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Unpacking the process of developing South Africa's national drug policy – lessons for universal health coverage

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ABSTRACT

Background: South Africa's National Drug Policy (NDP) was first issued in 1996, at a time of considerable political change.

Objectives: To revisit the lessons learned from the process of development and initial implementation of the NDP.

Methods: Six in-depth face-to-face interviews were held with purposively-selected key actors. Interviews, which followed pre-determined semi-structured questions, but were allowed to explore additional areas, were recorded and transcribed, and then subjected to abductive thematic analysis, informed by the Walt and Gilson model.

Results: Three key themes emerged, described as 'evidence', 'trust' and 'looking forward'. A paucity of evidence backed some of the key concepts in the NDP, and these have not been addressed as evidence has matured. The lack of trust which characterised the policy process impacted on the ways in which actors were able to or not able to engage, and therefore on the resultant content and the choices exercised. The coherence of the policy, its articulation with other health reforms, and its contribution to subsequent efforts to ensure universal health coverage in South Africa have all been weakened by the failure to revise the document over time.

Conclusion: As South Africa advances its plans for universal health coverage, there is an urgent need to revisit key components of the NDP which are no longer fit for purpose.

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KEYWORDS policy; universal health coverage; actor engagement; policy development; implementation

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Introduction

South Africa's national medicines policy[1] was published in 1996, during the first post-apartheid administration (South African Department of Health, 1996). The South African National Drug Policy (NDP) has been widely lauded, most notably because of the perceived outcome of the court challenge mounted in 1997 by the Pharmaceutical Manufacturers' Association (PMA) and its member companies, and the impression that the policy was directly responsible for access to affordable antiretroviral therapy (Ford et al., 2011; Klug, 2012; Pharmaceutical Manufacturers' Association, 1998). Although the subsequent linkages are evident, they are by no means as simple as often portrayed. In order to understand the constraints faced at the time of the policy's development, it is important to frame the context of the policy processes at that point.

The NDP was developed in response to the need to revisit all health policy and legislation in the country, in the wake of the democratic transition following the first election based on universal suffrage, held in April 1994. The first post-apartheid Minister of Health, Dr Nkosazana Dlamini-Zuma, initiated a series of policy committees and inquiries after the formation of the Government of National Unity. The National Drug Policy Committee (NDPC) was established in August 1994, and urged to present its report by the end of that year. After an internal drafting exercise, the Cabinet-approved policy document was published in February 1996 (South African Department of Health, 1996). In parallel, in January 1995, the Minister created a Committee of Inquiry into a National Health Insurance System (the Broomberg-Shisana committee) (South African Department of Health, 1995). Although South Africa inherited a Westminster-style policy process, in which initial draft policies are commonly published as Green Papers, followed by final policy documents as White Papers, this process was not followed in relation to the NDP. Instead, it was appended to the White Paper on the Transformation of the Health System in South Africa, issued in 1997 (Minister of Health, 1997a). The Westminster process was only entrenched in 2020, in the form of a Cabinet-approved National Policy Development Framework (The Presidency, 2020).

The South African NDP, as published in 1996, addressed three sets of objectives, described as health objectives, economic objectives and national development objectives (South African Department of Health, 1996). The objectives are shown in Table 1. It was arranged as 13 chapters, with the operative chapters covering legislation and regulations, medicine pricing, medicines selection, procurement and distribution, rational use, human resources development, research and development, technical co-operation, traditional medicines, and monitoring and evaluation.

[1]Over time, the nomenclature has changed; WHO now refers to national medicines policies, as opposed to national drug policies. The usage of the time is followed, where appropriate.

Table 1. Objectives of the South African National Drug Policy, 1996 (South African Department of Health, 1996).

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

The World Health Organization (WHO) first published guidance on the development of an NDP in 1988 (WHO, 1988), with a second edition (entitled 'How to develop and implement a national drug policy') issued in 2001 (WHO, 2001). The South African process therefore fell between these two editions. Both WHO guidelines predated the development of the WHO Guideline Review Committee, which was intended to improve the quality of such documents and ensure an explicit link between evidence and guidance (WHO, 2012). The guidance on developing national medicines policies has not been revisited since 2001. The 1988 guidance document explained the role of NDPs as follows: 'The goal of a drug policy is to develop, within the resources of a country, the potential that drugs have to control common diseases and alleviate suffering' (WHO, 1988). It recognised that 'countries are at different stages of development and may already have various policies and methods for their implementation'. In particular, the guidance recognised the need for clear legislative enablement of the policy components, aligned to the circumstances of each country: 'The legal framework must take into account not only policy objectives but also the administrative, social, and health infrastructure, the available manpower, and other resources. The formulation of a drug policy should be followed immediately by enactment of appropriate legislation and introduction of regulations to provide a legal basis and make the policy enforceable'. National medicines

policies are therefore a critical component of overall national health policy, but need to be carefully aligned and co-ordinated with those policies. The 2001 guidance explained that the 'national drug policy as a whole should also be periodically evaluated, preferably every two to three years' (WHO, 2001).

By 2015, a total of 95 countries were known to have issued at least one official national medicines policy, including a growing number of upper middle-income and high-income countries (Wirtz et al., 2017). A 2013 review of the evolution of the national medicines policy concept noted that high-income countries were responsible for the largest proportional increase in such efforts in the preceding 5–10 years, and that they were more likely to have implementation plans updated (Hoebert et al., 2013). These authors highlighted the policy processes in four selected countries, including South Africa, and emphasised the need for effective stakeholder engagement, enabling a 'sense of collective ownership of the final policy'. One of the most recent updated documents has been the Australian National Medicines Policy, issued in 2022 (Australian Department of Health and Aged Care, 2022). This replaced a 2000 document, which has been credited with having 'provided the fabric for medicines regulation and approvals … , affordable and timely access to medicines … , and quality and safe use of medicines' (McLachlan & Aslani, 2020, 2023). Despite including a commitment to periodic review, the South African NDP has not been updated or revisited in any form since 1996, although elements of the policy have been adjusted over time as they have been implemented (Gray et al., 2002, 2017).

Spurred on by the Sustainable Development Goals (2015–2030) many countries are attempting to address universal health coverage (UHC), which demands effective and co-ordinated essential medicines policies (United Nations, 2015). Based on an assessment of 71 national medicines policies, it has been argued that greater coherence between such policies, human rights law and UHC schemes would assist in addressing the persistent barriers in medicines access (Perehudoff et al., 2019). South Africa has inserted aspects related to medicines policies into the National Health Insurance (NHI) Act, which was passed by both the National Assembly and National Council of Provinces and assented to by the President (Republic of South Africa, 2023). The NHI Act represents South Africa's attempt to advance UHC and includes a commitment to the application of health technology assessment as a key component in the determination of the benefit package and the pricing of health technologies, including medicines. However, there are already threats of litigation to prevent implementation of this legislation. This is not the first litigation threat. South Africa's NDP has been the subject of repeated legal challenges, not only the aborted PMA challenge in 1997–2001, but also three separate Constitutional Court cases (reversing the promulgation of an Act of

Parliament, challenging the introduction of a dispensing licence for prescribers, and the medicine pricing intervention) (Pharmaceutical Manufacturers Association of South Africa, 2000; The Affordable Medicines Trust, 2005; Minister of Health, 2005).

The process of developing and initially implementing the South African NDP therefore holds important potential lessons for health policy reform, and in particular, NHI, not just for South Africa, but for other middle-income countries as well. This paper seeks to revisit the lessons learned, as uncovered in a series of purposively targeted in-depth interviews held with South Africa actors engaged in the initial steps of that process.

Methods

A series of in-depth face-to-face interviews were held with purposively selected key actors over an extended period of time in 2013 and 2014. Key actors involved in the development of the policy document, the subsequent implementation process and stakeholder engagement were identified. Each interview followed a pre-determined set of initial semi-structured questions, but was allowed to explore additional areas as the discussion evolved. Interviews were recorded and transcribed (Otter.ai, Inc., Mountain View CA) and then subjected to abductive thematic analysis, informed by the Walt and Gilson 'triangle' model of policy analysis (Walt & Gilson, 1994). Consideration was therefore given to the interaction between context, process and content, and the extent to which actors were or were not able to engage with and shape the eventual policy and its implementation. The insights sought from the interviews were also complemented by the extensive document reviews conducted previously (Gray et al., 2002, 2017).

All interviewees provided signed informed consent and also self-selected an anonymised descriptor for their roles or positions as actors in the policy process. The identity of interviewees was kept confidential. The study was conducted with the prior approval of the University of KwaZulu-Natal Biomedical Research Ethics Committee (BE008/010).

Results

A total of six in-depth interviews were conducted, with respondents who self-identified as academics (R1, R2), a clinician educator (R3), professional officer (R4), previous government official (R5) and pharmacist (R6). Of the six, four had been members of the NDPC, whereas the others could be considered key stakeholders engaged in responding to and/or implementing the resultant policy document. Interviews were wide-ranging and lasted between 40 and 95 minutes. Four interviews lasted over an hour. Informed by the Walt and Gilson concepts of 'context', 'actors', 'processes' and 'content',

analysis of the interview transcripts revealed three key themes: 'evidence', 'trust' and 'looking forward'.

'Evidence'

This theme encapsulated such concepts as time pressures, the level of evidence relied on in developing the NDP, the sources of such evidence, the role of consultation, as well as engagement with other countries and WHO. The availability of evidence is a critical contextual consideration, but also impacts on the process followed and thus the quality of content of the final policy document.

Given the urgency of the post-apartheid reform process, the policy committees established by the Minister of Health were under extreme pressure. As R1 put it: 'it was a great urgency to get results from a process that was terribly short on time'. There was also a strong sentiment that, as the liberation movement, the African National Congress (ANC) had to demonstrate the ability to govern. R1 recalled being told: 'Someone has said to them, you must get on with it. You'll be the government one day'. Critically, the NDPC was under strict instructions, as R6 explained: 'We were told not to consult'. R5 confirmed this point: 'the Minister said, I don't want you to do extensive engagement with stakeholders. … I want you to give me your technical input now into the process. Then we'll get into the technical detail, the consultation with stakeholders, later'.

The NDPC was given seven specific tasks, which were then to provide the basis for the policy document *per se*. The tasks posed were (South African Department of Health, 1996):

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 of treatment using epidemiological approaches.
3. Develop an Essential Drugs List to be used in the public sector and prepare treatment guidelines for the 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.

The last of these referred to the organogram of the National Department of Health. As no report from the NDPC was placed in the public domain, the

evidence base for the policy prescriptions included in the 1996 document cannot easily be traced. The available published evidence, especially from high quality systematic reviews, was limited (Gray & Suleman, 2015). The respondents' comments are illuminating: 'I was no expert in the area' (R1); 'we didn't really know what a national medicines policy was' (R6). The compromise was evident: 'my approach was always to essentially make sure we don't go down the same road that other people did. In an attempt to be, if you like, over scientific about these things, but then on the other hand also not to forget the science' (R1). In part, this reflected a belief that policymaking was essentially a political act, separate from the science. R2 alluded to one of the Minister's special advisers as being 'absolutely resistant to my suggestion, repeated suggestion, that was the science fed into policy and responded to policy needs and that you can't separate [them]'.

The 1988 WHO guidance was clear: 'in recognition of the fact that the success of any national drug policy depends on its general acceptance, mechanisms should be established for consultation with interested parties, including representatives of professional bodies, pharmaceutical manufacturers, and consumer and patient organizations' (WHO, 1988). Despite this, R1 contended: 'the advice was we had to stick to the WHO way of doing things'; but also conceded: 'of course we realized, throwing up a policy and paper and implementing it is completely different'. R5 characterised the subsequent translation of the NDPC's recommendation into the final policy document as being based on extensive '*training*' by WHO, and the final product as 'pretty much a textbook style'.

There was one notable exception, where three members of the NDPC visited Zimbabwe for a stakeholder consultation on their national medicines policy. R6 described the experience as follows: 'that helped to really deepen our understanding very quickly'; 'we could actually see a national medicines policy in action'; 'you could actually see … this is how you engage with stakeholders'. Zimbabwe was also the source of some of the evidence relied upon in proposing the introduction of a dispensing licence for prescribers.

'Trust'

This theme captured the concepts related to the selection of the NDPC members, the perceived impact of the 'old guard', and the pressure exerted on the NDPC. Trust is also key to the ability to effectively engage actors, during policy development and implementation.

The origins of the NDPC lay in the ANC Drug Policy Commission, with members selected from 'who was mostly involved in party level and then got the ministerial appointments' (R1). R1 also mentioned the concept of 'redeployment' of 'key academics' as 'change agents'. However, at least some of the 12-member NDPC were drawn from outside of party structures

and selected for their technical expertise. R6 noted that the 'expectation was impossible' and that 'the process was very difficult', but also that for 'such a disparate group, we actually did work quite well'. However, R6 noted the isolation of the NDPC from other policy committees active at the same time: 'the committee as a whole was not engaging with other committees'.

Trust is key to the political leadership which has initiated a policy development process. R2 demonstrated a keen awareness of the challenges inherent in a time of political transition: 'I wasn't unsympathetic to the need to have a fresh start'. R2 also recounted being told that the Minister had said 'I don't know who to trust', but added 'none of us had persuaded her that we were entirely trustworthy'. Noting that the Minister was 'surrounded by white males … everywhere she turned', R2 added 'I had great sympathy for it'. R2 underlined the point: 'It probably has been clear to you from our discussion that my overriding sentiment was one of understanding the complexity it must have been for the decision takers. And the uncertainty and the difficulty they had in drawing on the old guard'.

The policy development and implementation process was also novel for stakeholders, some of whom perceived themselves as being characterised as 'old guard', although one stated: 'I think we generally supported most of what was in the document' (R4). R4 did note that 'it was quite a new experience for most people'. In particular, R4 commented on the novelty of engagements with parliamentary portfolio committee members: 'people were used to submit(ting) a good document to a Minister', which was 'sort of either accepted or rejected'. However, R4 also noted that 'we were given almost as much time as some little splinter group'. Again, the sense is that technical expertise may have counted less than perceived political alignment.

'Looking forward'

This theme attempted to combine both the linkages and processes that underpinned and informed the policy development process, but also its initial co-ordination and implementation. The processes relied upon also have longer-lasting implications for ongoing monitoring, evaluation and revision of a policy document, and its continued relevance to emerging demands.

Although the interviewees confirmed the clear instruction to the NDPC not to engage in stakeholder consultation in the August to December 1994 period, it is less clear that the process remained as 'siloed' in 1995. Given the extent to which subsequent litigation was focused on the apparent attempt to introduce compulsory licensing via an amendment of the Medicines and Related Substances Control Act (Act 101 of 1965), R1's characterisation of the level of discussion on intellectual property as 'sort of simplistic' is

revealing. R1 further noted the lack of detail on intellectual property in the NDP, pointing to possible developments during the 'formulating period', and engagements with trade and industry officials.

The period that followed submission of the NDPC's report to the Minister of Health is more difficult to unpack. R5 struggled to recall the detail but felt 'we stopped somewhere. Not deliberately. But somehow we didn't go on'; 'It could be the court cases starting'. However, the first court action was only initiated in 1998, following the passage of the Medicines and Related Substances Control Amendment Act (Act 90 of 1997). In one regard, even while the NDPC's recommendations were being translated into the eventual policy document, key policy development processes were underway. One of these was the establishment of a Committee of Inquiry into a National Health Insurance System (the Broomberg-Shisana committee) in January 1995. In a press statement on 23 January 1995, the Minister of Health drew the linkage, after identifying the problems in the South African health system: 'Medicines are too expensive, aggravating the already critical situation.' The Committee was to report by the end of April 1995, but was specifically enjoined to 'consult with interested parties and the public in developing a plan addressing the policy objectives'. The approach of the government at that point was also made clear: 'After the preliminary report, and the Government's consideration of it, the committee may continue to improve and refine the plan based on feedback arising out of consultation'. The report of that Committee was issued before the NDP, but made reference to the recommendations of the NDPC: 'The Committee strongly supports the intended introduction of a national essential medicines programme for the public sector as a whole, as proposed by the Drug Policy Committee' (South African Department of Health, 1995). The Broomberg-Shisana report also mentioned the plans to introduce a professional fee for pharmacist, replacing a percentage mark-up on medicines, and the plans to introduce dispensing licences. However, it envisaged a situation where medicines procured on tender for the state sector would be provided, at cost, to private pharmacies and dispensing practitioners, for supply to insured patients using such accredited private providers. R1 specifically recalled that the pricing component (the first task assigned to the NDPC) was linked to the thinking about social health insurance and resulted in the engagement of an international consultant, who subsequently led the externally funded South African Drug Action Programme.

There are also more positive indications in relation to the third task posed to the NDPC, that of developing an essential medicines list, with standard treatment guidelines. To do so within the allotted timeframe, without consultation, was clearly impossible. However, as R3 pointed out, 'some like-minded people had really got together to talk about the process'. R3 also felt that 'a lot of the work had occurred in back rooms', that 'for whatever reason, some people were privy to this concept, that it was going to happen'. Although R3

felt that 'it took us a while to understand the process', eventually 'we took ownership'. R3 added that the those involved in the early stages adopted a process informed by the WHO Drug Action Programme, taking the 'structure at face value'.

Implementing the NDP demanded amendment of a number of existing laws, including those dealing with the regulation of medicines and of health professionals such as pharmacists and medical practitioners. Despite R5 stating '*I don't recall Parliament actually discussing the NDP',* the implementation of the policy required engagement with the Portfolio Committee on Health, as the legislative reforms were attempted. R5 explained that the NDP was examined by the staff of the Department of Health, and that for '*those issues that required legislative amendments, we divided those into two. Those that were not too controversial . . . . And those that might need for us to get into protracted discussions with stakeholders'*. However, the Minister of Health was described as '*impatient',* and R5 recalled her stating: '*No, I want to have a big fight once and for all, I'm not going to have a number of battles*'.

Discussion

Although the NDP development process cannot be said to have been evidenced-based, it relied on basic principles and positions then promoted by the WHO. It was also issued at an opportune moment, described as a 'window of opportunity', albeit one complicated by rapid political change (Gray et al., 2002). Throughout the initial development process, there was evidence of a dearth of trust in the *bona fides* of a range of stakeholders, which created the opportunities for contestation and delay, rather than negotiation and renegotiation. Over time, the opportunities for engagement narrowed even further.

Reflecting on and understanding policy processes is critical for any country to ensure that the lessons that are gained from the process are retained and applied. In January 2024, Dr Nkosazana Dlamini-Zuma, Minister of Health at the time that South Africa's NDP was developed, announced her retirement from politics. A newspaper commentary asked the question: 'what was Nkosazana Dlamini Zuma really all about?' (Grootes, 2024). The commentary repeated the myth that the court action instituted by the PMA and its member companies was specifically about access to generic antiretroviral medicines, incorrectly crediting the Minister with having initiated that action, but it did make an important point: 'Perhaps the biggest contribution Dlamini Zuma made to South Africa was the major changes she introduced as Nelson Mandela's health minister (1994–1999). Within that five-year block, she introduced a new framework for the health sector, instituted court action against international pharmaceutical companies over their insistence on patents for HIV medications, oversaw the legalisation of abortion and

introduced legislation banning smoking in nightclubs and bars. We must never forget just how huge the opposition was to those bold moves'.

That the democratic transition in South Africa represented a typical 'political window', in which the conditions for major health sector reform are more feasible, is clear (Reich, 1995). There has not been a holistic evaluation of this process, nor have studies focussed on the political will, environment and pressures that existed at that point. A previous assessment, focused specifically on the medicines selection and legislative aspects, noted that 'the drug policy process in South Africa showed a high awareness of the actor environment, but insufficient recognition of the fact that policy implementation is inherently a process of constant negotiation and renegotiation' (Gray et al., 2002). It was also noted that 'over time, the opportunities for negotiation have tended to diminish rather than expand'.

A subsequent assessment drew attention to the 'understandable conviction that new approaches and solutions were needed to break from the past' (Gray et al., 2017). However, that evaluation of the implementation of the NDP specifically documented the limited opportunities for engagement; apart from the public hearings before the National Assembly Portfolio Committee, some provincial hearings, and the creation of the Industry Task Group (ITG) by the national medicines regulator, opportunities for engagement have narrowed. The result was that 'the NDP legislative programme remains littered with delays or partial reversals caused by litigation'.

This study provides corroboration of the lessons drawn from both previous assessments (Gray et al., 2002, 2017). The key themes that emerged from this series of in-depth interviews with participants is that policy development and implementation process have underscored the paucity of evidence on which the NDPC's recommendations were based, and which formed at least some of the key concepts included in the final policy document. The lack of trust which characterised that process, while not unique in a period of intense political change, impacted on the ways in which actors were able or not able to engage, and therefore on the resultant content and the choices exercised by those in positions of power. In turn, the coherence of the policy, its articulation with other health reforms, and its contribution to subsequent efforts to ensure universal health coverage in South Africa have all been weakened.

That the Minister of Health chose not to engage in the process of publishing a Green Paper in 1995, before the final policy document was released in 1996 was mirrored by her choice not to publish draft legislation for comment (which included some recommendations from the NDP), before tabling a series of Amendment Bills in early 1997 (Minister of Health, 1997b, 1997c, 1997d). However, when the vociferous response to these Bills led to their withdrawal and subsequent reintroduction, the changes made were minimal, and the Bills were eventually passed almost unchanged. Even more critically, despite two opportunities for public hearings before the

National Assembly Portfolio Committee on Health, with both verbal and written inputs, the changes proposed by the Portfolio Committee and then presented to the Assembly in the 'B' versions of the Bills were also minimal. In respect of the Medicines Amendment Bill, the Portfolio Committee proposed only eight changes to existing clauses and the addition of one new clause (Minister of Health, 1997e). None of those changes addressed the controversial section 15C, headed 'Measures to ensure supply of more affordable medicines'. That the Portfolio Committee did not make substantial changes to the Bills tabled by the Minister of Health can be related to the particular political moment in time. These Bills were tabled after the publication of the new South African Constitution in 1996 (Republic of South Africa, 1996), which was followed by the dissolution of the Government of National Unity. At a time of heightened political tension, compromise and co-operation were unlikely. A dearth of trust at a key point in the process can have important consequences. Weaknesses in process provided the attack points for litigants. Even though the PMA court action was withdrawn, other challenges were successful in delaying implementation or even altering details of the policy (Pharmaceutical Manufacturers Association of South Africa, 2000; The Affordable Medicines Trust, 2005).

This paper sought to identify lessons for health policy reform in South Africa, and in particular, NHI, from an examination of the process of developing and initially implementing the South African NDP, especially the political environment. Unlike the NDP, the NHI process used a different path. After publication of a Green Paper in 2011 (South African Department of Health, 2011), a White Paper in 2015 (Minister of Health, 2015), an amended White Paper in 2017 (Minister of Health, 2017), a document identifying structures and bodies to be established (South African Department of Health, 2017), and the publication of a Draft Bill for comment in 2018 (Minister of Health, 2018), the National Health Insurance Bill was finally tabled in 2019 (Minister of Health, 2019). Despite the COVID-19 pandemic, the Portfolio Committee received over 100 000 written submissions and heard oral presentations from 117 respondents between May 2021 and February 2022 (Solanki et al., 2022a, 2022b). Although fundamental questions about the design of the legislation were raised, the 'B' version eventually adopted by the National Assembly contained few changes, and that version was accepted without amendment by the National Council of Provinces (mirroring the legislative process after the NDP was published), and finally assented to by the President. The scene is therefore set, in an election year, for possible litigation and further contestation.

It is not the mechanics of the policy development process, *per se*, that increases the chance of successful implementation. However, weaknesses that were evident in the development and implementation of the NDP have the potential to hamper NHI processes going forward. It has been argued that the pricing interventions introduced in 1997 have evolved to

meet emergent demands: 'Policy has emerged from practice, informed by engagement with stakeholders, albeit at arms' length' (Gray et al., 2017). Nonetheless, among the key imponderables facing NHI are questions about medicines selection, pricing and procurement (Health Justice Initiative, 2022). Although there have been encouraging developments in relation to health technology assessment (Wilkinson et al., 2022), that alone cannot compensate for the lack of clarity on the pricing model to be followed. One of the few changes in the 'B' version of the NHI Bill was deletion of the previous amendment to the definition of a single exit price in the Medicines and Related Substances Act. The NDP suffered from such vagueness, being too broad in some instances, and lacking clarity in others. How much of this is due to a possible lack of institutional memory is unclear.

In order to support South Africa's attempt to achieve UHC, a revised national medicines policy would need to revisit the pricing interventions for medicines to be applied by the National Health Insurance Fund. It would also need to strengthen provisions for supporting national and regional manufacturing of medicines, including greater use of reliance models for regulatory action and co-ordination with continental developments, such as the nascent African Medicines Agency. Measures to ensure quality use of medicines would also need strengthening. However, while these are some of the key changes required, a more wide-ranging and inclusive review process would be needed.

This study had some strengths and weaknesses. In particular, it managed to include interviews with some of the key leadership figures engaged in the development and early implementation of South Africa's NDP. Although the time that had elapsed between the events and the interviews did mean that recall bias could not be eliminated, these were seminal events for the interviewees and so their recollections could be relied upon. A potential bias which could not as easily be discounted is the 'insider' nature of both authors' relationship with the processes under review. Although neither was a member of the NDPC, they did engage with the process as stakeholders and were later members of a number of ministerially-appointed structures, including the then Medicines Control Council and the Pricing Committee. The authors have also actively sought to challenge one another, as each has engaged with the process in very different ways (Erasmus & Gilson, 2008).

Conclusion

By examining the process of how South Africa's National Drug Policy was started, the actors involved and engaged, the context of the time, and the resultant content, important lessons can be drawn on health reform in the country, more broadly, as well as for other low– and middle-income countries engaging in health policy reform. As South Africa advances its plans for

universal health coverage, through National Health Insurance, there is an urgent need to revisit key components of the NDP which are no longer fit for purpose. Some priority components have been identified, such as the medicine pricing intervention. However, the political climate is such that there is again the risk that rushed and non-transparent processes will hamper the achievement of broad support for the policy options exercised.

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