

# South Africa's National Drug Policy: 20 years and still going?

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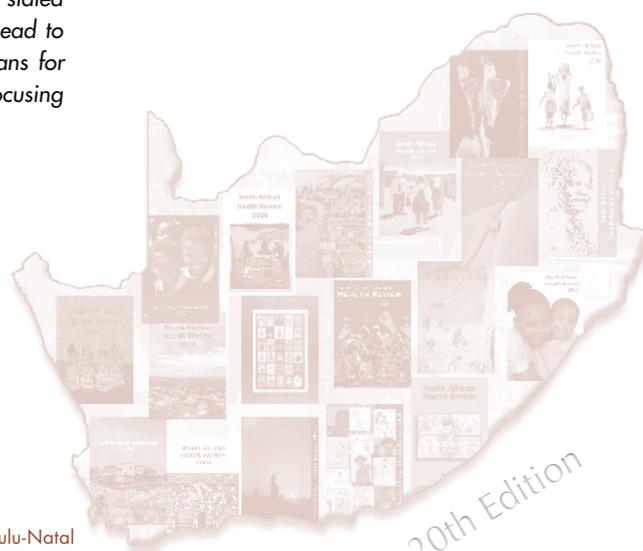
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It has now been 20 years since the National Drug Policy (NDP) was published in 1996. This was one of the earliest comprehensive policy documents issued by the first post-apartheid Department of Health, and was subsequently included as an appendix to the 1997 White Paper on the Transformation of the Health System in South Africa. The NDP was developed in response to seven policy questions/challenges posed by the Department, and set out three sets of objectives: health objectives, economic objectives, and national development objectives. Although elements of the implementation of the NDP have been addressed in previous editions of the South African Health Review and in various academic publications, no comprehensive evaluation has yet been attempted.

The process of implementing the NDP has varied from being straightforward to highly contested, with litigation by a variety of stakeholders and an important Constitutional Court judgment in relation to medicines pricing. A number of high-profile issues, in particular considerations of intellectual property law, have not been pursued as aggressively as expected. Other issues, such as the appropriate regulation of traditional medicines, remain unaddressed or inadequately addressed. This chapter critically examines the process of developing and implementing the NDP from 1994 to date, and for the first time, covers all the key elements of the policy and its stated objectives. Emphasis is on the impact of the policy, but also on looking ahead to identify which elements of the NDP need reconsideration in the light of plans for National Health Insurance. This analysis follows the Walt and Gilson model, focusing not only on content, but also the actors, context and process.

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## Introduction

The advent of democracy in 1994 posed significant health policy challenges for the new democratic government. The new Minister of Health, Dr Nkosazana Dlamini-Zuma, duly appointed a range of policy committees to inform government action. Among these was the 12-member National Drug Policy Committee (NDPC), appointed in August 1994. The NDPC presented its final report to the Minister in November 1994, and the Cabinet-approved policy document was issued in February 1996. Initial implementation was closely linked with the externally funded South African Drug Action Programme (SADAP).<sup>1</sup> Although the policy called for periodic review of the document, this has never occurred. Policy implementation continues to this day, albeit with the addition of new policy elements and details in response to changing circumstances, and despite resistance from various quarters.

## Methods

The present policy analysis used the Walt and Gilson approach<sup>2</sup> and was based primarily on publicly accessible documentation and peer-reviewed literature.

### The policy-development process

The policy development process initiated in August 1994 did not occur in a vacuum. Previous governments had established commissions of inquiry to investigate various aspects of medicines policy.<sup>3–5</sup> Each of these commissions noted problems with medicines supply, such as the overuse of branded medicines rather than generic equivalents, but none resulted in a cogent national medicines<sup>9</sup> policy, or the implementation of legislative changes (such as the enablement of generic substitution by pharmacists). Medicines regulation in South Africa was governed by the Medicines and Related Substances Control Act (101 of 1965), which came into effect in 1967.<sup>6</sup> The most recent amendments to the Act had not all been brought into effect by the time of the change of government in 1994.<sup>7</sup> In a last-gasp attempt, the apartheid-era Department of National Health and Population Development prepared a draft National Pharmaceutical Policy for South Africa in 1993.<sup>8</sup>

Nonetheless, the process by which the NDPC engaged with the terms of reference set by the Department of Health (Box 1) reflected the time pressure under which they had to operate, as well as the understandable conviction that new approaches and solutions were needed to break from the past. The policy-development phase and initial implementation of the NDP has been comprehensively reviewed; the review characterised the process as displaying “limited use of available knowledge, particularly from sources associated with the previous regime; some engagement with the broader drug policy community; preference for inputs based on the personal experiences and perspectives of individuals trusted by the Minister; ignoring advice that was not in alignment with central actors’ own views, with perhaps a failure to distinguish between opposition and constructive criticism; and less direct influence by international agencies than is the case in other developing countries”.<sup>9</sup> To some extent it was typical of processes that take advantage of periods of transition.<sup>10</sup> However, such processes also have to deal with the

constraints imposed by transition, such as “changes in leadership, loss of institutional memory and a rupture of old mechanisms of policy implementation”.<sup>9</sup>

### Box 1: The South African National Drug Policy Committee terms of reference, 1994

#### Seven key tasks:

1. Develop a pricing plan for drugs used in South Africa in the public and private sectors.
2. Develop a plan to ensure that drugs are tested and evaluated for effectiveness in the South African context, using epidemiological approaches.
3. Develop an Essential Drugs List to be used in the public sector and prepare treatment guidelines for health personnel.
4. Develop specific strategies to increase the use of generic drugs in South Africa.
5. Prepare a plan for effective procurement and distribution of drugs in South Africa, particularly in the rural areas.
6. Investigate traditional medicines.
7. Rationalise the structure for Pharmaceutical Services.

## Content of the National Drug Policy, 1996

The Cabinet-approved version of the NDP was finally issued in February 1996,<sup>1</sup> and was subsequently included as an appendix to the 1997 White Paper on the Transformation of the Health System in South Africa.<sup>11</sup> That White Paper opened with the statement: “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”. Implementation of the NDP should be judged against that professed aim of a unified health system, and the impact on both the public and private sectors.

The policy document sets out three main objectives, in the domains of health, economics, and national development, as outlined in Table 1.

The content of the policy was summarised in the 1996 *South African Health Review* (SAHR), with mention of a three-phase implementation plan based on the need for legislative intervention.<sup>12</sup> Subsequent progress reviews appeared in the 1997, 1998, 1999, 2000 and 2016 editions of the SAHR, each focused on a particular element.<sup>13–17</sup> Related chapters in the SAHR have dealt with access to antiretroviral treatment<sup>18</sup> and the use of mid-level workers in pharmacy.<sup>19</sup> The present analysis represents the first attempt to assess implementation and impact across all objectives outlined in the policy document.

## Legislation and regulations

The professed aim of this chapter of the policy was “to ensure that drugs reaching patients are safe, effective and meet approved standards and specifications”.<sup>1</sup> The intended steps were therefore to strengthen the Medicines Control Council (MCC) by ensuring its financial autonomy and investment in systems improvements (such as an electronic management information system (MIS)). Legislative changes were needed to introduce a five-year re-licensing system for all medicines, what was described as “an evaluation report

<sup>a</sup> In more recent usage, the term ‘drugs’ has been reserved for drugs of abuse, with the term ‘medicines’ preferred when referring to the licit market. Thus, the term National Medicines Policy would be preferred. Historical references to the NDP are therefore preserved, while abiding by the more modern terminology where possible.

Table 1: South African National Drug Policy objectives, 1996

Domain	Specific objectives
Health objectives	<ul style="list-style-type: none"> <li>• Ensure the availability and accessibility of essential drugs to all citizens.</li> <li>• Ensure the safety, efficacy and quality of drugs.</li> <li>• Ensure good dispensing and prescribing practices.</li> <li>• Promote the rational use of drugs by prescribers, dispensers and patients through provision of the necessary training, education and information.</li> <li>• Promote the concept of individual responsibility for health, preventive care and informed decision-making.</li> </ul>
Economic objectives	<ul style="list-style-type: none"> <li>• Lower the cost of drugs in both the private and public sectors.</li> <li>• Promote the cost-effective and rational use of drugs.</li> <li>• Establish a complementary partnership between government bodies and private providers in the pharmaceutical sector.</li> <li>• Optimise the use of scarce resources through co-operation with international and regional agencies.</li> </ul>
National development objectives	<ul style="list-style-type: none"> <li>• Improve the knowledge, efficiency and management skills of pharmaceutical personnel.</li> <li>• Re-orientate medical, paramedical and pharmaceutical education towards the principles underlying the NDP.</li> <li>• Support development of the local pharmaceutical industry and the local production of essential drugs.</li> <li>• Promote the acquisition, documentation and sharing of knowledge and experience through the establishment of advisory groups in rational drug use, pharmacoconomics and other areas of the pharmaceutical sector.</li> </ul>

Source: National Department of Health, 1996.<sup>1</sup>

exchange system with reputable regulatory bodies in other countries”, as well as a ‘fast-track’ procedure for essential medicines. The legislative-reform process has been the most contested, with considerable delays in implementation caused by litigation, initially by the transnational pharmaceutical industry.

The first Medicines and Related Substances Control Amendment Bill (30 of 1997) was tabled in Parliament but withdrawn after initial public hearings. A subsequent Bill was resubmitted to Parliament in August 1997 (Bill 72 of 1997), and passed as Act 90 of 1997.<sup>20</sup> Although some provisions dealt with issues highlighted in the NDP (for example, establishing the MCC as a juristic person, providing for expedited registration and re-registration every five years), the most controversial section appeared to provide for the issuing of compulsory licences for medicines. The new section 15C of the Act read: “The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may – (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent”. Although other provisions were also objected to, it was this provision that formed the basis for the legal challenge instituted by the Pharmaceutical Manufacturers’ Association (PMA) and 39 of its member companies in February 1998.<sup>21</sup> While this court action was ongoing, and on the advice of a ministerial advisory panel,<sup>22</sup> Parliament passed a new Amendment Act, which intended to replace the MCC with a new South African Medicines and Medical Devices Regulatory Authority (SAMMDRA).<sup>23</sup> Following the premature promulgation of this Act, without the necessary Regulations, the promulgation notice was reversed by the Constitutional Court.<sup>24</sup> When the PMA withdrew its court challenge in 2001, a subsequent Amendment Act was passed in 2002 (which repealed the SAMMDRA Act),<sup>25</sup> and both the 1997 and 2002 Acts were brought into effect from May 2003. Following a report by yet another ministerial advisory committee,<sup>26</sup> two more Amendment Acts have been passed by Parliament, in 2008<sup>27</sup> and 2015,<sup>28</sup> and now await promulgation. Once brought into effect, these two Amendment Acts (2008 and 2015) will replace the MCC with a new South African Health Products Regulatory Authority

(SAHPRA). The necessary Regulations were published for comment in January 2017.<sup>29</sup>

The final form of the proposed medicines regulatory authority (SAHPRA) bears little resemblance to what was proposed in the NDP. While section 15C has been retained, after 2003 it was interpreted to enable parallel importation, not compulsory licensing, and has never been used. The expedited registration provision inserted in 1997 will be removed, having been blamed for a burgeoning backlog in medicines registrations.<sup>30,31</sup> While South Africa has made considerable progress in advancing harmonisation (for example, joining the Pharmaceutical Inspection Co-operation Scheme, introducing the electronic Common Technical Document, achieving observer status at the International Conference on Harmonization, and joining the Zazibona initiative), there are still considerable challenges facing the new Authority. In January 2016, the African Union adopted a Model Law on Medical Product Regulation.<sup>32</sup> Domestication of the law entails consideration of how national law conflicts with the Model Law. One of the key provisions of the Medicines and Related Substances Act that has not been addressed is section 34, which hampers attempts to advance transparency in medicines regulatory practice. To date, the MCC has not been able to make a comprehensive medicines register publicly accessible, nor does it publish the grounds for registration decisions, in the form of public assessment reports.

The second target for this section of the policy was to ensure that “only practitioners who are registered with the relevant Council and premises that are registered and/or licensed ... may be used for the manufacture, supply and dispensing of drugs”. The key provision here was the introduction of a dispensing licence for authorised prescribers. Following a successful court challenge, this provision has been progressively weakened, but remains on the statute books as a regulatory hurdle, even though it has failed to reduce the number of dispensing practitioners.<sup>33</sup>

The inspectorate functions of the MCC were also constrained as a result of a court challenge.<sup>34</sup> No provincial inspectorate has been established. No MCC-operated laboratory has been established, and the contracted services at the Universities of the North West and Free State have been retained.

Although the medicines that may be prescribed by emergency personnel, optometrists and dental therapists have been listed for this purpose in the Schedules, little progress has been made in creating a specialist register for nurses, and an exceptional mechanism (section 56(6) of the Nursing Act, 2005) is still relied upon.<sup>35</sup> Other quality enhancement mechanisms have been mandated in other legislation, notably with the creation of the Office of Health Standards Compliance by the National Health Act, 2003.<sup>36</sup> Draft norms and standards Regulations for all health establishments were issued for comment by the Minister of Health in January 2017.<sup>37</sup> However, an enforceable code of marketing practice has not been developed, as enabled by the Act. The remit of the MCC (and in time SAHPRA) has been extended to cover medical devices and *in vitro* diagnostics.<sup>38</sup>

The 2002 Centre for Health Policy (CHP) assessment noted that “the NDP was confronted by a wide variety of sophisticated extra governmental players, including a well-established domestic pharmaceutical industry able to mobilise technical and legal resources to oppose policy”.<sup>9</sup> It also noted that while the NDP process “showed a high awareness of the actor environment”, there was only “partial recognition of the fact that policy implementation is inherently a process of constant negotiation and renegotiation”. Most importantly, the CHP analysis noted that “over time, the opportunities for negotiation have tended to diminish rather than expand”. The formal opportunities for engagement over legislation have been provided by public hearings before the National Assembly Portfolio Committee on Health (and, in 2015, provincial hearings), and by the opportunity to comment on draft Regulations and Guidelines. In addition, since the withdrawal of the PMA court challenge, an Industry Task Group (ITG) has provided for engagement between the MCC and industry stakeholders. However, the NDP legislative programme remains littered with delays or partial reversals caused by litigation. Amendments to South Africa’s intellectual property policy have been signalled but not yet implemented.<sup>39</sup>

Following adoption of the NDP, the chief directorate responsible for development and implementation of the policy identified sections that could be implemented immediately without any legislative changes, and those that would require changes to either the Pharmacy Act or the Medicines and Related Substances Control Act. Those requiring legislative amendments were placed in two categories: those likely to be accepted, albeit grudgingly in some instances, by the pharmaceutical industry, and those that would almost certainly lead to litigation. Generic substitution was considered to fit in the first category, and parallel importation in the second. However, a planned phased approach, which would have avoided some sections being held hostage by opposition to others, was not implemented as the Minister of Health opted for an ‘all-or-nothing’ approach. A single Amendment Act was therefore passed initially, and predictably interdicted, resulting in unnecessary delay of the less controversial elements, such as generic substitution.

One of the changes brought about by the 1997 Amendment Act was the extension of application of the Medicines Act to the State (similar to the provision in the Pharmacy Act). In July 2005, when these changes came into effect, the Chief Director: Pharmaceutical Policy and Planning, requested the Rational Pharmaceutical Management Plus (RPM Plus) project, which was funded by USAID and managed by Management Sciences for Health (MSH), to conduct an audit of all public-sector pharmacy facilities in order to determine their

compliance with the amended Pharmacy and Medicines Acts. The audit was conducted in eight provinces (the Western Cape had conducted its own audit earlier), and resulted in the allocation of additional resources to address identified deficiencies. One major outcome of the process was that virtually no public-sector hospital pharmacy operated without a full-time pharmacist.

## Medicine pricing

Although the aim of the “Drug pricing” chapter of the NDP, namely “to promote the availability of safe and effective drugs at the lowest possible cost” was clear, the means to achieve this were not clearly outlined.<sup>1</sup> The NDP stated that the aim would “be achieved by monitoring and negotiating drug prices and by rationalising the drug pricing system in the public and private sectors, and by promoting the use of generic drugs”.

The last of these changes – mandatory offer of generic substitution by all dispensers – was enabled by Act 90 of 1997; it was delayed by the PMA court challenge, and only brought into effect in 2003. Evidence from private-sector sales of selected pharmacological groups show that the change was anticipated by medical scheme administrators, who used mechanisms such as co-payments to promote generic substitution, even in advance of the legal change.<sup>40</sup> Overall, the level of generic utilisation in the private sector is only discernible from reports placed in the public domain by one medical scheme administrator, Mediscor. By 2015, 56.2% of items claimed were generic medicines, up from 38.3% in 2004.<sup>41</sup> Put another way, the 2015 report stated that, “in 76.5% of instances where a generic equivalent was available, the generic medicine was used”. Only biosimilars are now considered to be non-substitutable.

The highly contested introduction of a single exit price (SEP) for all medicines sold in the private sector, with a mandated maximum annual adjustment (single exit price adjustment or SEPA), and separate mandated maximum dispensing fees for pharmacists and licensed dispensing practitioners, has been comprehensively reviewed.<sup>15,16,42,43</sup> Following reversals in the High Court and Supreme Court of Appeal, the Minister of Health prevailed in the Constitutional Court, and the SEP/SEPA/dispensing-fee system was eventually implemented.<sup>44</sup> Though not discernible in the NDP, other proposed interventions, such as international benchmarking, have yet to be implemented.<sup>45</sup> Although the methodology for pharmacoeconomic evaluations has been finalised, such submissions remain voluntary.<sup>46,47</sup> Regulations to control bonusing, sampling and other perverse incentive schemes have also not been finalised.<sup>48</sup> That said, the prohibition on bonusing and sampling, included in the Act, is in place and is a major design component of the pricing intervention.

The medicine pricing interventions that have evolved are difficult to trace to the original policy document. In essence, this has been a demonstration of what was identified by the CHP analysis as missing: a “high degree of organisational reflexivity – the ability to learn from experience” (p. 82).<sup>9</sup> Policy has emerged from practice, informed by engagement with stakeholders, albeit at arms’ length. A degree of flexibility was evident in 2016, when the Minister of Health (on the advice of the Pricing Committee) enabled an additional maximum SEPA of 2.9%, in recognition of the effect of major currency shifts.<sup>49</sup> Another example of an emergent policy, not based on a principle set by the NDP, has been the use of therapeutic class tenders in the

public sector. That mechanism implies the application of therapeutic rather than generic substitution, which has yet to be enabled by legislation.

## Medicines selection

The aim of this chapter of the NDP reflected the clear influence of the World Health Organization (WHO): “to promote the rational choice of drugs and associated items to be used in South Africa, in accordance with the Essential Drugs concept”.<sup>1,50</sup> The policy called for the creation of a National Essential Drugs List Committee, appointed by the Minister of Health, which would be responsible for the selection of medicines to be used in the public sector. This is perhaps the easiest component of the policy to track, at least in terms of the creation of the national committee and the publication of standard treatment guidelines (STGs). The National Essential Medicines List Committee has been maintained, together with the requisite Expert Review Committees for each level of care, and a succession of editions of the STG/EMLs has been published. Although enabled by the National Health Act (61 of 2003), no Regulations have been issued to govern this process. A quantitative assessment of the outcomes of the public-sector selection process has been published, showing changes over time.<sup>51</sup> In-depth interviews with committee members have documented the refinement of selection methods over time.<sup>52</sup> Importantly, these committee members emphasised that “the development of an EML is only the starting point of the essential drugs programme (EDP) process; it must be effectively linked to the processes for procurement, supply, training, and monitoring and evaluation of prescribing and medicine use for it to make a positive impact and valuable contribution to better healthcare”.

Although small-scale surveys of adherence to STGs have been published,<sup>53</sup> there has been only one nationwide attempt to assess the quality of medicines use (using the WHO/INRUD indicator methodology) in 2003.<sup>54</sup> Some changes from baseline surveys conducted in 1998 were discernible: e.g. the mean number of items per prescription decreased from 2.5 in 1998 to 2.2 in 2003, the percentage of medicines prescribed from the EML increased from 65% to 90%, and the percentage of encounters in which an injection was prescribed decreased from 11% to 5%, but the percentage of encounters in which an antibiotic was prescribed increased from 36% to 47%. Some assessments of the quality of medicines use in the private sector have also been conducted, using medical scheme claims databases.<sup>55–62</sup>

The Lancet Commission on Essential Medicines Policies has provided a comprehensive overview of the many interventions shown to advance quality use of medicines.<sup>63</sup> The Commission has also underscored the critical role of rational medicines selection in supporting the development of sustainable medicines benefit packages for universal health coverage (UHC). As South Africa implements National Health Insurance (NHI) (as UHC is termed locally), more attention must be paid to the use of tools such as health technology assessment (HTA) to support medicines selection.<sup>64</sup> Although some contact has been made with HTA agencies in other settings, such as the UK and Thailand, no formal process is yet in place. The limits of the tender system are clearly demonstrated when confronted by the need for expensive, single-source medicines such as those needed in oncology, drug-resistant tuberculosis, hepatitis C

and as second- and third-line antiretrovirals. The Lancet Commission has also recommended that “governments and the main public or private payers should establish independent pharmaceutical analytics units (or equivalent) to focus on generating information for action to promote quality use”. No equivalent to the Australian NPS MedicineWise has been created in South Africa, dedicated to promoting quality use of medicines and measuring the impact of attempted interventions.

As with many other areas of the NDP, there have been positive developments not envisaged in 1996, such as a mobile ‘app’ for the STG/EMLs. However, any attempts to reach out to the private sector have, to date, been tentative. In particular, there has been no clear articulation with the Prescribed Minimum Benefit algorithms used in the private sector.<sup>65</sup>

## Procurement and distribution

The NDP aimed to “ensure an adequate supply of effective and safe drugs of good quality to all people in South Africa”, by “promoting cost-effectiveness in the public sector and by utilizing private sector facilities where appropriate”.<sup>1</sup> Procurement processes were influenced by the fiscal federalism entrenched from 1996, when the final Constitution came into effect. A number of ministerial committees have addressed the issue of medicines procurement.<sup>66,67</sup> Reporting on medicines availability in public-sector facilities has been highlighted in the Pharmaceutical Dashboard that is now a regular feature of National Health Council meetings, and technological innovations (such as the Stock Visibility System (SVS) initiative and the roll-out of the RxSolution software in all provinces) are in process. In 2015/16, through the Central Chronic Medicines Dispensing and Distribution (CCMDD) programme, just under 400 000 patients received their prescribed medicines from over 1 000 pick-up points. Although not without its challenges, the system considerably improved distribution of medicines closer to patients’ homes. In addition, the SVS had been implemented in just under 2 000 clinics countrywide by 2016, while electronic stock management (RxSolution) was rolled out to hospitals in all provinces bar the Western Cape. It is noteworthy that this is the first time that a uniform stock-management system has been implemented in all public sector hospitals. All these initiatives were implemented with the support of donor-funded implementing partners.

Nonetheless, publicly accessible data on medicines availability are rare. Some evidence of withdrawal of essential medicines from the market has been documented.<sup>68</sup> The civil society-driven Stop Stock Outs Project (SSP) published its third report in 2016, based on telephonic surveys of public sector facilities.<sup>69</sup> Also in 2016, a report on the management of pharmaceuticals at national and provincial levels of the public sector was issued by the Auditor-General of South Africa (AGSA).<sup>70</sup> Although the AGSA noted the existence of current efforts to address the quality of pharmaceutical services, including the CCMDD programme and the Ideal Clinic initiatives, the overall assessment was critical. It was noted, for example, that while the necessary operational policies were in place, they were not implemented consistently. The AGSA was of the opinion that pharmaceutical budgets did not align with health needs, and that pharmaceutical infrastructure (both human and physical) was inadequate to meet patient needs. Inadequate performance by the provincial pharmaceutical depots was also identified.

The NDP also set out to “stimulate the national pharmaceutical industry to manufacture and market drugs on the National List of Essential Drugs, and to promote national self-sufficiency in the production of these drugs”.<sup>1</sup> While some elements have been implemented (such as local preference policies in procurement, consistent with other national policies), concerted action in this regard is difficult to identify. There is an unresolved tension between the NDP’s economic and health objectives. This tension has not been comprehensively assessed in the present analysis and warrants a separate effort. The Department of Trade and Industry’s Industrial Policy Action Plan 2016/17–2018/19 notes the decision by Cipla, for instance, to invest R800 million in a new biosimilars facility at the Dube Tradeport.<sup>71</sup> In 2007, the 52nd National Conference of the African National Congress resolved to “explore the possibility of a state-owned pharmaceutical company that will respond to and intervene in the curbing of medicine prices”.<sup>72</sup> The Department of Science and Technology has been investigating various options for the state-owned Khetlaphela facility at Pelindaba.<sup>73</sup>

The ability to assess progress with regard to the procurement and distribution of medicines, even if only for the public sector, is hampered by lack of transparency. Where progress is being made, reporting is internal (such as to the National Health Council), and it is only when reports such as that from the AGSA or from civil society are released, that insight into the performance of pharmaceutical logistics can be gleaned. The mismatch between what is reported, and what is intended, is palpable. Exactly how the systems currently in place for medicines procurement and distribution might have to be altered to fit the strictures of a funder-provider split under NHI has yet to be detailed, or even debated.

## Rational use of drugs

The NDP aimed to “promote the rational prescribing, dispensing and use of drugs by medical, paramedical and pharmaceutical personnel and to support the informed and appropriate use of drugs by the community”.<sup>1</sup> The identified interventions were “appropriate training, the provision of scientifically validated drug information for professionals and the community, the establishment of hospital therapeutic committees, good dispensing practice and an enhanced role for the pharmacist, and control of commercial marketing practices”. Considerable impact on undergraduate and post-graduate curricula at health science tertiary institutions is evident, although the extent to which changes have been institutionalised in the health system remains, sadly, undocumented. Where support has been provided from donor-funded programmes, such as the USAID-funded Strengthening Pharmaceutical Systems (SPS) and Systems for Improved Access to Pharmaceuticals and Services (SIAPS) programmes executed by MSH, process indicators have been reported. Importantly, such support has resulted in significant policy decisions, at both provincial and national level; for instance, SPS and SIAPS support of the Gauteng Health Department’s efforts led to publication of Gauteng Health’s PTC Manual, which was subsequently disseminated provincially by the NDoH to influence possible adoption as national policy.

As mentioned, a self-regulatory Marketing Code Authority (MCA) has been established, but its code of practice does not have legal backing, and the enforceable code envisioned by section 18C of the Medicines and Related Substances Act (1965) is still not in place. Introduction of a patient information leaflet should have improved

patient access to approved medicines information, but its impact has not been assessed. No other patient-directed or community-directed activities can be traced directly to the NDP or SADAP. Although the WHO has provided model medicines formularies for adaptation by national authorities, the *South African Medicines Formulary* (SAMF) remains a university-driven effort, owned by the South African Medical Association, and distributed on a for-profit basis. The AGSA’s report underscores the consequences of persistent under-investment in pharmaceutical systems,<sup>61</sup> despite a marked increase in the number of pharmacists employed in the public sector since implementation of the occupation-specific dispensation (OSD) remuneration package.<sup>74</sup>

The NDP envisaged expanded “research on social and cultural factors which influence medicines usage”, which would have required specific support for operational research, and deliberate engagement with academic partners as well as the responsible science councils (Medical Research Council and Human Sciences Research Council). Although there were efforts in this regard by SADAP, nothing remotely approaching the level of investment that has characterised the Australian system (NPS Medicinewise) was possible in South Africa.

Perhaps the most debated line in this chapter is one that, at first glance, is unremarkable: “At primary level prescribing will be competency, not occupation, based.” That injunction has been accomplished by the amendment of section 22A of the Medicines and Related Substances Act, 1965, which recognises authorised prescribers other than medical practitioners and dentists. However, as shown above, the process is not yet complete, in particular with reference to the recognition of specialist nurse prescribers.

Recently, particular attention has been focused on the rational use of antimicrobials. In 2001, the National Antimicrobial Resistance Strategy Framework was launched in an attempt to improve “the appropriate use of antimicrobials over the next five years” in order “to manage antimicrobial resistance and limit further increases in resistant microbial infections, and improve patient outcomes”.<sup>75</sup> It is still too early to determine if this framework will be successful.

## Human resources development

The NDP aimed to “develop expertise and human resources to support the successful implementation of the policy and to promote the concepts of essential drugs and rational drug use and ensure their adoption throughout the country”. One of the key proposals was to encourage the requirement of continuing competence as a basis for registration of health professionals. Continuing professional development provisions have been instituted for most health professionals, but are, inexplicably, still not finalised for pharmacists. Some progress is evident in the publication of draft qualifications for a new cadre of pharmacy-support personnel (pharmacy technicians), published for comment in late 2016.<sup>76,77</sup>

## Research and development

The NDP aim was to “promote research that will facilitate the implementation, monitoring and evaluation of the National Drug Policy and/or meet the health care needs of the country”.<sup>1</sup> As with the operational research envisaged as part of rational medicines use, no specific, ring-fenced funding of research specifically

intended to support the NDP was provided. Where research has been conducted, as cited in this chapter, funding has been obtained from a variety of sources. Only one nationwide assessment of the Essential Drugs Programme was conducted, in 2003.<sup>54</sup> Comparison with provincial baseline data from 1998 was possible, but no follow-on assessment was possible.

### Technical co-operation with other countries and international agencies

The NDP envisaged “ongoing technical cooperation with international agencies, such as the WHO, and the maintenance and strengthening of this cooperation”.<sup>1</sup> There was support for initial development of the policy document; a draft version was discussed with WHO staffs,<sup>8</sup> and the UK Department for International Development’s support for SADAP was provided via the WHO. The extent of contact with the African regional office of the WHO has been less obvious. In the post-apartheid era, South Africa has re-established contact with such structures as the Commonwealth Pharmacists Association and the International Pharmaceutical Federation. As noted before, there is also greater involvement in international medicines regulatory harmonisation efforts. Contact has also been established with HTA agencies, including NICE International.

### Traditional medicines

The NDP echoed the wording of the NDPC’s terms of reference, aiming to “investigate the use of effective and safe traditional medicines at primary level”. The policy details varied from the specific (“marketed traditional medicines will be registered and controlled”), to the long-term and aspirational (“a national reference centre for traditional medicines will be established”). The reference centre was instructed to compile a “national formulary of Medicines Control Council approved ‘essential traditional medicines’”.

A draft Policy on African Traditional Medicines for South Africa was published for comment in 2008.<sup>78</sup> The draft policy envisaged the establishment of a National Institute of African Traditional Medicines, although the regulation of African Traditional Medicines (ATM) was considered to fall within the ambit of a medicines authority regulatory. Nonetheless, it was argued that the “current legislation” did not cater for ATM and that *sui generis* legislation was warranted. Despite the passage of the Traditional Health Practitioners Act of 2007, no such enabling legislation has yet been developed, tabled or passed by Parliament.<sup>79</sup>

### Monitoring and evaluation

The NDP aimed to “support the successful implementation of the National Drug Policy through establishing mechanisms for monitoring and evaluation of performance and impact that will identify possible problems and effective strategies”. In particular, it was planned that a full evaluation of the NDP would take place every three years. No such evaluation has been conducted, beyond the evaluations of SADAP conducted for the donor, for which no reports were placed in the public domain. Point 9 of The Health Sector 10-point Plan for 2009–2014, was review of the NDP. The mid-term report, published in 2011, stated that “The Drug Policy was reviewed in 2009”.<sup>80</sup> Although no new policy document was produced, the

report noted the “development and passing of legislation to improve the performance of the Medicines Control Council”. Although not placed in the public domain, a comprehensive report on the NDP, with detailed recommendations for future work, was developed by a task team appointed by the then Minister, Barbara Hogan, in 2009.<sup>81</sup>

### Overall assessment

The WHO guidance for the development of national medicines policies was updated in 2001, after development of the NDP.<sup>50</sup> A careful, stepwise process of developing and implementing a prioritised action plan was recommended. However, as the 2002 CHP analysis pointed out, “the challenge of implementation is less a matter of following blue-prints and recipes than of ‘learning by doing’” (p. 82).<sup>9</sup> It is clear from the assessment provided in this analysis that the NDP has, in part, not been implemented as originally envisaged. However, in significant sections of the policy, notably in relation to medicine pricing, policy detail has emerged over time. That said, the observation that “over time, the opportunities for negotiation have tended to diminish rather than expand” is still appropriate.<sup>9</sup> While formal opportunities for engagement, such as parliamentary hearings and opportunities to comment on draft legislation (mainly secondary), have been presented, other consultative fora (such as the National Health Consultative Forum) have largely lapsed. Much of the detailed debate now occurs in the National Health Council technical committees, with membership restricted to senior bureaucrats and political office-bearers. Where space for engagement has been created, that has been restricted to specifically mandated actors, such as the MSH-managed and USAID-funded projects (RPM Plus, SPS and SIAPS), with some academic involvement from selected pharmacy schools. Emphasis has largely been on systems-strengthening activities and the deployment of tools that have the intended effect of making essential medicines available and their use rational. What is entirely unclear is whether the original 1996 policy document is still regarded as a guide to action. That the 2009 review did not produce an updated National Medicines Policy is obvious. In the process of finalising the White Paper on NHI, careful consideration should be paid to systems for delivering affordable, quality essential medicines. The abbreviation ‘NDP’ now refers to the National Development Plan,<sup>82</sup> but a clear and comprehensive National Medicines Policy is still needed to guide this critical component of UHC.

### Disclosure

The analysis provided in this chapter represents both an ‘insider’ and ‘outsider’ perspective, as the authors were intimately involved at various stages in the process. AG contributed to two external reviews of SADAP, has been a member of various ministerial task teams in this area, and currently serves on the Medicines Control Council and National Essential Medicines Committee. FS has served on various ministerial task teams and is the current chair of the Pricing Committee. BP was a member of the NDPC, has chaired two ministerial task teams, and was Chief Director: Registration, Regulation and Procurement in the National Department of Health.

## References

- 1 South African National Department of Health. National Drug Policy for South Africa. Pretoria: NDoH; 1996.
- 2 Walt G, Gilson L. Reforming the health sector in developing countries: the central role of policy analysis. *Health Policy Plan.* 1994;9(4):353–70.
- 3 Republic of South Africa. Report of the Commission of Inquiry into High Costs of Medical Services and Medicines (The Snyman Commission). Pretoria: Government Printer; 1962.
- 4 Republic of South Africa. Report of the Commission of Inquiry into the Pharmaceutical Industry (The Steenkamp Report). Pretoria: Government Printer; 1978.
- 5 Republic of South Africa. Final report of the Commission of Inquiry into Health Services. Pretoria: Government Printer; 1986.
- 6 Republic of South Africa. Medicines and Related Substances Control Act (101 of 1965). Renamed the Medicines and Related Substances Act (101 of 1965) since 2003.
- 7 Republic of South Africa. Medicines and Related Substances Control Amendment Act (94 of 1991).
- 8 South African Department of National Health and Population Development. Draft National Pharmaceutical Policy for South Africa. Pretoria: SADNHPD; 1993.
- 9 Gray A, Matsebula T, Blaauw D, Schneider H, Gilson L. Policy change in a context of transition: drug policy in South Africa 1989–1999. Johannesburg: Centre for Health Policy, University of the Witwatersrand; 2002.
- 10 Reich MR. The politics of health sector reform in developing countries: three cases of pharmaceutical policy. *Health Policy.* 1995;32:47–77.
- 11 South African National Department of Health. White Paper for the Transformation of the Health System in South Africa. General Notice No. 667, Government Gazette No. 17910, 16 April 1997.
- 12 Summers R, Suleman F. Drug Policy and Pharmaceuticals. In: Harrison D, editor. *South African Health Review 1996.* Durban: Health Systems Trust; 1996.
- 13 Gray A, Eagles P. Drug policy. In: Barron P, editor. *South African Health Review 1997.* Durban: Health Systems Trust; 1997.
- 14 Gray A. Equity and the provision of pharmaceutical services. In: Ntuli A, editor. *South African Health Review 1998.* Durban: Health Systems Trust; 1998.
- 15 Gray A, Suleman F. Drug policy – from macro development to health district implementation. In: Crisp N, Ntuli A, editors. *South African Health Review 1999.* Durban: Health Systems Trust; 1999.
- 16 Gray A, Matsebula T. Drug pricing. In: Crisp N, Ntuli A, Clarke E, editors. *South African Health Review 2000.* Durban: Health Systems Trust; 2001.
- 17 Bangalee V, Suleman F. Towards a transparent pricing system in South Africa: trends in pharmaceutical logistics fees. In: Padarath A, King J, Mackie E, Casciola J, editors. *South African Health Review 2016.* Durban: Health Systems Trust; 2016.
- 18 Ijumba P, Poole C, George G, Gray A. Access to antiretroviral therapy. In: Ijumba P, Day C, Ntuli A, editors. *South African Health Review 2003/2004.* Durban: Health Systems Trust; 2004.
- 19 Gray A, Gengiah T, Naidoo P. The pharmacist's assistant – a case study of a mid-level worker option. In: Ijumba P, Barron P, editors. *South African Health Review 2005.* Durban: Health Systems Trust; 2005.
- 20 Republic of South Africa. Medicines and Related Substances Control Amendment Act (90 of 1997). Government Gazette Vol. 390, No. 18505, Cape Town, 12 December 1997.
- 21 Pharmaceutical Manufacturers' Association v President of the Republic of South Africa. Case No. 4183/98; High Court of South Africa, Transvaal Provincial Division.
- 22 Dukes G, Hill S, Summers R, Bannenberg W. The medicines regulatory system in South Africa: review and proposals for reform. Pretoria: South African National Department of Health, 1998.
- 23 Republic of South Africa. South African Medicines and Medical Devices Regulatory Authority Act (132 of 1998).
- 24 Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex Parte President of the Republic of South Africa and Others (CCT31/99) [2000] ZACC 1; 2000 (2) SA 674; 2000 (3) BCLR 241 (25 February 2000).
- 25 Republic of South Africa. Medicines and Related Substances Amendment Act (59 of 2002).
- 26 Report of the Ministerial Task Team on the Restructuring of the Medicines Regulatory Affairs and Medicines Control Council and Recommendations for the new Regulatory Authority for Health Products of South Africa. Pretoria: South African National Department of Health, 25 February 2008.
- 27 Republic of South Africa. Medicines and Related Substances Amendment Act (72 of 2008). Government Gazette, Vol. 426, No. 32148, Cape Town, 21 April 2009.
- 28 Republic of South Africa. Medicines and Related Substances Amendment Act (14 of 2015). Government Gazette, Vol. 607, No. 39585, Cape Town, 8 January 2016.
- 29 Minister of Health General Regulations to the Medicines and Related Substances Act. Government Notice No. 50, Government Gazette No. 40577, 27 January 2017.
- 30 Leng HMJ, Sanders D, Pollock AM. Pro-generics policies and the backlog in medicines registration in South Africa: implications for access to essential and affordable medicines. *GaBI J* 2015;4(2):58–63.
- 31 Leng HMJ, Pollock AM, Sanders D. The impact of the Medicines Control Council backlog and fast-track review system on access to innovative and new generic and biosimilar medicines of public health importance in South Africa. *S Afr Med J.* 2016;106(4):350–3.
- 32 PharmaAfrica. African Union Heads of State make a major policy decision to improve medicines regulation. 1 February 2016.
- 33 The Affordable Medicines Trust v the Minister of Health and Others 2005 JOL 13932 (CC).
- 34 Mistry v Interim National Medical and Dental Council and Others (CCT13/97) [1998] ZACC 10; 1998 (4) SA 1127; 1998 (7) BCLR 880 (29 May 1998).
- 35 Gray A. Prescribing and dispensing by nurses – neglected steps in the legislative process. *HIV Nursing.* 2010;1(2):28–31.
- 36 Republic of South Africa. National Health Act (61 of 2003). Government Gazette Vol. 469, No.26595, Cape Town, 23 July 2004.
- 37 Minister of Health. Norms and standards regulations applicable to different categories of health establishments. Government Notice No. 10, Government Gazette No. 40539, 4 January 2017.

- 38 Minister of Health. Medicines and Related Substances Act: Regulations: Medical devices and in vitro diagnostic medical devices. Government Notice No. 1515, Government Gazette, No. 40480, 9 December 2016.
- 39 Minister of Trade and Industry. Draft National Policy on Intellectual Property, 2013. General Notice No. 918, Government Gazette No. 36816, 4 September 2013.
- 40 Gray AL, Santa-Ana-Tellez Y, Wirtz VJ. Impact of the introduction of mandatory generic substitution in South Africa: private sector sales of generic and originator medicines for chronic diseases. *Trop Med Int Health*. 2016; 21(12):1504–12.
- 41 Mediscor. Mediscor Medicines Review 2015. Centurion: 2015.
- 42 Gray A, Suleman F. Pharmaceutical pricing in South Africa. In: Babar Z, editor. *Pharmaceutical Prices in the 21st Century*. Cham: Springer International Publishing; 2015.
- 43 Suleman F, Gray A. Pharmaceutical Policies in South Africa. In: Babar Z, editor. *Pharmaceutical Policy in Countries with Developing Healthcare Systems*. Cham: Springer International Publishing; 2017.
- 44 Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others (CCT 59/2004) [2005] ZACC 14; 2006 (2) SA 311 (CC); 2006 (1) BCLR 1 (CC) (30 September 2005).
- 45 Minister of Health Medicines and Related Substances Act. Regulations relating to a transparent pricing system for medicines and scheduled substances: (Benchmark Methodology). Government Notice No. R.354, Government Gazette No. 37625, 12 May 2014.
- 46 South African National Department of Health. Medicines and Related Substances Act. Publication of the guidelines for pharmaco-economic sub-missions. Government Notice No. R.68, Government Gazette No. 36118, 1 February 2013.
- 47 Stander MP, Bergh M, Miller-Jansön H. A first step towards transparency in pricing of medicines and schedules substances – publication of guidelines for pharmaco-economic submissions. *S Afr Med J*. 2014;104(1):10–11.
- 48 Minister of Health. Medicines and Related Substances Act. General regulations relating to bonusing and sampling. Government Notice No. R.642, Government Gazette No. 37936, 22 August 2014.
- 49 Minister of Health. Medicines and Related Substances Act. Interim adjustment of single exit price of medicines and scheduled substances (SEPA) for 2016. Government Notice No. 893, Government Gazette No. 40188, 5 August 2016.
- 50 World Health Organization. *How to develop and implement a national drug policy*. 2nd ed. Geneva: WHO; 2001.
- 51 Perumal-Pillay VA, Suleman F. Quantitative evaluation of essential medicines lists: the South African case study. *BMC Health Serv Res*. 2016;16(1):687.
- 52 Perumal-Pillay VA, Suleman F. Selection of essential medicines for South Africa – an analysis of in-depth interviews with national essential medicines list committee members. *BMC Health Serv Res*. 2017;17(1):17.
- 53 Cassimjee M, Suleman F. Adherence to hypertension treatment guidelines in state facilities in KwaZulu-Natal, South Africa. *J Eval Clin Pract*. 2009;15(6):1077–81.
- 54 South African National Department of Health. *Impact of the Essential Drugs Programme at Primary Health Care level in South Africa*. Pretoria: NDoH; 2003.
- 55 Van Heerden JA, Burger JR, Gerber JJ. Inappropriate medicine prescribing in older South Africans: A cross-sectional analysis of medicine claims data. *S Afr Med J*. 2016;106(10):1010–6.
- 56 Meuwesen WP, du Plessis JM, Burger JR, Lubbe MS, Cockeran M. Prescribing patterns of non-steroidal anti-inflammatory drugs in chronic kidney disease patients in the South African private sector. *Int J Clin Pharm*. 2016;38(4):863–9.
- 57 Truter I, Kotze TJ, Knoesen BC. Dispensing of the combination of amoxicillin with clavulanic acid to elderly patients: a database analysis. *Value Health*. 2015;18(7):A748.
- 58 Truter I. Anti-dementia medicine dispensing patterns: a community pharmacy database analysis. *Value Health*. 2015;18(7):A746.
- 59 Truter I. Prescribing patterns of anti-migraine medicines in South Africa using a claims database. *Int J Clin Pharm*. 2015;37(3):447–51.
- 60 Truter I, Shankar S, Bennie M, Woerkom MV, Godman B. Initiatives in South Africa to enhance the prescribing of generic proton pump inhibitors: findings and implications. *J Comp Eff Res*. 2015;4(2):123–31.
- 61 Truter I. Prescribing of drugs for Alzheimer's disease: a South African database analysis. *Int Psychogeriatr*. 2010;22(2):264–9.
- 62 Katende-Kyenda NL, Lubbe MS, Serfontein JH, Truter I. Inappropriateness of antimicrobial prescription in private primary health care settings in South Africa. *S Afr Med J*. 2006;96(8):704–5.
- 63 Wirtz VJ, Hogerzeil HV, Gray AL, et al. Essential medicines for universal health coverage. *Lancet*. 2017;389(10067):403–76.
- 64 Blecher M, Pillay A, Patcharanarumo W, et al. Health financing lessons from Thailand for South Africa on the path towards universal health coverage. *S Afr Med J*. 2016;106(6):533–4.
- 65 Nicolosi E, Gray AL. Potential costs savings from generic medicines – protecting the Prescribed Minimum Benefits. *S Afr Fam Pract*. 2009;51(1):59–63.
- 66 Gray A, Pharasi B (chair), Quinot G, Suleman F, Dubula V. Report of the Ministerial Task Team on procurement: ensuring medicines availability at facilities through innovative procurement and distribution models. Prepared for the South African National Department of Health. Pretoria: NDoH; 2013.
- 67 Pharasi B (chairman) et al. *Medicines Procurement Reform in the Public Sector – Challenges and Opportunities for Improvement of Medicines Procurement in South Africa's Public Sector*. Prepared for the South African National Department of Health. Pretoria: NDoH; 2010.
- 68 Wilmshurst JM, Blockman M, Argent A, Gordon-Graham E, Thomas J, Whitelaw A, McCulloch M, Ramiah M, Dyeshana H, Ireland J; Drugs and Therapeutics Committee. Leaving the party – withdrawal of South African essential medicines. *S Afr Med J*. 2006;96(5):419.
- 69 Stop Stock Outs Project. 2015 Stop Stockouts National Survey: Third Annual Report – South Africa. 2016.
- 70 Auditor-General South Africa. Performance audit of the management of pharmaceuticals at departments of health. Pretoria; AGSA:2016.
- 71 South African National Department of Trade and Industry. *Industrial Policy Action Plan 2016/17–2018/19*. Pretoria; DTI: 2016.

- 72 African National Congress. 52nd National Conference: Resolutions. 20 December 2007. [Internet]. [cited 24 April 2017]  
URL: <http://www.anc.org.za/content/52nd-national-conference-resolutions>
- 73 Skosana I. New state-run pharmaceutical company to produce ARVs by 2019. *Bhekisisa*, 17 February 2016.
- 74 Day C, Gray A. Health and related indicators. In: Padarath A, Barron P, editors. *South African Health Review 2017*. Durban: Health Systems Trust; 2017.
- 75 South African National Department of Health. *Antimicrobial Resistance National Strategy Framework, 2014–2024*. Pretoria: NDoH; 2014.
- 76 South African Pharmacy Council. Qualification for pharmacy support personnel: diploma: pharmacy technician. Board Notice 196 of 2016, *Government Gazette* No. 40522, 23 December 2016.
- 77 South African Pharmacy Council. Qualification for pharmacy support personnel: occupational certificate: pharmacy technician. Board Notice 198 of 2016, *Government Gazette* No. 40522, 23 December 2016.
- 78 Minister of Health. Draft Policy on African Traditional Medicines for South Africa. General Notice No. 906, *Government Gazette* No. 31271, 25 July 2008.
- 79 Republic of South Africa. *Traditional Health Practitioners Act (22 of 2007)*. *Government Gazette* Vol. 511, No. 30660, Cape Town, 10 January 2008.
- 80 South African National Department of Health. *Progress Report on the Implementation of the 10 Point Plan of the Health Sector 2009–2014*. Pretoria: NDoH; 2011.
- 81 Matsoso MP (chair) et al. *Report of the Medical Products Technical Task Team*. Prepared for the South African National Department of Health. Pretoria: NDoH; 2009.
- 82 National Planning Commission. *National Development Plan 2030*. Pretoria: National Planning Commission; 2012.