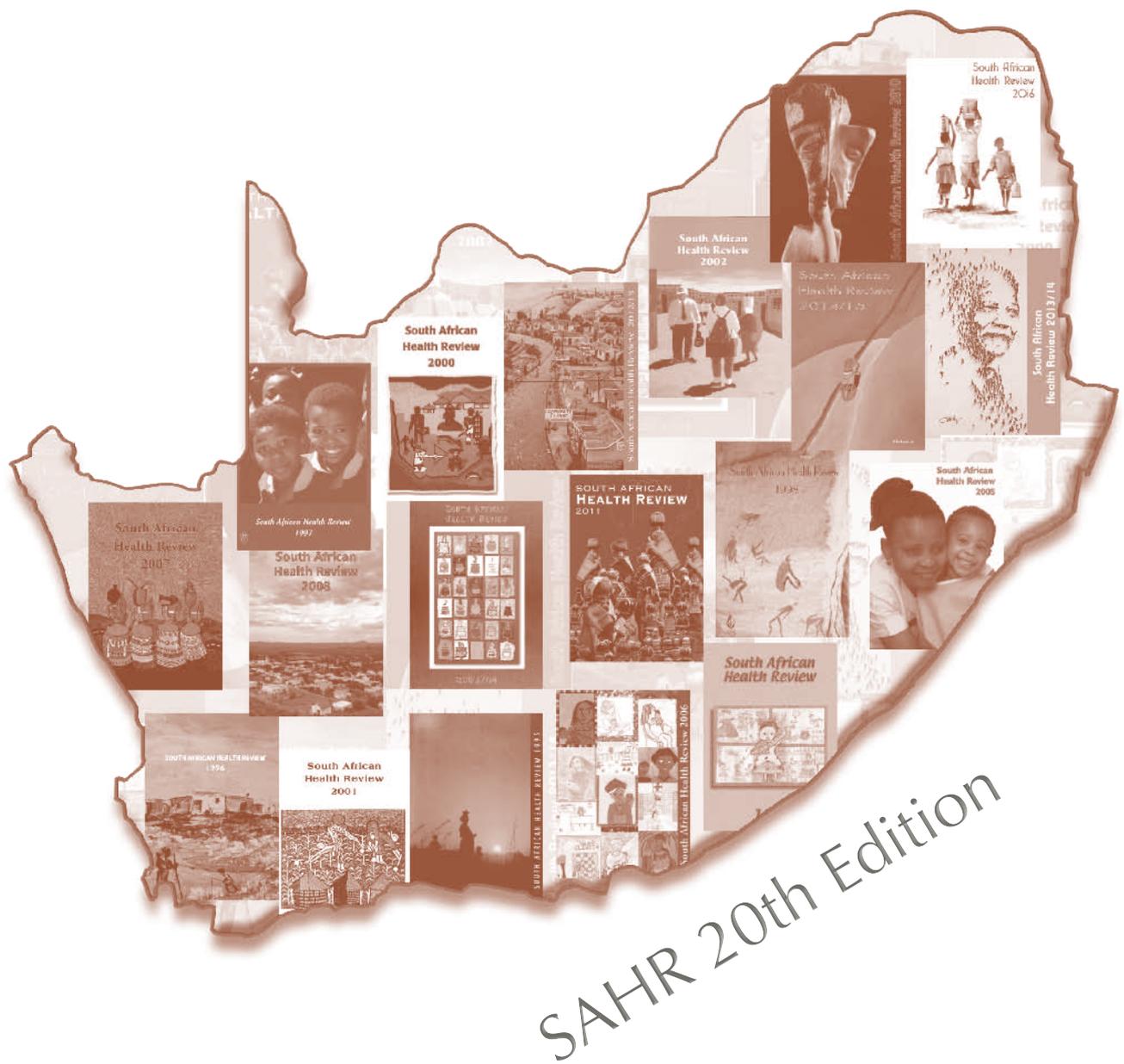


Health systems issues: macro



Health Policy and Legislation

2

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Although the introduction of National Health Insurance still dominates the health policy space in South Africa, there is little evidence of legislative action in this regard since the comment period on the White Paper ended in 2016.

No proposed amendments to the Medical Schemes Act have yet been revealed. Neither the National Health Laboratory Service Amendment Bill nor the National Public Health Institute of South Africa Bill have yet been tabled in Parliament.

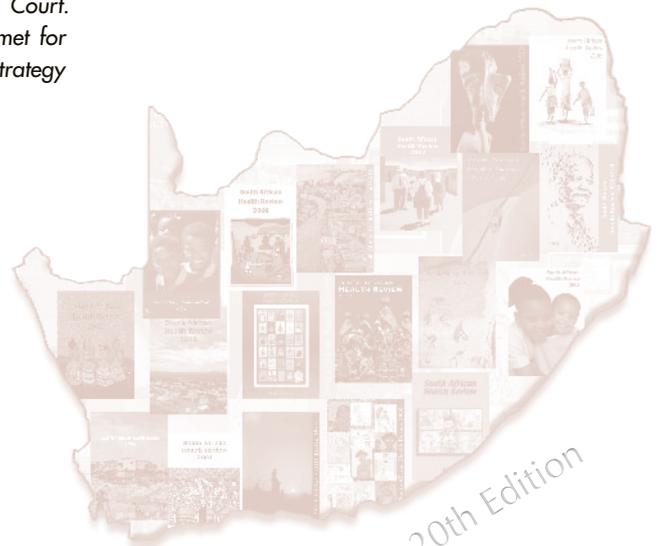
A draft Dental Technology Professions Bill has been published for comment. However, important regulations have been published in terms of the National Health Act, which should enable the operationalisation of the Office of Health Standards Compliance.

The South African Health Products Regulatory Authority is expected to replace the Medicines Control Council in 2017, and will also have to tackle the long-neglected issue of medical device regulation.

No radical redesign of the Health Professions Council of South Africa seems likely.

Two important court judgments were delivered in 2017 – in the Dermalex case, and in respect of the appeal against the Stransham-Ford decision by the High Court. The National Ministerial Advisory Committee on Antimicrobial Resistance met for the first time, but implementation of the Antimicrobial Resistance National Strategy Framework 2014-2024 still demands urgent attention.

Although the introduction of National Health Insurance still dominates the health policy space in South Africa, there is little evidence of legislative action in this regard since the comment period on the White Paper ended in 2016.



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Introduction

The inaugural *South African Health Review*, published in 1995, noted the appointment of a National Health Legislation Review Committee, tasked with developing a “comprehensive, development-oriented Public Health Act” for South Africa.¹ The Department of Health was described as “reluctant to amend legislation on a piecemeal basis”. The chapter also noted the risks attendant on a process of wholesale reform of health legislation: “unless this process is carefully managed and properly co-ordinated, administrative chaos and increased fragmentation of the health system may ensue”. In the spirit of the times, the chapter also emphasised the need for “active community participation in the formulation of legislation”, noting that “not only are undemocratic legislative processes ideologically unacceptable, but they also give rise to legislation that is poorly implemented”.

This chapter, taking advantage of the 20th edition of the *Review*, provides a concise summary of health-related legislative instruments at the national level that have been the subject of change since the last edition was published in 2016. These include primary legislation (in the forms of Bills or Acts of Parliament), secondary legislation (Regulations published by the Minister of Health) and tertiary legislation (Board Notices issued by statutory health councils). However, changes to provincial health legislation or health-related municipal by-laws are beyond the scope of this chapter. Important health-related jurisprudence is also described, as are selected national policies and the processes for their development and implementation.

In addition, the chapter attempts to identify key unfinished business, where provisions have not been implemented, or legislative processes appear to have stalled. A recent World Health Organization report has underlined the “flexible and enabling role” of public health law in the realisation of the right to health.² The report suggests a number of principles that can be used to evaluate the adequacy of existing law, as well as the need for reform. In essence, these principles are encapsulated in the duty of governments to “ensure that health care facilities, goods and services, as well as public health services, facilities and programmes, are available, accessible, culturally acceptable, scientifically and medically appropriate and of good quality”. Health legislation and policy are a means to an end.

National legislation related to health

Unlike in 2015, when just one health-related Act was passed (the Medicines and Related Substances Amendment Act 14 of 2015³), Parliament did not pass a single health-related law in 2016. Two draft Bills which had previously been published for comment have yet to be tabled (National Health Laboratory Service Amendment Bill⁴ and National Public Health Institute of South Africa Bill⁵). A draft Dental Technology Professions Bill has been gazetted for comment by the Dental Technicians Council, but has also not yet been tabled in Parliament.⁶ This is a comprehensive Bill which seeks to repeal the existing South African Dental Technicians Act (19 of 1979). The Medical Innovation Bill (Private Member’s Bill 1 of 2014⁷) remains before Parliament, but appears to be in abeyance while the Medicines Control Council considers how to apply existing provisions to enable access to cannabis for medical purposes.⁸

National Health Act

National Health Insurance

The key policy and legislative issue facing South Africa remains the effort to ensure universal health coverage through National Health Insurance (NHI). The White Paper published in December 2015 envisaged a three-phase process of implementation over a 14-year period.⁹ The first of these was intended to last five years, from 2012/2013 to 2016/2017, and to focus on strengthening the public health sector, but also implementing key enablers such as the Office of Health Standards Compliance (OHSC).

Phase 2, starting in 2017, is intended to enable the registration of the population and the creation of a transitional NHI Fund. The Department of Health Annual Performance Plan 2016/17–2018/19 notes that a key policy initiative will be to facilitate the implementation of NHI, noting the need to develop systems and processes for the NHI Fund, such as provider payment systems, patient registration systems, health provider registration systems, and fraud and risk mitigation systems.¹⁰ It is expected that some amendments to the Medical Schemes Act will be necessary. However, to date, no details of such amendments have been released. The expected input from the Treasury on the financing options for NHI has also not been issued. However, in the 2017 Budget Speech, the Minister of Finance indicated that clarity would be provided later in the year.¹¹ The Minister of Finance also provided an insight into the potential scope of the NHI Fund, noting that the initial focus would be to: “improve access to a common set of maternal health and antenatal services and family planning services”; “expand the integrated school health programmes, including provision of spectacles and hearing aids”; and “improve services for people with disabilities, the elderly and mentally ill patients, including provision of wheelchairs and other assistive devices”.

Office of Health Standards Compliance

The year 2016 marked critical steps being taken in the implementation of the Office of Health Standards Compliance (OHSC). Final regulations outlining procedures for the functioning of the OHSC and the Health Ombud were issued in November 2016.¹²

The first report from the Ombud, relating to the transfer of psychiatric patients from the Life Esidimeni facility in Gauteng (the so-called ‘Gauteng Marathon Project’), was issued on 1 February 2017.^{13,14} The Ombud found “*prima facie* evidence, that certain officials and certain NGOs and some activities within the Gauteng Marathon Project violated the Constitution and contravened the National Health Act and the Mental Health Care Act (2002)”. He further found that “some executions and implementation of the project have shown a total disregard of the rights of the patients and their families”. The responses to the report are ongoing, but have included the resignation of the provincial MEC responsible for Health, the suspension of the Head of Department and other senior officials, and remedial action to ensure the safety of patients who were transferred to inappropriate facilities. An *ad hoc* tribunal chaired by a retired Judge President has been appointed by the Minister of Health to process appeals lodged against the Health Ombud’s report.¹⁵

Although the Health Ombud’s report can be regarded as evidence of the potential power and reach of the OHSC and its structures, some elements remain subject to development. For instance, Regulation 21 calls on the OHSC to develop an enforcement policy, and to

publish this in the Gazette. Most importantly, the OHSC will rely on the existence of clear and implementable standards. Draft norms and standards Regulations were issued for comment by the Minister in January 2017.¹⁶ Importantly, Regulation 2 states that these norms and standards would apply to all health establishments. Among the proposed norms is the provision of an antimicrobial stewardship programme and a pharmaceutical and therapeutics programme at all health establishments. A call for nominations for the OHSC Board was issued in June 2016.¹⁷

Secondary legislation

The issuing of secondary legislation in terms of the National Health Act (61 of 2003) continues, with a short amended Regulation on the removal of tissue, blood and gametes from living persons that was issued for comment in May 2016.¹⁸ In July 2016, extensive draft Regulations on emergency medical services were published for comment. These included lists of medicines to be available in different types of emergency response vehicles, a provision also impacted upon by the Schedules to the Medicines Act.¹⁹ In September 2016, final Regulations on artificial fertilisation, which require fertility clinics to be authorised by the Director-General, were issued.²⁰ The Director-General is also required to establish an electronic database to capture details of all donated gametes and the outcomes achieved. Gametes from a single donor may not be used for more than 12 live births.

Lastly, Notices were issued in terms of the National Health Act to elicit nominations for the National Health Research Ethics Council²¹ and National Health Research Committee.²²

The National Health Act enables the issuing of a wide range of Regulations. Apart from those dealing with the controversial chapter 6 (such as the certificate of need), a glaring omission is the envisaged Regulations on the “development of an essential drugs list and medical and other assistive devices list” (section 90(1)(d)).

Medical Schemes Act

The planned but as yet unannounced amendments to the Medical Schemes Act will be crucial to the next step of implementing NHI. Nonetheless, some progress has been made, with the issuing of final Regulations that serve to clearly demarcate the boundaries between the business of a medical scheme and that of insurance companies.^{23,24} The Regulations allow insurers to continue to offer medical expense shortfall policies (so-called ‘gap cover’) and non-medical expense as a result of hospitalisation policies (so-called ‘hospital cash plans’), within prescribed limits. However, after a two-year exemption period, insurers would no longer be allowed to offer primary health care insurance policies, which offered limited benefits. It is expected that these policies will be replaced by the Low-Cost Benefit Options (LCBOs) still being investigated by the Department of Health, and which will remain subject to the strictures of the Medical Schemes Act (131 of 1998). How LCBOs will operate under NHI remains the subject of debate. Critically, the application of the demarcation was again delayed, with the publication of an exemption framework by the Council for Medical Schemes in March 2017.²⁵ The exemptions are expected to remain in place for up to two years, by which time the LCBOs should be in operation.

In May 2016, The Registrar of Medical Schemes issued draft rules on conduct of elections for medical scheme trustees.²⁶ In August 2016, the Registrar invited comment on a proposed declaration to

enable clear differentiation between the brand names and identity of medical schemes and administrators or other corporate entities.²⁷

Though not operating in terms of the Medical Schemes Act, the Competition Commission’s Health Market Inquiry will have a major impact on this sector. The terms of reference were amended in December 2016 to further extend the completion date to 15 December 2017.²⁸ The Panel held public hearings between February and May 2016, and has scheduled a further round in April–June 2017. The initial round dealt specifically with the relationships between stakeholders in the private health market. The Commission continues to publish stakeholder submissions and documents generated by the Inquiry on its website.^a According to its terms of reference, the Inquiry may recommend new or amended legislation, Regulations and policies, and may make recommendations to regulatory authorities such as the Council for Medical Schemes, Health Professions Council of South Africa and both the national and provincial health departments. Such recommendations will presumably inform the design of amendments to the Medical Schemes Act, in order to advance NHI.

Statutory Health Councils

The range of subordinate legislation issued by various statutory health councils, related to the regulation of specific professions’ scopes of practice, registration and qualifications, is extensive. Only those that are of particular interest, or where controversial aspects are regulated, are described below.

Health Professions Council of South Africa

As was noted in the 2016 edition of the Review, the 10-year period allowed for the registration of dental assistants expired in 2015.²⁹ Despite a court challenge, the need for registration was upheld. In July 2016, the Minister of Health, on the recommendation of the Health Professions Council of South Africa (HPCSA), issued a draft regulation for comment which would provide some flexibility.³⁰ Once issued in final form, dental assistants already in practice will be given four months to apply for registration, and a further two years in which to pass the Board examination. A similarly contested scope of practice for psychologists, initially published in 2011,³¹ was declared invalid by the Cape High Court in November 2016.³² Although the order of invalidity was postponed for 24 months, the professional board concerned and the Council were instructed to consider postponing any disciplinary action for acting outside the prescribed scope until new Regulations were promulgated.

Final Regulations defining the scope of practice of clinical associates were issued in November 2016.³³ As with the Regulations on emergency services issued in terms of the National Health Act, these Regulations underscore the complexity of ensuring consistency between different pieces of legislation. Although the Medicines and Related Substances Act (101 of 1965) allows for the recognition of persons other than medical practitioners and dentists who are registered with the HPCSA as authorised prescribers, the scheduled substances (medicines) to be prescribed by such persons have to be listed for this purpose in the Schedules. Regulation 2(h) states that the scope of practice of clinical associates includes “prescribing medicines for common and important conditions according to the primary health care level Essential Drug List (EDL) and up to

^a A full list of all documents received and published by the Inquiry can be found on www.compcom.co.za/healthcare-inquiry

Schedule IV, except in emergencies when appropriate drugs of higher schedules may be prescribed". This is insufficient to meet the needs of section 22A of the Medicines Act. The scope of practice further allows for the counter-signature by a supervising medical practitioner of any prescription for a medicine not on the EDL. Every prescription issued by a clinical associate must reflect the name of a supervising medical practitioner. No enabling provision for such a category of 'dependent prescriber' exists in South African law.

No formal proposals for radical redesign of the HPCSA have been issued, either by the Council or by any other stakeholders. No movement on that score therefore seems likely in the short term.

South African Nursing Council

It is striking that the only gazetted Notices issued in terms of the Nursing Act in 2016 dealt with fees to be paid to the Council (SANC). As was noted in 2016, updated regulations to enable the effective operation of section 56 of the Nursing Act (dealing with the recognition of certain nurses as authorised prescribers) have yet to be issued. Nonetheless, there was some movement in this regard. In May 2016, the Director-General issued a document described as a "Policy for issuing of authorisations to professional nurses to perform functions provided for in terms of section 56(6) of the Nursing Act 33 of 2005".³⁴ It stated that:

Nurses who hold such authorisation may only prescribe medicines for adults and children in accordance with the latest version of the Primary Health Care Essential Medicines List and Standard Treatment Guidelines (PHC STG and EML) and associated provincial formulary or code list as approved by the provincial pharmaceutical and therapeutics committee.

Pharmacists and pharmacy support personnel may dispense a prescription issued by a nurse authorised to prescribe medicine in terms of Section 56(6) of the Nursing Act, provided that the nurse has only prescribed medicine which he/she has been authorized to prescribe in terms of the authority issued to him/her. A nurse may, however, not dispense a repeat of a prescription for specialised or hospital level medicines prescribed by a medical practitioner.

One of the key barriers preventing the SANC from creating specialist registers is the absence of suitable qualifications. The policy document listed a number of options that should be taken into account when issuing a section 56(6) permit. These include the following:

- > appropriate postgraduate qualification or other suitable course/s accredited by the South African Nursing Council; or
- > Adult Primary Care Guide (PC101) (all modules) or Integrated Management of Childhood Illness (IMCI) – for 0 to 5 years or other in-service training approved by the NDoH in consultation with provinces or municipalities.

The policy introduced a new time limit for permits (three years, renewable), which does not appear in the Act or regulations. A database to capture the details of all nurses holding such permits was also envisaged. Updated regulations, to replace those issued in 1984 in terms of the previous Nursing Act (50 of 1978), are urgently needed, not least to enable nurses to have access to Schedule 5 and 6 medicines at primary health care level. The creation of specialist registers and the recognition of formal qualifications for this purpose is also a priority.

South African Pharmacy Council

The propensity of the South African Pharmacy Council (SAPC) to issue important notices, either for implementation or comment, at the very end of the year was upheld in 2016. On 23 December 2016, the SAPC issued updated Good Pharmacy Practice (GPP) rules dealing with community or institutional pharmacies providing pharmaceutical services from a mobile unit, community or institutional pharmacies operating websites, the transportation of thermolabile medicines, and the sale of HIV self-tests.³⁵ The last of these removed the prohibition on the sale of such tests by pharmacies. Draft GPP rules providing minimum standards for the sale of HIV screening tests were also published for comment.³⁶ The proposed minimum standard avoids the pitfalls of an overly bureaucratic approach, which might create unnecessary barriers to accessing both the tests and the necessary information about their conduct and interpretation.

The SAPC is in the midst of a complex process of reform of the categories of pharmacy support personnel. As was noted in the 2014/2015 edition of the Review, until the Medicines Act and the Regulations to the Pharmacy Act were amended, the Council proposed to register the new cadre of pharmacy technicians as pharmacist's assistants (post-basic).³⁷ One small step forward was taken in 2016, with the gazetting of a draft qualification for the pharmacy technician, for comment, in the formats required by the Higher Education and Training authorities and the Quality Council for Trades and Occupations.^{38,39}

The 2013/2014 edition of the Review noted that, despite repeated signals from the SAPC, the Regulations relating to continuing professional development (CPD) for persons registered in terms of the Pharmacy Act had not been gazetted in final form.⁴⁰ No reasons for the delay have been advanced by either the Ministry or the Department of Health.

Allied Health Professions Council of South Africa

Apart from routine notices dealing with elections, fees and honoraria, the only significant subordinate legislation emanating from the Allied Health Professions Council of South Africa (AHPSCA) has been a decision on the composition of an inquiring body for disciplinary inquiries.⁴¹

South African Dental Technicians Council

As noted above, the draft Dental Technology Professions Bill has been gazetted for comment by the South African Dental Technicians Council, but has yet to be tabled in Parliament.⁶ The Bill proposes to create a new South African Dental Technology Professions Council, recognise the category of clinical dental technologist and specialist training in the area, and to regulate both the practice/laboratories and the products (artificial teeth, dental and oral prostheses).

Under the existing legislation (Act 19 of 1979), the right to supervise a dental laboratory was restricted to holders of a BTech (Dent Tech) degree, unless the technician was already doing so.⁴²

Traditional Health Practitioner Council

As was noted in 2016, draft regulations in terms of the Traditional Health Practitioners Act (22 of 2007) were published for comment in 2015.⁴³ The comment period was extended to April 2016, but no final regulations have yet been issued.⁴⁴ The Department of Health Annual Performance Plan 2016/17–2018/19 notes that a

Traditional Health Practitioners Bill has been drafted for submission to Parliament.¹⁰ The intended effect will be to create a Council to replace the Interim Traditional Health Practitioners Council established in terms of Act 22 of 2007. However, no further details are available.

Medicines and Related Substances Act

The transition from the Medicines Control Council (MCC) to the South African Health Products Regulatory Authority (SAHPRA) will occur once the Medicines and Related Substances Amendment Acts of 2008 and 2015 take effect.^{45,46} The transition process is a complex one, involving, among others, the constitution of a new authority in terms of the Public Finance Management Act,⁴⁷ the appointment of a Board, and the transfer of existing MCC secretariat staff to the new authority. In order to effect a seamless transition, the Council will continue to perform its current functions, and its decisions, procedures and activities will be deemed to be those of the new authority, until the latter comes into existence. The Board of SAHPRA will be appointed by the Minister, and the authority comes into existence once the Board has its first sitting. The Board, after consultation with the Minister, will appoint a suitably qualified person as the CEO of SAHPRA. The General Regulations for SAHPRA have been drafted, and were published for comment in late January 2017.⁴⁸ The expectation is that SAHPRA will be operational on 1 April 2017, although the first meeting of its board may occur some time later. However, as the comment period on the draft regulations is for three months (ending 26 April 2017), it appears that the promulgation of the 2008 and 2015 Amendment Acts is likely to be delayed.

SAHPRA will not only have responsibility for the regulation of medicines, but also for medical devices and *in vitro* diagnostics (IVDs). Medical devices were included within the ambit of the Medicines Act in 1991,⁴⁹ and this aspect of the MCC's work has been somewhat controversial, particularly in view of the lack of the relevant regulations being promulgated, which has given rise to litigation and significant court challenges. This deficiency has now been remedied with the issuing of final regulations relating to medical devices and IVDs in December 2016.⁵⁰ In particular, regulation 8(6) requires that "(a) medical device or IVD, in respect of which an application for registration is made, must comply with the Essential Principles for Safety and Performance of Medical Devices which include requirements for quality, safety and performance, as determined by the Council". Regulation 11 provides for the classification of medical devices and IVDs according to four categories of risk "where risk relates to the patient, user or to public health".

As intimated earlier, certain manufacturers have argued before the courts that in the absence of the promulgation of the relevant regulations, medical devices were not subject to registration by the MCC. This argument was upheld in two decisions of the Gauteng High Court in 2014 (*Galderma*) and 2015 (*Allergan*).^{51,52} In the *Dermalex* judgment in the same division, delivered late in 2016, the Court departed from the decisions in *Galderma* and *Allergan*.⁵³ The Court was particularly critical of the decision in *Allergan*, stating that "the *Gelderma*^b judgment is not authority for the proposition that it is for a Court and not the Medicines Control Council to decide

whether a substance is a "medicine" or a "medical device". It held, further, that these two decisions had erred in their interpretation of the decision in *Rath*⁵⁴ in the Cape High Court that "a body such as the MCC has no power to classify products either as "medicines" or "medical devices". It concluded that, while the Court "is the final arbiter in these matters on the ordinary grounds of review of the MCC's decision", it "is not to second-guess the decision of the MCC as regards the correctness of its classification". These two developments – the *Dermalex* judgment and the issuing of final Regulations – will go a long way to ensuring that the MCC and its successor, SAHPRA, will be able to effectively regulate medical devices and IVDs.

Another major area of extension of the remit of the MCC has been in relation to complementary medicines. Draft Regulations were issued for comment in July 2016, which extended the definition of complementary medicines from those associated with particular disciplines regulated by the AHPCSA to include "health supplements".⁵⁵ Health supplements are defined as substances that supplement the diet, have a nutritional physiological effect, or include pre- and probiotics, but which are sold in pharmaceutical dosage forms not usually associated with foodstuffs.

In March 2017, the Medicines Control Council issued draft guidance on the "Cultivation of Cannabis and Manufacture of Cannabis-related Pharmaceutical Products for Medicinal and Research Purposes".⁵⁶ The licensing of active pharmaceutical ingredient manufacturers, on which the licensing of cannabis cultivators would rely, will require promulgation of the 2015 Amendment Act.

The Medicines Act enables the MCC to declare a substance to be a medicine in terms of category A as described in General Regulation 25(1), and thus subject to registration. In May 2016, the MCC declared any preparation containing ibogaine to be registrable.⁵⁷ Ibogaine is a naturally occurring psychoactive substance, originally extracted from plants indigenous to West Africa, which has been claimed to be of use in managing opiate addiction.

South Africa's medicine pricing provisions are enabled by the Medicines Act, even though they do not involve the MCC in any way. The usual procedure each year is for the Pricing Committee to request inputs, and then recommend the annual maximum single exit price (SEP) increase (adjustment), and the dispensing fees for pharmacists and for holders of section 22C(1)(a) dispensing licences, for promulgation by the Minister of Health in the form of regulations. However, in 2016, in recognition of the effect of major currency shifts, the Minister enabled an additional SEP adjustment of up to 2.9%.⁵⁸ A number of important medicine pricing interventions remain unimplemented, with draft Regulations not having been issued in final form. These include more careful designation of what constitutes unacceptable incentive schemes, a transparent and enforceable logistics fee, and the staggered application of international benchmarking (external reference pricing). It is unclear why these clearly signalled interventions remain unimplemented. In addition, as the submission of pharmaco-economic analyses remains voluntary, it is unclear how many (if any) have been submitted, or how these submissions have been viewed by the Department of Health. Further to a call for nominations issued in April 2016, a new Pricing Committee was appointed in early 2017.⁵⁹

^b The applicant's name (*Galderma* Laboratories) has been spelt as '*Gelderma*' in Court papers.

Foodstuffs, Cosmetics and Disinfectants Act

Among a number of regulations issued in terms of the Foodstuffs, Cosmetics and Disinfectants Act (54 of 1972), dealing with fortification of foodstuffs,⁶⁰ fungus-produced toxins,⁶¹ additives in food,⁶² maximum levels for metals in foodstuff,⁶³ and the labelling, advertising and composition of cosmetics,⁶⁴ perhaps the draft Regulation that has garnered the most attention is that relating to the reduction of the sodium content of certain foodstuffs.⁶⁵ The proposed reductions in a wide range of processed foods would come into effect between June 2016 and June 2019. However, final Regulations have yet to be issued in this regard. An editorial in the *South African Medical Journal* noted that “South Africa is playing a leading role in salt reduction globally”.⁶⁶ The editorial also noted that, since salt is fortified with iodine, it would be necessary to monitor iodine intakes and perhaps adjust iodine levels in future. However, most importantly, the editorial noted the range of interventions that would be needed to achieve the ultimate health goals of salt reduction, beyond legislation or even compliance with that legislation.

Mental Health Care Act

The Mental Health Care Amendment Act (12 of 2014) was brought into effect by a proclamation notice on 4 June 2016.⁶⁷ This is a brief piece of legislation, enabling the Director-General of Health to delegate some, but not all, powers conferred by the principal Act. More importantly, the Minister of Health issued a final set of amended Regulations in terms of the Mental Health Care Act (17 of 2002) in December 2016.⁶⁸ A number of the new Regulations would appear to have direct implications for the process of de-institutionalisation that followed the cancellation of the Gauteng Department of Health’s contract with Life Esidimeni. Regulation 6, for instance, now reads as follows:

Within available resources the State must provide subsidies to appropriate nongovernment organisations or volunteer organisations for the provision of community care, treatment and rehabilitation to meet the objectives of the Act.

However, Regulation 43(1) reads:

Any service which is not a designated psychiatric hospital or care and rehabilitation centre, but which provides residential or day-care facilities for 5 people or more with mental disorders must in terms of the Act –

- (a) obtain a licence from the provincial department concerned to operate; and
- (b) be subjected to at least an annual audit by designated officials of the provincial department concerned.

Health-related jurisprudence

Apart from the court decisions already listed, the most important health-related judgment was that of the Supreme Court of Appeal (SCA) in *Stransham-Ford*.⁶⁹ On 30 April 2015, the Gauteng High Court had granted an order in favour of a terminally-ill patient, Robert Stransham-Ford, allowing him to have a consenting medical practitioner help him end his life either by the administration of a lethal agent or by providing him with same to administer it himself.⁷⁰ Further, the Court held that such medical practitioner would not be acting unlawfully and hence would not be liable to criminal

prosecution or professional sanction, and that the common-law crimes of murder and culpable homicide, in such circumstances, unjustifiably limited his constitutional rights, were overbroad and in conflict with the provisions of the Bill of Rights relating to human dignity, and freedom to bodily and psychological integrity.

This decision was appealed against by, among others, the Ministers of Health, and of Justice and Correctional Services, and the Health Professions Council of South Africa. In summary, the appeal was based on the following issues, among others: the existence of factual evidence that contradicted facts put forward before the High Court: the Court, in considering whether death by terminal disease infringed one’s rights had failed to appropriately balance the rights of dignity and bodily integrity against the unqualified right to life and equality; if the law were to be changed to permit physician-assisted euthanasia (PAE) and physician-assisted suicide (PAS), in the context of the disparities in healthcare (particularly palliative care) availability, poverty and economic pressures could cause families to put pressure on elderly or sick relatives to resort to such measures in order to relieve the financial burden on the family of their continued existence; and provisions relating to euthanasia in permissive foreign jurisdictions were difficult to enforce. On 6 December 2016, the appeal was upheld on the following three grounds: firstly, at the time the order was made, Stransham-Ford had died and, because of the personal nature of the relief sought, the cause of action ceased to exist upon his death. Accordingly, no order should have been made on a cause of action that no longer existed. Secondly, the High Court incorrectly applied the current law and failed to make a distinction between PAE and PAS. The haste with which the Court proceeded to rule on such a controversial area was found to be altogether inappropriate. Thirdly, the order was made on an inadequate factual record, without all the required and relevant information before the Court and without granting reasonable opportunity to interested parties to adduce evidence before the Court. This was underscored by the substantial new information presented to the SCA. The Court held that it was thus inappropriate for the High Court to attempt to reconsider the common law regarding murder and culpable homicide in such circumstances.

While this may not be the final word on this complex and emotionally-charged issue, it is clear that the courts are not willing to pronounce definitively on PAE and PAS, and it remains for the legislature to deal with the unfinished business.

Other legislation with implications for health

A number of other Bills, while not tabled by the Minister of Health, have some relevance for the health sector.

Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill (6 of 2016)

The purpose of this Bill⁷¹ is to provide for the protection, promotion, development and management of indigenous knowledge systems (IKS). It defines IKS as knowledge which has been developed within, and has been assimilated into, the cultural make-up or essential character of an indigenous community. IKS includes knowledge of a scientific or technical nature, knowledge of natural resources, and indigenous cultural expressions. The Bill aims to recognise indigenous knowledge as ‘property’ within the meaning of section 25 of the Constitution, and thus as ‘prior art’ in respect of intellectual

property protection. The Bill establishes the National Indigenous Knowledge Systems Office (NIKSO), which will, *inter alia*, determine the criteria for licences to use indigenous knowledge, promote commercialisation, regulate the equitable distribution of the benefits accruing from such knowledge, register indigenous knowledge, and provide for the accreditation of indigenous knowledge practitioners. Section 11 of the Bill sets out the criteria for determining what falls within the ambit of indigenous knowledge. The intellectual property is deemed to be owned by the indigenous community collectively, which is held in trust by a trustee who may be a natural or juristic person duly delegated to represent that indigenous community; and where the owner of the indigenous property cannot be identified, NIKSO is to act as custodian. While the intent of the Bill to empower the indigenous communities to take ownership of, and benefit from, their indigenous knowledge is laudable, significant problems loom with regard to implementation. Most notable is the breadth and ambiguity of the meanings of key terms like 'indigenous communities', issues of eligibility of trustees, and the problem of identifying discrete indigenous communities. Further, the notion of a trustee appears paternalistic and offensive to the otherwise democratic impulses of the Bill.

Children's Amendment Bills (Bills 13 and 14 of 2015)

Two Children's Amendment Bills have been prepared. The purpose of the first Amendment Bill⁷² is to amend the Children's Act (38 of 2005), so as to give effect to recent Court judgments.⁷³ The Bill seeks to provide better protection to child offenders, which is warranted considering the constitutional imperative that the best interests of the child be paramount. The Children's Second Amendment Bill⁷⁴ was necessitated by the declaration of unconstitutionality of certain of the provisions of the principal Act.⁷⁵ The Bill extends the definition of adoption social worker, provides for the provincial head of social development to transfer a child or a person from one form of alternative care to another form of alternative care, and provides that an application for a child to remain in alternative care beyond the age of 18 years must be submitted before the end of the year in which the relevant child reaches the age of 18 years.

Red Tape Impact Assessment Bill (13 of 2016)

The Red Tape Impact Assessment Bill is a private member's Bill which seeks to provide for the assessment of regulatory measures developed by the executive, the legislatures and self-regulatory bodies, in order to determine and reduce red tape and the cost of red tape for businesses.⁷⁶ The Bill provides for the mapping of proposed regulatory measures and the preparation of a red tape impact statement, as well as for the evaluation of existing regulatory measures. It establishes a Red Tape Impact Assessment Unit whose duties and powers will include the development and provision of general guidelines on conducting red tape impact assessments and on preparing red tape impact statements. If passed, this Bill could impact a wide range of health regulatory bodies, such as the MCC/SAHPRA and the statutory health councils. Significantly, it is focused on red tape which affects business, with no mention of its impact on the general public. Ironically, it may well represent a new form of 'red tape', and thus serve to delay legislation by introducing a new bureaucratic hurdle.

Health-related policy

The National Department of Health's website should be a careful and complete repository of all current national health-related policies, but also the means to engage with stakeholders about the content of proposed policies. It is therefore disturbing that the 'Policies and Guidelines' page shows no documents for 2016. The 'Strategic document' page contains some policy-related documents. Some pointers can also be gleaned from the Annual Performance Plan 2016/17–2018/19¹⁰ and the most recent Annual Report.⁷⁷ Apart from the focus on NHI and SAHPRA, the APP 2016/17–2018/19 highlights the role of Operation Phakisa and the Ideal Clinic initiative. One of the strategic policy interventions is described as integrated clinical services management (ICSM), defined as

a health system strengthening model that builds on the strengths of the HIV programme to deliver integrated care to patients with chronic and/or acute diseases or who came for preventative services by taking a patient-centric view that encompasses the full value chain of continuum of care and support.

Framework and Strategy for Disability and Rehabilitation Services in South Africa (2015–2020)

The foreword notes that this policy document was developed by a Task Team appointed in 2013, and representing a wide range of stakeholders, including disabled people's organisations, academics, professional organisations, provincial representatives, the private sector and other government departments. The primary goal of the strategy is to "integrate comprehensive disability and rehabilitation services within priority health programmes (including Maternal and Child Health, District Health Services, HIV/AIDS, TB, Health Promotion, Nutrition, Tertiary Services, Mental Health and Substance Abuse and Human Resources) from primary to tertiary and specialised health care levels".

Antimicrobial Resistance National Strategy Framework 2014–2024

Although the first meeting of the National Ministerial Advisory Committee (MAC) on Antimicrobial Resistance occurred in December 2016, little concrete evidence exists yet on the implementation of the strategy. In particular, the comprehensive review of the Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act (36 of 1947) has yet to commence. The proposed 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) has also not been put into effect. There is discussion, nonetheless, about how to improve control of the use of specific high-profile, last-resort antimicrobials used in both animal and human health, such as colistin.

Other clinical policies

Although not shown on the Department of Health's website, at least two extensive clinical guidelines were issued in final form in 2016; the Adherence Guidelines for HIV, TB and NCDs (February 2016) and the HIV Testing Services Policy (2016). Both guidelines emphasised the wide stakeholder engagement and consultation that had taken place.

National Policy Framework and Strategy on Palliative Care (2017–2022)

Although not mentioned in the APP or the Annual Report, nor reflected on the NDoH web site, the work of the Steering Committee on Palliative Care is worth mentioning. Unusually, the chair of the Steering Committee is a provincial MEC for Health (Dr Sibongiseni Dhlomo, from KwaZulu-Natal). The proposed policy has three broad goals, at least in draft form:

- Goal 1. To strengthen systems across all levels of the health service, from the tertiary level to the patient in the home, in order to deliver equitable, integrated palliative care services
- Goal 2. Ensure adequate numbers of appropriately qualified healthcare providers to deliver palliative care at all levels of the health service
- Goal 3. To strengthen governance and leadership to support implementation of the policy.

One of the objectives is to provide equitable and sustained access to appropriate medications and related consumables, so as to deliver palliative care. To this end, a Drug Availability Task Team has been established, with representation from the National Essential Medicines List Committee. This is an attempt to ensure co-ordination between the policy drafting process and the structure responsible for medicines selection, thus avoiding conflict between the palliative care guideline and the standard treatment guidelines.

Other policies with an impact on the health sector

The Department of Trade and Industry (DTI) published the Intellectual Property Consultative Framework for comment in July 2016.⁷⁸ The Framework identifies the intersection between intellectual property and public health as a priority area that requires immediate domestic review. As with previous iterations of the policy, the framework has both positive and negative features. Among the former is the acceptance of: a substantive search and examination model for the consideration of pharmaceutical patent applications, to counter the excessive degree of patenting permitted under the current depository system, which has resulted in the approval of a large number of undeserving 'evergreening' patents which delay the entry of generic competitors and hence, access to affordable medicines. There is also provision for stricter patenting standards, a streamlined administrative process for considering applications for compulsory licences (as opposed to the expensive, cumbersome judicial process relied upon at present) and more effective use of competition regulation to counteract the incidence of pricing monopolies. On the negative side, the framework fails to adequately reference the human rights paradigm in its approach to policy-making, include the full panoply of flexibilities (exemptions, exceptions and country-specific options) to enhance access to quality-assured, affordable medicines as permitted under international law, and clearly commit to strict guidelines and time-frames for the finalisation of the policy and its progression to the relevant implementing legislation.⁷⁹ The DTI has received many submissions from a variety of stakeholders (civil society, academics, industry), which are in the process of being reviewed.

Conclusion

Health legislation is an important enabler of the implementation of health policy, as a necessary if not always sufficient component. Since 1995, when the first edition of the Review appeared, South Africa has been engaged in a constant process of public health law reform. Despite significant gains, some legislative processes remain stalled. Examples include the certificate of need provided for in the National Health Act, the introduction of compulsory continuing professional development for pharmacists, the recognition of specialist nurses as prescribers, and the introduction of international benchmarking for medicine prices. Ensuring coherence between multiple legal instruments is always challenging. The process of introducing NHI remains contested, with the legislative component still poorly developed. The ability of the OHSC to issue and enforce compliance notices has yet to be tested. On a more positive note, progress towards the creation of SAHPRA, to replace the MCC, is evident. A recent Court judgment has also clarified the role of the medicines regulatory authority. Effective regulation of medical devices can now start, with a risk-based approach used to identify priority targets. The ability of the Department of Health to engage in meaningful stakeholder engagement has been demonstrated in the process of development of individual policy documents, but would be strengthened by a more complete and well-maintained website. In short, 2016 was very much like the curate's egg – good in parts.

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