and provincial and facility-based Pharmacy and Therapeutics Committees (PTCs).

In an unpublished analysis of provincial expenditure conducted by a Ministerial Task Team on Procurement in 2009, the following challenges were identified:

- High use of single-source medicines and medicines for which there were no generic equivalents;
- Apparent lack of adherence to the nationally determined STGs;
- High levels of buyouts, outside of the nationally determined tenders;
- High usage of expensive medicines, particularly in oncology; and
- Inappropriate usage of medicines that were not cost effective and were not listed on the national Essential Medicines List (EML).16

Standard Treatment Guidelines and Essential Medicines Lists

Currently the initial selection of medicines for the public sector is determined by the ministerially appointed NEMLC, as advised by its Expert Review Committees. These review committees are made up of a mix of experts with clinical, process and methodological knowledge. Each expert takes responsibility for a set of STGs and the accompanying EMLs. These are the Primary Care STG/EML, the Hospital Level (Adult) STG/EML, the Hospital Level (Paediatric) STG/EML, and the newly released Tertiary and Quaternary Care EML. The Tertiary and Quaternary Care EML is intended to be a dynamic document, which will be continually updated and issued only in electronic format. The first edition, published on 2 November 2012, is a list of medicines that are recommended, or, in some cases, that are not recommended, for use at tertiary provincial or quaternary (academic) hospitals. Each medicine was reviewed by the relevant committee in relation to specific clinical indications and settings. For example, a medicine (e.g. botulin toxin) may be recommended for focal dystonias, but not for spasticity. Where a medicine was explicitly stated as not recommended, this was because the committee had deemed it lacking in terms of availability of robust, high quality evidence regarding its efficacy and effectiveness or had identified a potential to cause undue harm.

While some experts serve on more than one committee, the Expert Review Committees generally act independently of each other. The decisions of the NEMLC, for the most part, guide procurement of medicines in the public sector and form the basis for initiating medicines tender processes. In relation to programmes funded through conditional grants (notably the ARV programme), these decisions are binding at provincial level.

The provincial PTCs also have a degree of autonomy, as their provincial Member of the Executive Council (MEC) or Head of Department enables them to make selections of medicines funded from provincial budgets. While the provincial PTCs may provide input into the NEMLC and take advice from that structure, no formal central advisory body exists that applies evidence-informed and health economic principles to making recommendations. Decision making regarding the selection of health products may, therefore, vary from province to province, which results in inequitable access to medicines and other health-related products. Enabling closer coordination between provincial PTCs and formalising the decision-making process are likely to be key challenges faced in the proposed NHI.

The challenge is especially acute in relation to high-cost items such as the new biologics and oncology medicines. Currently, selection decisions about high-cost medicines and technologies are not consistent and more often than not appear to be based on the persuasive powers of the specialists that request the product. Clinical evaluation is carried out, but formal investigation into the cost effectiveness of the product rarely occurs. In addition, no follow-up process exists that measures the outcomes (both clinical and cost) of selecting such products. Indeed, in most instances of medicine selection, measurement of costs and outcomes is lacking.

Nonetheless, a measure of success has been achieved with the application of pharmacoeconomic analysis in some selection processes. An example is the selection of capcitabine for the treatment of metastatic colorectal cancer, which led to the treatment being approved by the NEMLC in 2012.18

Role of the Pharmacy and Therapeutics Committees

While each of the provinces is expected to have a fully functional provincial PTC and local committees at each hospital, progress in this regard has been patchy. In the last quarter of 2011, the Gauteng Provincial PTC was re-instated with a range of sub-committees (Safety and Quality; Rational Medicines Utilisation;
Formulary; and Procurement Advisory). These sub-committees made significant progress in achieving their goals for 2012. The Western Cape and KwaZulu-Natal have been identified as more successful than the other provinces in selecting medicines. All of the PTCs that exist have faced considerable challenges in terms of their broader mandate, in particular in relation to pharmacovigilance and the promotion of rational medicines use.

As indicated, provincial medicines selection processes should be guided by the national STG/EMLs. However, cases may occur where a province requires access to specific medicines that are not on the national EML. This has especially been the case in those provinces with academic hospitals and specialist units, such as renal or cardiac transplant facilities. This process will be considerably aided by the publication of the Tertiary and Quaternary Care EML.

Provincial selection decisions may also result from upward motivation from the district and hospital PTCs. If a medicine that is required is not on the EML or the provincial formulary, it may be motivated for by a clinician, with the necessary supporting evidence. An alternative, which is also best managed by the provincial PTC, is to allow for access on a named-patient basis.

A 2011 qualitative study by the School of Public Health at the University of the Witwatersrand on the use of HTA in the selection and procurement of medicines showed that while the development, procurement and use of health technology falls within each province’s jurisdiction, not every province has a formalised health technology policy. Those provinces that lacked HTA guidelines and policies believed this resulted in faulty procurement, which may lead to medicines service delivery problems.

**Medicines selection under National Health Insurance**

**Centralised health technology assessment body**

The availability of robust, locally applicable HTA will greatly assist in informing medicines selection processes both in the public and private sectors.

It has been widely recognised that a centralised process for HTA (that assesses clinical efficacy and effectiveness, health economics and budget impact) is required to address the shortage of skilled resources in the areas of clinical evaluations and health economics assessment. A centralised HTA process will also create a united viewpoint to guide healthcare policy and coverage decisions.

Institutions such as the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom, the Canadian Agency for Drugs and Technology in Health (CADTH) in Canada and the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia have become recognised as opinion leaders in the field of HTA. These institutions guide clinical decision making around the world.

As SA moves towards an NHI system, it is envisaged that a similar centralised process for HTA will be required. The Human Resources for Health SA strategy paper indicates that an “NDoH National Coordinating Centre for Clinical Excellence in Health and Health Care will be established”. The operations of the Centre will be located in various sites, which will include academic sites of excellence, the Medical Research Council, and the NDoH.

However, a central office will provide a coordinating function and bring together associations, professional groups, provincial departments of health and the academic community to define and oversee clinical quality professional health care.

The establishment of such an institution requires vision, drive and resources. The need for training and skilling resources in evidence-informed medicine and pharmacoeconomics is increasingly recognised. Steps towards addressing this shortcoming have been taken by various academic institutions. The Health Economics Unit at the University of Cape Town, for example, offers a certificate diploma and master’s degree in health economics, while a master’s degree in pharmacoeconomics was introduced by the University of KwaZulu-Natal in 2011. Related topics are also covered within certain post-graduate courses at other universities, such as the master’s degrees in clinical epidemiology at the universities of Pretoria and Stellenbosch. In addition, basic training in evidence-based medicine and pharmacoeconomics is offered by various organisations and associations such as the Pharmaceutical Care Management Association of SA. Considerable involvement of all stakeholders and the political will to drive a process of co-ordinating a centralised HTA function are required for successful implementation and integration of these initiatives.

**Medicines procurement – a shift towards centralisation**

Medicines procurement in the public sector has been conducted under the auspices of the Coordinating Committee for the Provisioning of Medical Supplies (COMED) since 1988. However, while this structure has been hosted within the Department of Health, and has coordinated the efforts of the provinces and other participating departments (Correctional Services and Defence), the National Treasury has been responsible for awarding all contracts. Following reports of deterioration in medicines availability across the country, a Ministerial Task Team was established in 2009 to assess the state of medicines procurement in the public sector and make recommendations for procurement reforms. The Task Team favoured the strengthening of a more centralised role in the procurement of medicines, which included the establishment of a Central Procurement Agency (CPA). It was envisaged that the CPA might eventually migrate out of the NDoH and become an independent public entity responsible directly to the Minister of Health. Subsequent to this, support for the establishment of the CPA was secured in SA’s Round 10 grant from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) in 2010. The establishment of the CPA was approved by the National Health Council in 2011, with the Directorate Affordable Medicines (DAM) effectively becoming its core structure. A number of critical posts were filled, supported by funding from the Global Fund, which enabled the DAM to strengthen its infrastructure and resources so that it could start the management of pharmaceutical tenders independently of the National Treasury.

The ability and capacity of the NDoH to prepare, advertise, adjudicate, award and manage the relatively large national medicines tenders on its own was put to the test with the decision to take over management of tenders for three critical priority programmes (anti-tuberculosis, anti-infective and family planning medicines) in 2011. Technical assistance with the preparation of the
tender process was provided by partners such as the USAID-funded Strengthening Pharmaceutical Systems (SPS) programme managed by the MSH, in close collaboration with the Clinton HIV/AIDS Initiative (CHAI, now known as the Clinton Health Access Initiative).

It may be too early to judge the impact of the NDoH’s taking over the management of medicines tenders from the National Treasury. There does appear to be consensus within the DAM and the provinces, though, that the NDoH is gradually achieving the required efficiencies in the tender process.

Being responsible for the management of its own tenders has given the NDoH the opportunity to take a broader view of the various functions in the supply chain and bring about linkages that should optimise scarce resources in the long run. Market intelligence is now applied for the first time in the tender process, with price adjustment applications being evaluated critically on the basis of global trends in API price increases and formulation costs. The option to conduct price negotiations with preferred bidders has been built into the special conditions of tender and price negotiations have resulted in additional savings on a number of contracts.

The NDoH has claimed significant savings in several tenders since it took over, compared to the previous tenders, as illustrated in Table 1 below. The savings have been calculated on the difference in the estimated cost implications, based on the quantities tendered for, between new and previous contract prices, for items that were awarded on both contracts.

These figures represent between 1% and 50% of the value of the same volume of items and a total saving of 27%. As the contracts were re-constituted (e.g. all antibiotics were grouped together, new specifications were drafted and items were removed), percentage savings on the total cost of the tenders cannot be meaningfully represented at this stage.

The re-organisation of the tender system at the central level has raised confidence levels in the DAM and led to expectations of considerable efficiency gains in the foreseeable future. This has to be attributed to the fact that the NDoH is in charge of the processes and is able to take responsibility for its actions and control the outcomes. Turn-around time of the tenders has been shortened from about nine months to as little as four months. The management of risk has also been brought closer to the department affected by the risk.

Medicines availability in the provinces

The delivery of healthcare services is a provincial competence. Thus the imposition of any reform that includes central control of the pharmaceutical budget and of the medicines distribution chain is bound to be met with resistance. This is expected even though the majority of provinces are struggling to provide a high quality pharmaceutical service.

Yet, indications exist that the DAM has managed to secure the cooperation of provinces in implementing measures intended to improve medicines supply chain management and processes. One such example is employment of the so-called “ARV monitors”. In December 2009, following a request from the South African Government to the United States Government, the latter agreed to meet a portion of the two-year funding gap for ARVs by providing US$ 120 million over a period of two years. This support was contingent on a number of conditions. One of these was that measures be put in place to build capacity within the national and provincial departments of health to strengthen logistics and forecasting systems. In response to USAID’s request for USAID partners to support this initiative, the MSH-managed SPS programme placed technical advisors with appropriate pharmaceutical and logistics skills – and officially designated “ARV Monitors” in each of the provincial pharmaceutical depots and another at the NDoH. The agreement was that the posts would be supported for a period of 18 to 24 months by MSH. After this time the NDoH and the provinces would have the option of absorbing the posts into their staff establishments.

The ARV monitors reported on the availability of ARVs and tuberculosis medicines, vaccines, anti-malarial and tracer medicines at depots to the provincial authorities. Through the provincial authorities the monitors also reported to the NDoH. This monitoring process enabled the compilation of a national database on stock availability, supply challenges and usage patterns. Furthermore, the monitors were involved to a varying extent, depending on each province’s situation, in monitoring facilities and assisted with appropriate supplies to facilities in cooperation with provincial staff. Stock-outs of ARVs in the provincial depots reportedly decreased from 12% countrywide when monitoring first started to 2.4% at the end of the two-year intervention. Forecasted requirements for the remaining year of the contract period have been much more accurately determined and communicated to suppliers.

Table 1: Savings achieved on current tenders compared to previous year

<table>
<thead>
<tr>
<th>Tender number</th>
<th>Description</th>
<th>Nominal savings on previous tenders</th>
</tr>
</thead>
<tbody>
<tr>
<td>HP01-2011TB</td>
<td>Tuberculosis Agents</td>
<td>R68 million</td>
</tr>
<tr>
<td>HP02-2011AI</td>
<td>Anti-infective Agents</td>
<td>R170 million</td>
</tr>
<tr>
<td>HP04-2012ONC</td>
<td>Oncology and Immunological Agents</td>
<td>R70 million</td>
</tr>
<tr>
<td>HP06-2012VP</td>
<td>Small Volume Parenteral and Insulin Devices</td>
<td>R69 million</td>
</tr>
<tr>
<td>HP07-2012DAI</td>
<td>Drops, Aerosols, Inhalers and Inhalants</td>
<td>R3 million</td>
</tr>
<tr>
<td>HP08-2012SSD</td>
<td>Semi-solid Dosage Forms</td>
<td>R4.5 million</td>
</tr>
<tr>
<td>HP09-2012SD</td>
<td>Solid Dosage Forms (tablets)</td>
<td>R105 million</td>
</tr>
</tbody>
</table>

Source: Zeeman, 2012.21
The ARV monitors, through their liaison with all the relevant stakeholders in the chain, have provided a valuable link between selection, procurement, distribution, clinical options and use. Their posts have been retained, with the majority of the incumbents being re-appointed with funds allocated by the Global Fund. This resource has the potential to achieve improved outcomes in all areas of medicines use and has to be seen as key to resolving forecasting problems for all classes of medicines in the pharmaceutical supply chain.

The litmus test of the efficacy of any public sector’s pharmaceutical supply system is the availability of medicines in PHC facilities. Sadly, the reality is that stock-outs at this level are still widely reported. Monitoring of availability at primary care facilities remains a challenge that needs to be addressed at district and provincial levels. A key attribute of the ARV monitor arrangement was that monitors were sufficiently funded to allow them to travel regularly between the depot and the facilities, which included the PHC facilities. This is in stark contrast to the situation of the district pharmacists in many of the provinces, who are often restricted to providing only remote support from their offices owing to budgetary restrictions on their mobility. The sustainability of the impact of the presence of ARV monitors in the districts will hinge largely on their continued ability to pay regular physical visits to the facilities. In addition, their focused activities set the ARV monitors apart from the district pharmacists. Furthermore, with the piloting of PHC re-engineering and the deployment of district-based clinical specialist teams in selected districts the role pharmaceutical services will play remains largely undefined. The current experience of the monitors may inform the future role of pharmaceutical personnel in the NHI districts.

The role of the state in pharmaceutical manufacturing

The production of APIs in the country has been keenly debated by the Department of Trade and Industry (dti) over many years. In 2008, the dti commissioned an investigation into the local production of APIs for ARVs. This was followed by a feasibility study into API production in the country, in which the dti collaborated with the NDOH and the Department of Science and Technology.

According to the dti, the South African pharmaceutical industry is a key contributor to the country’s Gross Domestic Product (GDP). In 2008/09 it spent R11.95 billion, which included R4.40 billion on salaries and wages, R1.35 billion on capital investment and R1.75 billion on research and development (which incorporated clinical research). The industry paid taxes of R2.35 billion. This consisted of R1.60 billion in income tax and R740 million in value added tax. The sector’s spending on corporate social investment (CSI) was R640 million, with Roche’s support of the PheloPhepa Train an example of such spending.

At the same time, though, the dti cautions that the country’s pharmaceutical manufacturing base has been eroded; 37 plants reportedly closed down between 1995 and 2010 and resulted in the loss of 6 500 jobs. This is perhaps indicative of global trends towards the concentration of pharmaceutical manufacturing in a limited number of settings. In addition, the medical products sector (pharmaceuticals, medical diagnostics and medical devices) has become the fifth largest contributor to South Africa’s imports burden. Imports of pharmaceuticals (excluding APIs) grew from R6.20 billion in 2002 to R15.96 billion in 2011. Pharmaceuticals in finished-dosage form account for 80% of the sector’s total imports, growing at 12.5% p.a. over the past four years, from R7.30 billion in 2006 to R11.6 billion in 2010. On the API side, SA imports 95% of its API requirements, which includes all APIs for ARVs and antibiotics. Some have argued that this is an untenable situation, as SA has the world’s largest HIV and AIDS burden and is accordingly the world’s largest consumer of ARVs, yet continues to rely wholly on imports of ARVs for the support of its treatment programme.

The Walwyn Report of 2008 noted, however, that local production of APIs for ARVs would face stiff competition from Chinese and Indian manufacturers and that a local production facility would only survive if it received government support. It recommended the establishment of a public-private partnership (PPP) with a local manufacturer. It reasoned that such a PPP would be able to compete over the medium term, if the government provided support in terms of the required capital and the private sector partner transferred state-of-the-art process technology and manufacturing expertise.

A further feasibility study on the same subject was presented to Cabinet in 2010 and was, by all accounts, approved for implementation. A media statement issued in February 2012 announced the establishment of such a joint PPP venture, which involved the South African Government.

The potential success of this venture may be judged by carefully considering the Brazilian experience. The Government of Brazil, as one of the Latin American countries most affected by the HIV epidemic, pursued an aggressive HIV and AIDS strategy from the early 1990s. This included a mandatory ARV therapy programme through the public health system and the active promotion of the development of the Brazilian pharmaceutical industry, with state-owned laboratories part of this initiative. The provisions of the TRIPS Agreement were applied to enable engagement in aggressive price bargaining with multinational pharmaceutical manufacturers. Implementation of the Generics Act, approved in 1995, fostered competition among producers and facilitated the reduction of prices. A further effect of the Act was that it strengthened the local pharmaceutical industry and the network of 18 publicly owned laboratories operated by various government units and universities.

By 2006, 80% of all the medicines marketed in Brazil were locally produced and Brazilian companies accounted for 75% of the total sales value. In 2001, 63% of the ARVs were produced by local manufacturers. By 2006, 7 public laboratories produced multi-source versions of 8 of the 15 medicines used in ARV therapy.

Among the key success factors cited as contributing to the phenomenal growth of the Brazilian domestic pharmaceutical industry was the establishment of publicly supported institutions.

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b Personal Communication: A. Kudlinski, Department of Trade and Industry. September 6, 2011.
for biomedical research and development, which led to increased production capability of government-owned pharmaceutical facilities. According to some data, two-thirds of research and development spending in Brazil came from the government, while only one-third was invested by the private sector. An additional factor was the promulgation in 2004 of legislation that encouraged more public-private cooperation by making it easier for public and private enterprises to share resources, raise capital and clarify intellectual property rights.

The abovementioned positive points notwithstanding, critics point out that the real ‘secret’ behind the high local contents and reduction of penetration of imported pharmaceuticals in Brazil is the promulgation of Federal Act No. 12 349 / 2010 “Public Procurement Law” (enacted 15 December 2010), which mandated the use of government procurement to stimulate the economy.26 The Act established price preference for domestic products and services for all sectors of the economy (including pharmaceuticals) of up to 25% relative to imports. Imported finished pharmaceutical products are subject to customs duties from 15% to 17% in Brazil, in contrast South Africa imposes no duty on pharmaceuticals. Furthermore, while Brazil was successful in reverse-engineering technologies for ARV APIs such as stavudine, zidovudine, nevirapine and lamivudine in the early 2000s, it encountered technology barriers in its attempts to manufacture more advanced ARV APIs, such as efavirenz, emtricitabine, and lopinavir/ritonavir. Currently, Brazil imports most of its ARV APIs from India and China. Some experts maintain that technology barriers in the manufacture of advanced chemical APIs or biologics and vaccines are so high (as Brazil has learnt) that it is cheaper and safer to license a technology rather than develop it domestically.27

While complete autonomy in relation to API production for ARVs is probably not unachievable, any progress in this regard will require the highest levels of political will and massive investment of resources. The Brazilian experience has demonstrated aptly that the road to self-sufficiency in the production of APIs does have potholes. In addition the achievement of the goal of reducing the country’s trade deficit in the process of supporting the country’s massive ART programme may have to be aided by the enactment of unpopular legislative measures. API production in the country may have to remain a longer-term goal that will not impact on medicines availability in the foreseeable future.

Conclusion and recommendations

This chapter has provided examples of aspects of the NDP that are currently implemented with some degree of success, especially as far as reducing the cost of medicines is concerned. Although the impact may not have been quantified in all the cases, considerable anecdotal evidence exists of the impact that many of the measures based on the NDP and implemented by government have had on medicines affordability.

The selection of medicines is considered key in ensuring equitable access to health care. The processes of selection may differ, depending on the sector (public or private) in SA. The application of the principles of evidence-based medicine, pharmacoconomics and budget impact analysis, however, should serve as strong criteria in the decision-making process and lead to effective medicines selection.

The selection of medicines requires a coherent approach. SA’s move towards NHI should provide an opportunity to engage with all stakeholders to ensure a successful transition to a more centralised system.

In addition, overseas examples of the use of academic units with expertise in the fields of health economics, evidence-based medicine, critical appraisal and other HTA aspects provides lessons that can be drawn on in SA. A willingness and enthusiasm in the academic sector to engage in these processes should be strongly encouraged and fostered.

Conducting full HTAs in SA may be unnecessary, as information can be drawn from other countries and institutions, which have the relevant expertise. While the HTA needs of the private and public healthcare sectors may differ presently, these are likely to become more streamlined with the introduction of NHI.

Developments in medicines procurement in the public sector in the past few years or so would seem to indicate that the transfer of the management of pharmaceutical tenders to the NDoH may ultimately lead a more cost-effective system of medicines procurement compared to previous years.

The fully fledged establishment of the CPA, which would centralise control of the country’s pharmaceutical budget, may have far-reaching Constitutional implications.

None of the measures implemented in the medicines supply chain seem to have a positive impact on medicines availability at PHC level. As indicated in this chapter, far more effort needs to be made at district level in this regard.

The move towards the production of APIs for the production of ARVs in the country is a positive one, but the fruits of such a venture, if eventually successful, may not be enjoyed in the foreseeable future. Also, little reason exists for believing that the establishment of a state-owned pharmaceutical manufacturing company will lead to a reduction of medicines prices.

Implementation of the country’s NDP was not accompanied by a monitoring and evaluation plan that would have allowed for a systematic assessment of its impact. Some clear benefits have emerged in some areas, such as in pricing and the establishment of the NEMIC and PTCs to oversee medicines selection and rational use. However, a comprehensive picture of the impact of the implementation of the NDP can only be gained through a robust review process. Such a review would also present an opportunity for the country’s pharmaceutical services to be realigned and re-engineered for NHI.

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References
