

Health Policy and Legislation

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The health policy and legislation arena has been dominated in 2015/2016 by the release, after much delay, of the White Paper on National Health Insurance (NHI). Although a White Paper is expected to provide finality on a policy in a manner which is ready for implementation, including the development of any necessary legislation, the NHI document leaves many questions unanswered. The need for major changes to existing legislation is signalled in the White Paper, but few details are provided on exactly how those changes might be made. In addition to changes to the National Health Act and the Medical Schemes Act, and perhaps even the Constitution, the possibility of a new NHI Act is also floated. Two small steps, in the form of drafts Bills to amend the National Health Laboratory Service Act and to create a new National Public Health Institute of South Africa, have been taken. However, neither Bill has yet been tabled in Parliament.

The Medicines and Related Substances Amendment Acts of 2008 and 2015 will need careful promulgation, once the necessary secondary (regulations) and tertiary (guidelines) legislation have been developed. The new South African Health Products Regulatory Authority is not expected to come into operation before 2017, and will have to face not only the backlog in registration applications for medicines that is the legacy of the Medicines Control Council, but also complete and entrench the effective regulation of complementary medicines and medical devices.

While there have been strident calls for a fundamental redesign of the Health Professions Council of South Africa in order to create an independent, self-regulatory council for the medical and dental professions, it is unclear whether these calls will be heeded.

The Medical Innovation Bill, one of the few Private Member's Bills to be tabled, still languishes in Parliament.

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Introduction

A number of targets for reform of legislative instruments under the control of the National Department of Health were included in the Strategic Plan 2014/15–2018/19.¹ Those listed included:

- promulgation into law of a National Health Insurance Bill by 2018/19;
- implementation of a functional National Pricing Commission to regulate health care in the private sector by 2017;
- adjustments to the prices of original and generic medicines; and
- regulation of all complementary and alternative medicines, medical devices and *in vitro* diagnostics by 2018/19.

With the release of the White Paper on National Health Insurance in December 2015,² and the Presidential assent to the Medicines and Related Substances Amendment Act (14 of 2015)³ this process can be considered to be under way. However, as is described in more detail below, both of these processes still face considerable challenges and will require concerted effort if the ambitious deadlines are to be met. As always, the Annual Report of the National Department of Health provides a listing of legislation which falls under the portfolio of the Minister of Health, as well as other legislation with which the National Department must comply.⁴

As in 2014/2015, the pace of health legislation in Parliament has again been slow in the 2015/2016 period, with only the Medicines Amendment Bill having been finalised. Parliament is still in the process of discussing the Medical Innovation Bill (Private Member's Bill 1 of 2014), but no progress seems to have been made in this regard.⁵ The Medical Research Council has released a policy brief on the issue of 'medical marijuana'.⁶ Drawing heavily on a published meta-analysis,⁷ the policy brief notes the dearth of high-quality evidence for the claimed efficacy and safety of cannabinoids.

It is unclear whether the International Health Regulations Bill, which was initially published for comment in 2013,⁸ will be tabled in Parliament. The draft Bill provides for the domestication of the International Health Regulations (IHR) of 2005.⁹ However, the changes brought about by the National Health Amendment Act (12 of 2013) have already ensured the transfer of Port Health services to the national sphere. The Annual Report 2014/2015 stated that this transfer was completed by March 2015 and that 44 ports of entry were assessed as being compliant with the IHR.

The relevance of the IHR was underlined by the World Health Organization's decision in February 2016 to declare the Zika virus outbreak in South America, and its assumed association with neurological disorders (Guillain-Barré Syndrome) and neonatal malformations (microcephaly), as a "Public Health Emergency of International Concern" (PHEIC).¹⁰ This is only the fourth such declaration, with previous PHEICs being for pandemic influenza, Ebola virus disease and poliomyelitis.

As in previous editions of the Review, this chapter focuses on health-related legislative instruments at the national level that have been the subject of change since the last edition was published in 2015, including secondary and tertiary legislation, in the form of Regulations published for comment or finalised by the Minister of Health, or Board Notices issued by statutory health councils. Any changes to provincial health legislation or health-related municipal

by-laws are outside of the scope of this chapter. Important health-related jurisprudence is also described. In addition, the chapter briefly covers major national health-related policy documents. In 2015/2016, the policy and legislation arena was dominated by the release of the White Paper on National Health Insurance.²

National legislation related to health

National Health Act

National Health Insurance

The major event of 2015/2016 has been the release, after many delays and announcements that a document was "imminent", of the White Paper on National Health Insurance (NHI).² The expectation was that the document would provide a clear way forward, fill the gaps identified in relation to the Green Paper,¹¹ and in particular include clear guidance, backed by the Treasury, on the financing options to be exercised. The White Paper falls short of a number of these expectations, and leaves many questions unanswered. To what extent this is a reflection of ongoing differences of opinion between the Department of Health and the Treasury is unclear. In the Budget Speech delivered by the Minister of Finance on 24 February 2016, it was announced that a document on the financing options would be released "shortly".¹² The attainment of universal health coverage (UHC) is a complex process, but a necessary one which has been enshrined as one of the Sustainable Development Goals (SDGs).¹³

The basic premise of the NHI proposals is redress of the current fragmentation between the public and private sectors. The ultimate goals are those of UHC: "Population coverage under NHI will ensure that all South Africans have access to comprehensive quality health care services". The cardinal features of NHI are summarised as "universal access", "mandatory prepayment of health care", "comprehensive services", financial risk protection", a "single fund", using a "strategic purchaser" and a "single payer".

The White Paper describes a three-phase process of implementation over a 14-year period:

- Phase 1 (five years; 2012/2013 to 2016/2017), focused on strengthening the public health sector, but also implementing key enablers such as the Office of Health Standards Compliance (OHSC).
- Phase 2 (five years; 2017/2018 to 2020/2021), focused on registration of the population and the creation of a transitional NHI Fund to purchase non-specialist Primary Health Care (PHC) services from "certified and accredited public and private providers", but also with some amendments to the Medical Schemes Act.
- Phase 3 (four years; 2021/2022 to 2024/2025), focused on bringing the NHI Fund into full operation as a strategic purchaser and single payer of comprehensive health services, including specialist services, which will require wide-ranging legislative reforms.

The creation of the OHSC was dealt with in detail in the 2014/2015 edition of the Review.¹⁴ Importantly, the draft Regulations on the functioning of the OHSC published for comment in February 2015 have yet to be issued in final form.¹⁵ As a result, the enforcement

policy envisaged by draft Regulation 21 has also not been issued. Such steps are critical to ensuring that the OHSC has the necessary powers to ensure compliance with the standards that are endorsed or created.

From a legislative perspective, one of the key steps in the implementation process will be the amendment of the Medical Schemes Act (131 of 1998). The White Paper is rather vague on the exact reforms to be implemented. The contribution of the existing Prescribed Minimum Benefits (PMBs) to the “rising costs of the private health sector” is acknowledged, but the problem is also firmly located within the context of the dominance of the fee-for-service reimbursement model in that sector. However, another key cost driver is identified as the “uncontrolled introduction of new healthcare technology”, which is alleged to be associated with “cost increases without an improvement in the quality of care”. A poorly referenced claim is made that “[s]pending through medical schemes in South Africa is the highest in the world and is six times higher than in OECD countries”. A later reference seems to indicate that this refers to the percentage of expenditure on medical schemes, claimed to be “more than 6 times the 2013 OECD average of 6.3%”, rather than the quantum of per capita expenditure.

One of the most debated points in relation to NHI is that of the basket of services to be covered, also referred to as the benefit package. The White Paper states that “NHI will provide a comprehensive package of personal health services”, but also that priority-setting and progressive realisation will characterise that process: “NHI will not cover everything for everyone”. Instead of providing details of the proposed benefit package, the policy document proposes the creation of an NHI Benefits Advisory Committee to determine “service entitlements for all levels of care”. This set of “benefits” will be clearly linked to detailed treatment guidelines, an Essential Medicines List, and an essential devices and diagnostics list, based on the best available evidence and assessments of cost-effectiveness. To do so will require the creation of a substantial health technology assessment (HTA) capacity, where at present the only sustained effort has been in relation to the public sector Standard Treatment Guidelines/Essential Medicines Lists. As described in a previous edition of the Review, the submission of data for pharmacoeconomic assessment of newly authorised medicines remains voluntary.¹⁶ However, the most difficult question relates to whether medical schemes will be restricted to offering complementary (‘top-up’) cover for services not covered by the NHI benefit package, or will be allowed to offer comprehensive cover for those who choose such cover in addition to making their mandatory payments to the NHI Fund. Although the initial impression was that only the ‘top-up’ option would be possible, this was later denied by the Minister.¹⁷ This position appears to be consistent with the statement in the policy document to the effect that “Individuals will not be allowed opt out of making the mandatory prepayment towards NHI, though they may choose not to utilise the benefits covered by the NHI Fund”. Nonetheless, the ultimate goal is that “medical schemes will offer complementary cover to fill gaps in the universal entitlements offered by the State”.

In order to ensure that financial risk protection is extended to those who use the public sector, the White Paper proposes that the Uniform Patient Fee Schedule (UPFS) in the public sector be abolished in the early stages of the transition. In addition, it states that “a massive reorganization of the health system would be required to create a

new platform for service provision and health care financing”. In particular, the policy document proposes that legislative changes to the “functions, responsibilities and relationships within the three spheres of government”. This implies wide-ranging changes to the National Health Act, and perhaps to the Constitution. However, no specific examples are identified, nor are draft amendments provided in the White Paper. An early intervention, which has been repeatedly signalled but not yet implemented, is the transfer of central hospitals to the national sphere. However, in addition, an NHI Act is planned, which will establish the NHI Fund and its governance structure, the NHI Commission. It is envisaged that the NHI Fund will report to the NHI Commission on a quarterly basis and to Parliament annually. Surprisingly, and perhaps naively, the White Paper states that “[e]stablishing the Fund and the accompanying public entity will be a straight process legislatively”.

The creation of the NHI Fund requires attention to more than just the financial flows. The White Paper identifies the need for governance and accreditation structures, purchasing systems, risk mitigation systems, health technology assessment, and monitoring and evaluation systems. The basic structure will need to be in place by the early stages of Phase 2, when the transitional Fund will need to be able to purchase PHC services “from certified and accredited public and private providers at non-specialist level”, and also from Emergency Medical Services (EMS) and the National Health Laboratory Service (NHLS).

While vague in relation to many PHC services, some detail is provided in relation to pharmaceutical supply and laboratory services. It is envisaged that accredited and contracted private sector community (retail) pharmacies will be enabled to procure medicines on nationally agreed pharmaceutical contracts (presumably tenders), and will be paid a “capitated administration fee”. In addition to contracting with the NHLS, it is envisaged that the NHI Fund will also contract with “certified and accredited private laboratory service providers”, but only “based on need”. It is suggested that volume thresholds will be set for such providers, above which reimbursement will be limited to the marginal cost of providing the service.

In line with the identification of fee-for-service reimbursement as a problem, the White Paper repeatedly expresses a preference for capitated payment options, with active risk management based on increased access to high-quality data on utilisation and outcomes. For example, it is envisaged that ambulatory specialist services will be reimbursed by means of a “capped case-based fee”. To inform such risk management systems, the e-Health strategy should be effectively implemented without delay.

Other legislation will also have to be amended, notably addressing the existing barriers to the establishment of multidisciplinary practices. This is a long-standing issue, which received considerable attention in the 2002 report of the Taylor Committee of Inquiry into a Comprehensive Social Security System.¹⁸ The proposed National Health Laboratory Service Bill¹⁹ and National Public Health Institute of South Africa Bill²⁰ can be considered to be part of the systems strengthening activities of phase 1.

Much of the media coverage of the White Paper and the reactions from various stakeholders have focused on the financing options listed. Only “illustrative projections” are provided, and no clear preference between the listed funding options (direct taxation, indirect taxation, payroll taxation and premiums) or their

combinations is evident. Five scenarios are painted instead; the first combines a surcharge on taxable income, an increase in value-added tax (VAT) and a payroll tax. The other scenarios each eliminate one or more of those components. It is stated that: "NHI's financing requirements are uncertain, and in part depend on public health system improvements and medical scheme regulatory reforms which have not yet been fully articulated". This is perhaps the clearest indication that the White Paper is not the final word on the matter, and that the policy development process is continuing. Consultation with various structures will be required, including the Presidential Coordination Committee (PCC) on Intergovernmental Relations and Fiscal Arrangements (IGFR) and the Financial and Fiscal Commission (FFC). In order to formalise the development process, terms of reference for National Health Insurance "work streams" have been gazetted.²¹ The six work streams are:

- Prepare for the establishment of the NHI Fund;
- Design and Implementation of NHI Health Care Service Benefits;
- Prepare for the purchaser-provider split and accreditation of providers;
- The role of medical schemes in an NHI environment;
- Complete NHI Policy paper for public release; and
- Strengthening the District Health System.

Work Stream five which relates to the finalisation of the NHI policy paper for public release by Government is perhaps the most telling summary of the state of policy development related to NHI, let alone of the design and drafting of the legislative reforms that will be needed.

The debate over the White Paper on NHI also cannot be divorced from the ongoing Competition Commission market inquiry into the private healthcare sector, the terms of reference for which were amended in October 2015 to revise the completion date to 15 December 2016.²²

Secondary legislation

Apart from the NHI process, the issuing of secondary legislation in terms of the National Health Act continues. In July 2015, draft regulations for the operation of human milk banks were issued for comment.²³ It is proposed that authorisation from the Director-General will be necessary before a human milk bank can be established, and that a national human milk networking co-ordinating unit be created, with provincial equivalents. Quality measures were also outlined.

Draft Regulations to cover the provision of emergency medical services at mass gathering events (defined as those where the expected attendance was more than 1 000 people simultaneously at any given time) were published for comment.²⁴ The draft Regulations provide for the minimum staffing required for various events, based on an extensive scoring system.

The National Health Act (61 of 2003, as amended in 2013), makes provision for the appointment of an Ombud to the Director-General, in terms of section 81(1). The Minister issued a call for applications for the position in November 2015.²⁵

Health Professions Act

Although no draft amendment to the Health Professions Act has yet been prepared by the Ministry or the Department of Health, there is a widespread belief among the medical and dental profession that fundamental change is needed. It has been reported that the South African Medical Association (SAMA) had commenced with the development of a "legal white paper" in 2012.²⁶ The intention is to provide for an autonomous self-regulatory body for the medical and dental professions, separate from those for the other health professions currently regulated by the Health Professions Council of South Africa (HPCSA). A newly appointed HPCSA is in the process of reacting to the findings of a Ministerial task team into the functioning of the Council and its secretariat.

Despite these seismic events, the Minister and HPCSA continue to issue subordinate legislation in the form of Regulations and Rules. These included an exception to the process of registration as a specialist in family medicine,²⁷ draft regulations creating a list of new sub-specialities in medicine (allergology, forensic psychiatry, geriatric psychiatry and neuropsychiatry),²⁸ and draft regulations defining the scope of the profession of oral hygiene.²⁹

The last of these was not contested, as was a previous Regulation issued in 2005, which created the profession of dental assistants.³⁰ Although a period of 10 years was allowed before this provision became effective, many dental assistants remained unregistered in 2015, with predictions of major disruptions to service provision.³¹ A rejection of a Court challenge to the regulations by the South African Dental Association (SADA) was upheld by the Supreme Court of Appeal in November 2015.³²

In this case, SADA's appeal in the Supreme Court of Appeal sought to set aside Regulations made by the Minister, purportedly in terms of the Health Professions Act. The appeal devolved on this exercise of the Minister's power. The affected dental assistants, through the Dental Assistants Association of South Africa (DAASA), argued that statutory professional recognition would result in the recognition of the value of their work, protection in the workplace, and higher-quality service due to the mandatory training required. SADA challenged the Regulations on the basis of administrative law principles, arguing firstly, that the Minister was not empowered to make the Regulations, secondly, that the Minister paid no heed to their representations, and thirdly that the decision was ultimately irrational due to the fact that of all the dental assistants in the country, only a portion met the requirements outlined in the Regulations.

After reviewing various sections of the Health Professions Act, the Court rejected SADA's contention that the Act made no provision for opening a new register for any profession. The Court rejected this contention as anomalous, in that the Act would be rendered unworkable and no new health profession would be able to be established. Further, the Court held that regulation cannot occur and compliance cannot be ensured until and unless the scope of the profession has been defined. On SADA's contention that the Minister ignored its representations regarding potential unemployment as well as dentists and dental assistants being faced with criminal prosecutions, the Court found that the Minister and the HPCSA had been fully aware of these two risks, as adequate provision was made in the requirements set for the qualification, as well as in the Act. The Court noted that the dentists' interests were now nationally advanced within the HPCSA, and therefore rejected the notion that

SADA's representations had fallen on deaf ears. Additionally, the Court noted that the actions taken by the Minister and the HPCSA were in line with global trends related to the regulation of health-related professions. Finally, SADA attracted the opprobrium of the majority of the Court for its conduct towards dental assistants which were described as "condescending, patronising, disingenuous". The Court thus issued an order, unusual in constitutional litigation, that SADA pay the costs of the respondents. The decision is significant in that the members of DAASA, comprising predominantly black female dental assistants, now enjoy statutory recognition which will, among other benefits, provide them with a measure of protection in the workplace. The case also has a wider import in that the ability of statutory health councils to create new registers, for example for newly-designated mid-level health cadres, has been confirmed. However, despite this very clear signal from the Court, subsequent media coverage has indicated that the HPCSA may well be reconsidering the deadline for registration of dental assistants.³³ The HPCSA has just made a statement, but no change to the Regulation has been made.

Nursing Act

In the period under review, no new legislative instruments were issued in terms of the Nursing Act. The existing, and most unsatisfactory arrangement, whereby nurses are issued with permits in terms of section 56(6) in order to be able to prescribe medicines, remains in place, without updated regulations.

Pharmacy Act

The process of updating the Good Pharmacy Practice (GPP) standards continues. Although final versions of the draft GPP standards published in February 2015 have yet to be issued, the Registrar of the Pharmacy Council announced in February 2016 that the ban on the sale of HIV self-tests by pharmacists had been lifted in May 2015.³⁴ Updated GPP standards will also have to take into account the outcome of the *Medirite* challenge, which was finally decided in March 2015.³⁵

As was pointed out in the previous edition of the *Review*, pharmacies are among the few health facilities that require the equivalent of a 'certificate of need' before they can be opened, moved or altered.¹² The publication of proposed criteria for the issuing of licences for pharmacy premises in February 2014 was heavily contested.³⁶ A subsequent draft set of guidelines was published by the Minister of Health in November 2015.³⁷ In addition to setting new proposed criteria, the guidelines included recognition of the specific requirements of pharmacies which offer only a limited service, such as the conduct of clinical trials, the supply of veterinary medicines or the compounding of oncology products. Such pharmacies would be exempted from the requirements for meeting the norms for establishing new pharmacy premises. The proposed norms were for at least one community pharmacy per sub-district, with a usual ratio of one pharmacy per 5 000 population and one per 2 500 population in rural sub-districts. In rural sub-districts, exceptions could be considered if the proposed pharmacy is more than 20km from an existing pharmacy. Normally, new pharmacies should not be located closer than 500m from an existing pharmacy, except in rural sub-districts. A short comment period (45 days) was provided for, but no final guideline has yet been published.

This guideline would seem to ignore a number of circumstances that can lead to increased demand for services. For instance, the population using a shopping mall may be drawn from an area far wider than a sub-district, especially in a metropolitan area or other large city, and therefore support more than one pharmacy. In private hospitals, a separate community and institutional pharmacy may be present, in part driven by the presence of a large number of prescribers' consulting rooms. In such settings, the 500m proximity rule would seem to be unjustified. In the absence of an implementable 'certificate of need' as contemplated in the National Health Act, the imposition of strict 'need' criteria for one category of health professionals appears to be arbitrary and possibly discriminatory.

Allied Health Professions Act

The Allied Health Professions Council of South Africa (AHPCSA) issued a final Code of Ethics in December 2015.³⁸ This document exposes one of the contradictions that exist between the Allied Health Professions Act and the Medicines and Related Substances Act. Even though complementary medicines are currently defined in the Regulations to the Medicines Act as being those associated with one of the allied health professions regulated by the AHPCSA, section 22A of the Medicines Act only allows a practitioner (someone registered as such in terms of the Allied Health Professions Act) to prescribe substances listed specifically for that purpose in the Schedules. No such lists exist. Practitioners can only dispense if they hold a section 22C(1)(a) dispensing licence. However, as pointed out in the Code of Ethics, section 2 of the Allied Health Professions Act states that a practitioner (as opposed to a therapist) may prescribe or dispense medicines.

The AHPCSA has also issued a large number of policy documents, outlining the criteria for registration of persons who obtained qualifications outside of South Africa (with two of these, Board Notices 146 and 148 issued and then replaced by later versions, Board Notices 176 and 177 of 2015).³⁹⁻⁴⁷ In addition, it prescribed the professional titles and designations to be used,⁴⁸ amended the Continuing Education requirements for practitioners and therapists,⁴⁹ and set the composition of inquiring bodies for disciplinary procedures for the Professional Board: Homeopathy, Naturopathy and Phytotherapy.⁵⁰

However, the most important statement made by the AHPCSA in 2015 relates to the concept of homeopathic 'vaccines'. Noting the standard meaning of the term 'vaccine',^a the AHPCSA resolved that "no homeopathic substance should be termed or purported to be a homeopathic 'vaccine'".⁵¹ For a homeopath to do so would thus constitute unprofessional conduct.

Medical Schemes Act

No finality has yet been reached in relation to the challenge to Regulation 8, which governs the application of the prescribed minimum benefits (PMBs), by Genesis Medical Scheme (Western Cape High Court Case No. 15268/14). Nor has finality been reached in relation to the draft set of amendments to Regulation 8 which were published for comment in July 2015.⁵² However, in

a The definition relied upon is as follows: "Vaccines are biological preparations of antigenic materials that are believed to develop adaptive-immunity in recipients of the vaccine to a specific disease, are typically manufactured from attenuated or inert antigenic materials and are administered in either a prophylactic or therapeutic conventional medical approach against disease".

March 2016, the Constitutional Court dismissed Genesis Medical Scheme's application to appeal a 2015 judgment by the Supreme Court of Appeal to the effect that medical schemes could only direct patients to public sector hospitals for treatment of PMB conditions if they had a designated service provider contract in place with the relevant public health authorities.^{53,54}

In September 2015, the Council for Medical Schemes (CMS) released guidelines for low-cost benefit options (LCBOs), which would enable a scheme to apply for exemption in terms of section 8(h) of the Act.⁵⁵ In terms of these guidelines, LCBOs would be allowed greater flexibility in terms of the requirements for open enrolment, PMB coverage and/or broker remuneration. However, in October 2015, this draft guideline was withdrawn by the CMS.⁵⁶ Although the CMS indicated that it would publish a revised guideline, no date for such publication was set, and no such draft guidelines have yet been published. As outlined above, the implementation of NHI will require extensive review of the Medical Schemes Act, the details of which are as yet unclear.

Medicines and Related Substances Act

Planning for SAHPRA

Despite being erroneously tagged as a section 76 Bill (an ordinary Bill affecting the provinces), the Medicines and Related Substances Amendment Act (14 of 2015) was passed by Parliament after an extensive series of public hearings in the provinces, and assented to by the President in December 2015.³ However, the next steps are complex. Act 14 of 2015 comes into effect as soon as the previous Medicines and Related Substances Amendment Act (72 of 2008) is promulgated. It is unclear how this provision (section 27 of the Amendment Act) will operate if, as is expected, Act 72 of 2008 is brought into effect in phases. Most critically, the promulgation should be co-ordinated with the development of extensive new regulations and guidelines. In addition, the creation of SAHPRA will require careful attention to labour law issues as staff are transferred from the National Department of Health to the new Authority, and to the appropriate financing and initial capitalisation of the structure.

Together, Acts 72 of 2008 and 14 of 2015 will replace the existing Medicines Control Council (MCC) with a new South African Health Products Regulatory Authority (SAHPRA). Despite the use of the term "health product" in the title of the new Authority, Act 14 of 2014 reverses the introduction of the term "product" by Act 72 of 2008, returning to the terms "medicines, Scheduled substances, medical devices or IVDs" (*in vitro* diagnostic devices). Whereas Act 72 of 2008 provided for minimal governance structures, Act 14 of 2015 provides for a Board of the Authority, comprising not more than 15 persons appointed by the Minister of Health. The Minister will also appoint the chairperson and vice-chairperson. The competencies of Board members combine the managerial and the technical: no more than 10 persons shall have expertise in the fields of medicine, medical devices, IVD, pharmacovigilance, cosmetics and foodstuffs regulation, clinical trials, good manufacturing practice, public health or epidemiology; one shall have knowledge of the law; one shall have knowledge of good governance; one shall have knowledge of financial matters and accounting; one shall have knowledge of information technology; and one person shall have knowledge of human resource management.

A confusing element is introduced by section 2(c) of Act 14 of 2015. This section of the Amendment Act introduces a new section 2(5) to the substantive Act, as follows: "The Authority acts through its Board". At the level of governance, this is clear. However the basic premise of the shift from the MCC to SAHPRA is that decision-making power in relation to the regulation of medicines and medical devices is to be vested in the Authority (comprising full-time employed staff), rather than in the Council (comprised of external experts). Section 2H of Act 14 of 2015 enables the Board to "appoint one or more committees from among its members to assist it with the performance of its functions". It would therefore seem unlikely that these committees would be sufficiently broad in composition and scope to provide the staff of SAHPRA with technical advice on regulatory applications (such as applications for registration), in the same way that the expert committees of the MCC do now. A new section 3(9) of the Act therefore enables the Chief Executive Officer of SAHPRA (who will replace the Registrar of Medicines) to appoint "committees, as he or she may deem necessary, to investigate and report to the Authority on any matter within its purview". One of the sections that has not been amended by either the 2008 or the 2015 Amendment Acts is that related to "secrecy". Instead, SAHPRA will need to ensure the maximal degree of transparency, and in particular ensure that the technical advice provided by expert committees is made available to the public, and can be contrasted with the decisions eventually taken by the staff, as delegated by the Chief Executive Officer. It is exactly this ability to hold SAHPRA accountable that will foster the development of trust in its regulatory decisions, in the eyes of the public, health professionals and the pharmaceutical and medical device industries. Very carefully drafted regulations and guidelines will be needed before such processes can be implemented. Another urgent need is for final regulations in respect of medical devices, taking into account the comments elicited in April 2014.⁵⁷

As expected, the final wording of the 2015 Amendment Act entrenched the role of the Pricing Committee in advising the Minister on matters relating to pricing policy, notably in section 18A of the Medicines Act. While the regular updates to the single exit price^{58,59} and the dispensing fee for pharmacists⁶⁰ have been issued, no progress has been made with finalising the list of "prohibited acts" referred to in section 18A of the Act, which was published for comment in August 2014.⁶¹ The draft included an extensive list of "incentive schemes" that would be considered to be discounts or rebates, including such "hidden" equivalents as "unacceptable marketing fees or co-marketing fees", "formulary listing payments", "loyalty fees", or "shelf space fees". In addition, final regulations dealing with the methods for international benchmarking of medicines prices have not been issued yet.⁶²

As was covered in detail in the previous issues of the Review, the process to bring complementary medicines under effective regulatory control has been slow and highly contested. In particular, the proposed changes to the definition of a complementary medicine, published for comment in September 2014, have yet to be finalised.⁶³ The new definition would introduce the concept of a 'health supplement', which would not be a product in line with one of the complementary disciplines regulated by the AHPCSA.

South Africa is a major port of entry for goods intended for distribution across the continent. However, at times, products are also received which are intended for the local market, and which do not meet the

applicable standards. In August 2015, the MCC used section 23 of the Medicines Act to declare a list of topical preparations containing corticosteroids as undesirable.^{64–66} The products were imported into the country and were purportedly manufactured in India, Indonesia and Italy.

African harmonisation

In February 2016, the media carried this news:

Africa has taken a major step in accelerating access to the needed safe, efficacious and quality medicines for the treatment of priority diseases by adopting the African Union Model Law on Medical Product Regulation. The Summit of Heads of State and Government of the African Union that convened in Addis Ababa, Ethiopia from 30 to 31 January 2016 adopted the Model Law in recognition of the need to promote and protect the public health of Africa's citizens.⁶⁷

The Model Law is designed as an enabling framework, intended to assist countries which have no or inadequate regulatory frameworks for the approval of medical products (defined as medicines, vaccines, diagnostics and medical devices). A 2010 World Health Organization (WHO) study of 26 sub-Saharan countries found that, while most of them had legal provisions for the most essential aspects of medicines control, their regulatory systems presented some critical weaknesses (fragmentation of responsibilities; many gaps and grey areas; a multitude of provisions which were difficult to implement; little power and autonomy; oversight over a limited range of regulatory functions with little accountability or managerial commitment; lack of sustainable funding; staff shortages and regulatory requirements and processes not in line with recommended WHO standards).⁶⁸

The Model Law is intended to serve as a reference guide in the review and development of national legislation that will enable the Member States to undertake their obligation to protect the health of their people and, especially, to contribute to building stronger regulatory systems to tackle the proliferation of substandard medical products on the continent which poses a major public health threat.

In addition, the Model Law is expected to facilitate harmonisation of regulation of medical products by Member States through their Regional Economic Communities (RECs) with the support of the African Medicines Regulatory Harmonization (AMRH) Programme. Through the programme, RECs are harmonising medicines regulations and facilitating work-sharing among countries for faster, quality, predictable and transparent approval of medical products in African countries. The ultimate goal is to facilitate faster access to life saving medical products.⁶³

Traditional Health Practitioners Act

Progress in relation to the effective operation of the Traditional Health Practitioners Council has been slow. A necessary step was taken in November 2015, with the publication for comment of draft Regulations in terms of the Traditional Health Practitioners Act (22 of 2007) into operation.⁶⁹ Given the nature of traditional health practice and the training of practitioners, some of the proposed Regulations seem ill-suited, and reliant on mechanisms of control that are more appropriate to more formalised settings. For example, while a minimum level of education for a student practitioner in the categories divination, herbalism, traditional birth attendant practice

and traditional surgeon (circumcision) practice is set at ABET Level 1, equivalent to a school Grade 3, the Regulations require that the tutor or institution be "registered and accredited by the Council to provide the training or course". The specified durations of training are as follows:

- divination – 12 months (to include diagnosis, preparation of herbs and traditional circumcision);
- herbalism – 12 months (to include the identification and preparation of herbs, sustainable collection of herbs and traditional consultation);
- traditional birth attendant practice – 12 months (to include issues of conception, pregnancy, delivery of the baby, and pre- and post-natal care); and
- traditional surgeon (circumcision) practice – five years (including observation of three initiation schools and supervised practice for two years).

In addition, it is stipulated that a student practitioner in divination or herbalism must be at least 18 years of age, and a student practitioner in traditional birth attendant practice or traditional surgeon (circumcision) practice must be at least 25 years of age at registration in order to practise.

The application form for "trainers" requires submission of "copies of teaching/learning materials", which seems to anticipate the availability of such materials. Whether that is practical in this setting remains to be seen. At times the draft regulations can only be described as skeletal, stating, for instance, that "Council may take disciplinary measures to any contravention of the Regulations".

Draft legislation

Two draft Bills that provide important building blocks for health systems strengthening have been published for comment, but have not yet tabled in Parliament.⁷⁰

National Health Laboratory Service Amendment Bill

The National Health Laboratory Service Amendment Bill has as its primary objectives:

- to amend the National Health Laboratory Service Act, 2000, so as to define certain expressions and to delete a definition;
- to make the Preferential Procurement Policy Framework Act, 2000, applicable to the National Health Laboratory Service;
- to adjust the objects and duties of the Service; and
- to strengthen the governance and funding mechanism of the National Health Laboratory Service.¹⁸

The proposed amendments are routine in nature, except for two issues. Apart from a reference to the Preferential Procurement Policy Framework in the proposed amendment to section 3, no other funding mechanism is spelt out for the National Health Laboratory Service (NHLS). As regards governance, the Board and executive positions indicated in the Act are to be appointed and accountable to the Minister (section 9), placing control of this Service firmly in the hands of the Minister. This is somewhat of a departure from other governance mechanisms, such as the proposed SAHPRA Board.

National Public Health Institute of South Africa Bill

The National Public Health Institute of South Africa Bill has as its primary objectives:

“to provide for the establishment of the National Public Health Institute of South Africa in order to conduct disease and injury surveillance and to provide specialised public health services, public health interventions, training and research directed towards the major health challenges affecting the population of the Republic.¹⁹

The intent is therefore to separate the routine services of the NHLS from its research activities and devolve them on the new structure, the National Public Health Institute of South Africa (NAPHISA). The governance structure consists of a semi-autonomous Board, not dissimilar to that envisaged for SAHPRA in terms of the Medicines and Related Substances Amendment Act (14 of 2015).

Among the submissions made in response to the notice for comment are that, the Bill should adopt an unequivocally public health focus and approach; an integrated risk factor surveillance strategy, should ensure greater co-ordination between reference laboratories and referral services, and the intellectual property rights acquired by NAPHISA should not be used to shore up commercial monopoly.⁷¹

Health-related policy

This chapter does not attempt to track the implementation of all existing health-related policies, even at a national level. However, it does draw attention to major policy documents released by the National Department of Health in the period under review. All health policy should be considered for coherence with the demands of the Constitution, existing White Papers, and also the National Development Plan (NDP).⁷² The NDP sets broad goals, such as to “[p]rovide affordable access to quality health care while promoting health and wellbeing”, but also some clear specific directives, such as to “[p]hase in national health insurance, with a focus on upgrading public health facilities, producing more health professionals and reducing the relative cost of private health care”. It is clear that these concerns are directly addressed by the recently released White Paper on National Health Insurance, but that implementation still poses considerable challenges.

Antimicrobial Resistance National Strategy Framework 2014–2024

Global attention is being paid to the problem of antimicrobial resistance, and South Africa has responded with the elaboration of the Antimicrobial Resistance National Strategy Framework 2014–2024.⁷³ The implementation plan for the strategy has called for a comprehensive review of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act (36 of 1947), improved regulation of the use of antimicrobials for animal growth promotion and prevention of diseases in animal husbandry, alignment of the use of antimicrobials in food production with international norms and standards, with prescribed timelines for removing antimicrobials used in agriculture, changes to the scope of practice of some para-veterinary professionals relating to prescribing privileges, and the imposition of requirements for annual reporting of antimicrobial use by means of both Act 36 of 1947 and the Medicines and Related Substances Act (101 of 1965).⁷⁴ This will require close liaison with

and co-operation from the Department of Agriculture, Forestry and Fisheries (DAFF). The National Department of Health has issued a call for nominations to the National Ministerial Advisory Committee (MAC) on Antimicrobial Resistance, which will be tasked with working not only with DAFF, but also with the Departments of Trade and Industry, Science and Technology, Basic Education, Higher Education and Training, Water and Sanitation, Mining, Justice, Correctional Services, and Transport. The MAC will be tasked with a daunting range of interventions, including:

- institutionalisation of effective systems of antimicrobial stewardship (AMS) at national, provincial, and institutional levels in both the public and private sectors using the ‘one health’ approach;
- structured national surveillance and reporting systems for antimicrobial use and resistance in the human health and agriculture sectors for the detection of newly emerged resistance;
- the selection of antimicrobial agents on the Essential Medicine List (EML) based on trends and patterns of resistance;
- progress towards achieving compliance with the standards within the National Core Standards in all health establishments;
- the phased rationalisation or elimination of the use of antimicrobials in agriculture or as growth promoters in food animals;
- prevention strategies focusing on infection prevention and control and enhanced vaccination programmes;
- core curricula on antimicrobial resistance (AMR) for health and veterinary professionals;
- national community advocacy, awareness and education campaigns to reduce inappropriate use of antimicrobials in humans and animals;
- the development of rapid and point-of-care diagnostics; and
- research into molecular mechanisms of resistance, and dissemination of information on resistance, new medicines and diagnostics.

At least some of these interventions will require regulatory action, rather than reliance on educational or managerial interventions.

National Adolescent Sexual and Reproductive Health and Rights Framework Strategy 2014–2019

The aim of the Department of Social Development’s (DSD’s) Framework Strategy is to improve the health prospects and well-being of the current and future adolescent generation of South Africa, by investing in their sexual and reproductive health.

Among the threats necessitating such a strategy, as identified by the Department’s research, are: increased levels of sexual activity, high levels of substance use, increased maternal mortality, poor quality of antenatal care provided to young mothers, and increased levels of HIV and AIDS and sexually transmitted infections. The obstacles that hamper progress were found to be, among others, the lack of sexuality education, non-involvement of males, reluctance to acknowledge adolescents’ sexual curiosity, homophobia, and gender-based violence. The research also recommended strengthening current initiatives, sexuality and reproductive education, and the greater involvement of young males and the broader community.

The strategy is grounded in a human rights approach, and focuses on five priorities in achieving its aims. These are: increasing co-ordination, collaboration, information and knowledge-sharing on adolescent sexual and reproductive health and rights; developing innovative approaches; strengthening service delivery and support on various health concerns; creating effective community supportive networks for adolescents; and formulating evidence-based revisions of legislation, policies, strategies and guidelines on adolescent sexual and reproductive health and rights.

While there are some welcome approaches, such as the need to develop a comprehensive sexuality education curriculum and implementation framework for the country, aspects of the framework appear to take a conservative approach, as evidenced in its dated definitions of core concepts such as gender and sexual orientation, often conflating distinct types of relationships. It also does not sufficiently address the critical need for and role of psychological services in adolescent sexuality. As with all government policy and strategies, implementation will be key.

Conclusion

For a number of years, successive editions of the *Review* have recorded that, yet again, the much-anticipated White Paper on National Health Insurance had not been issued. This year, the publication of this seminal policy document can be recorded, but so can the sense that much remains unsettled and far from final. Some of the critical systems strengthening steps, such as the operationalisation of the independent Office of Health Standards Compliance, are far from complete. Even when the necessary enabling legislation is in place, as in the case of the South African Health Products Regulatory Authority, the process of bringing that legislation into operation is complex, and subject to delay and challenge. Previous issues of the *Review* have reflected on the Department of Trade and Industry's Draft Intellectual Property Policy of 2013, because of the impact of intellectual property rights on medicines pricing and access. Progress on this policy has been, at best, glacial. There is still much to be done.

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