South Africa is engaged in the complex task of advancing universal health coverage, in the form of a National Health Insurance (NHI) system. This will require the passage of new legislation and substantial changes to existing legislation. Two draft Bills have been published for comment, as well as provisional recommendations from the Competition Commission’s Health Market Inquiry which highlighted delays in implementation of the remaining components of the National Health Act.

The Gauteng Mental Health Marathon Project tragedy has focused attention on the implementation, or lack thereof, of health policy and legislation, as well as measures to improve quality of care. It has served as a litmus test for the National Health Act, the Office of Health Standards Compliance (OHSC), and the Health Ombud, in that it tested the efficacy and fitness for purpose of these instruments and institutions.

After 50 years, the Medicines Control Council (MCC) ceased to exist in 2018, and has been replaced by the South African Health Products Regulatory Authority (SAHPRA). This chapter provides a critical analysis of the process of reforming the regulator, and the challenges that lie ahead, with particular emphasis on the issue of transparency and the unfinished business of regulating health-product marketing.

Medicine pricing has been identified as a key challenge to expanding universal health coverage. In this regard, there are ongoing debates about the medicine pricing model applied in South Africa, as well as the need for intellectual property policy reform.
Introduction

This chapter provides a summary of health-related legislative instruments at national level that have been issued since publication of the 2017 Review, and a critical analysis of some of the landmark developments in the health sphere. The main focus is on health-related primary legislation (in the form 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). Other legislation with an impact on health is also touched upon briefly. Changes to provincial health legislation or health-related municipal by-laws are outside the scope of this chapter. Important health-related jurisprudence is also described, as are selected national-level health policies and the processes for their development and implementation.

National health-related legislation

No new health-related primary legislation has been enacted since the 2015 amendment to the Medicines and Related Substances Act. Two Bills tabled in 2017 are still in the process of being dealt with by Parliament, while two Private Member’s Bills have been ruled as undesirable and will therefore not be enacted. A further Private Member’s Bill has been published for comment. Three draft Bills have been published for comment, dealing with tobacco control, the National Health Insurance Fund, and proposed amendments to medical schemes legislation. Other public health-oriented targets have included the proposal to raise the age limit for alcohol consumption from 18 to 21 years, and the tax on sugar-sweetened beverages. Although the Minister’s preference for inclusion of the new restrictions in the proposed Liquor Amendment Bill has been reported, this Bill has yet to be published for comment or tabled in Parliament.1 Only a minor change to the labelling requirement for alcoholic beverages has been issued, as a regulation in terms of the Foodstuffs, Cosmetics and Disinfectants Act (54 of 1972).2

National Health Laboratory Service Amendment Bill (15 of 2017)

The National Health Laboratory Service Amendment Bill (15 of 2017) was introduced in the National Assembly on 14 May 2017.3 This Bill requires the concurrence of the National Council of Provinces (NCOP), as in terms of the Joint Tagging Mechanism it is to be handled in accordance with section 76 of the Constitution. A series of departmental briefings and public hearings have been hosted by the National Assembly Portfolio Committee on Health, and as a result, changes to the Bill were agreed to on 27 March 2018, as Bill 15A of 2017.4 The Second Reading debate was held on 24 April 2018, and the Bill was then forwarded to the NCOP for consideration. Events for public participation will need to be held in the provinces before the NCOP can take a decision on this piece of legislation.

The Bill deals predominantly with governance of the National Health Laboratory Service (NHLS), the composition of its board, its remit within the national health system, and the manner of its funding. Given concerns about the financial viability of the NHLS, the last matter has received the greatest attention. An initial proposed section (replacing section 20 of the substantive Act), to the effect that the “[s]ervice may charge such fees for services rendered as may be prescribed by the Minister, after consultation with the National Health Council and the Minister of Finance”, has been replaced in the amended Bill with a more extensive section calling for a financing mechanism that will “ensure that the Service is adequately and sustainably financed”. Provision is made for an appropriation by Parliament, in addition to fees collected for services rendered.

National Public Health Institute of South Africa Bill (16 of 2017)

The National Public Health Institute of South Africa Bill (16 of 2017) was tabled on 14 May 2017.5 This Bill has also been subjected to a series of departmental briefings and public hearings, but has not yet progressed beyond the National Assembly Portfolio Committee on Health. The Bill seeks to create a new national public entity, the National Public Health Institute of South Africa (NAPHISA), which will be funded nationally and be accountable to Parliament. NAPHISA will have five divisions: the National Institute of Communicable Diseases (NICD), the National Institute of Non-Communicable Diseases (NINCD), the National Cancer Registry (NCR), the National Institute for Violence and Injury Prevention (NIVIP), and the National Institute of Occupational Health (NIOH). Some of these are new (NINCD, NIVIP), while others already exist (NICD, NCR, NIOH) and will have to be moved from existing structures. In addition to being handled as a section 76 Bill (an ordinary Bill affecting the provinces), the Bill was referred to the National House of Traditional Leaders in September 2017 for comment, as NAPHISA may conduct research that touches on traditional practices or the areas of jurisdiction of traditional leaders.

Apart from governance measures and questions of financing, the main areas of contention with this Bill have related to the functions allocated to NAPHISA and how these can be differentiated from and co-ordinated with those of the South African Medical Research Council and the NHLS.

Medical Innovation Bill (Private Member’s Bill 1 of 2014)

The Medical Innovation Bill was first tabled in Parliament as a Private Member’s Bill by the late Dr M Oriani-Ambrosini MP on 18 February 2014.6 The content of the Bill has been described previously.7 On 22 September 2017, the National Assembly Portfolio Committee on Health adopted a motion of undesirability, thus terminating consideration of this Bill. In doing so, the Committee was convinced that the licensing provisions in terms of section 22A(9) of the Medicines and Related Substances Act (101 of 1965) and the guidelines proposed by the MCC were sufficient to create the necessary regulated access to cannabis for medicinal and research purposes. The guidelines were published in final form in November 2017.8

Choice on Termination of Pregnancy Amendment Bill (34 of 2017)

The Choice on Termination of Pregnancy Amendment Bill (34 of 2017) was tabled in the National Assembly on 6 December 2017 as a Private Member’s Bill by Ms C Dudley MP.9 The Bill sought to amend the Choice on Termination of Pregnancy Act (92 of 1996) by requiring firstly, that gestational age [the basis of determining access to abortion on demand] be confirmed by an ultrasound examination. The proposal required that ultrasound equipment be a pre-requisite in facilities designated as offering termination of pregnancy (TOP) services. Secondly, counselling of the woman requesting TOP would be made mandatory and would include “relevant information relating to the state of development of the fetus, including the provision of electronic images”. Thirdly, the opinion of both a social worker and a medical practitioner would be needed.

2018 SAHR
to assess whether a continued pregnancy would significantly affect the social or economic circumstances of the woman (in the case of pregnancies in the 13–20-week period).

The Department of Health opposed the Bill, citing the position of the World Health Organization (WHO), which characterised the proposed amendments as “not evidence-based, nor aligned with WHO recommendations”. On 9 May 2018, the National Assembly Portfolio Committee on Health adopted a motion of undesirability, terminating a consideration of this Bill. However, the proposer has requested that this motion be debated in the Full Assembly, stating: “[b]eing able to openly discuss these painful issues helps all South Africans feel they are part of nation building and not marginalised or ignored”. The decision not to proceed with this Bill coincided with release of the Guttmacher-Lancet Commission report on accelerating access to sexual and reproductive health care; the report highlighted persistent global “barriers embedded in laws, policies, the economy, and in social norms and values – especially gender inequality – that prevent people from achieving sexual and reproductive health”.12

National Health Amendment Bill (Private Member’s Bill, 2018)

The challenge in dealing with Private Members’ Bills was highlighted by a notice published in May 2018 in which Dr S Thembekwayo MP indicated her intention to table an amendment to the National Health Act (61 of 2003). Noting that South African citizens lack adequate access to healthcare services after hours, the Bill proposes that all clinics operate 24 hours a day, seven days a week. A period of one month was provided for public comment, but the Bill has not, as yet, been formally introduced. The proposal has obvious practical limitations, even though the problem it aims to address is real.

Draft Control of Tobacco Products and Electronic Delivery Systems Bill

A draft Bill to replace the existing Tobacco Products Control Act (83 of 1993), as amended, was published for public comment on 9 May 2018.14

The single most important change is implicit in the name of the Bill – it proposes that electronic delivery systems (whether intended to deliver nicotine or not), such as e-cigarettes, be brought within the ambit of the Act. A new definition of “relevant product” has therefore been added, which combines “tobacco product” and “electronic delivery system”. In terms of the Bill, no person may sell a relevant product to any person under the age of 18 years. Sales by remote means, including by postal services, Internet or other electronic means are also prohibited, as are sales in any health establishment, including pharmacies. Restrictions on advertising and marketing will also apply to all electronic delivery systems.

The second major change, one that the tobacco industry is likely to oppose vigorously, allows the Minister to prescribe standardised packaging and labelling of tobacco products, including packaging of a “uniform plain colour and texture”. Similar provisions would also apply to electronic delivery systems. Finally, the Bill proposes that the ban on smoking be extended to include any “enclosed public place or enclosed workplace”, without exception. Other places where smoking would be prohibited include “any motor vehicle when a child under the age of 18 years is present” and private dwellings used for “any commercial childcare activity, domestic employment or for schooling or tutoring”.

Legislating for National Health Insurance

The pre-eminent challenge facing the South African health system is the expansion of universal health coverage (UHC), in the form of National Health Insurance (NHI). To date, policy documents outlining the approach to NHI and its phased introduction have been issued in terms of the existing National Health Act (NHA). A second “White Paper” was issued in June 2017, which gave little additional clarity on the ways in which NHI will be handled legislatively. The principles of UHC and its imperative for the country were restated, as was the commitment to re-engineering primary healthcare (PHC) services and building the necessary quality improvement processes (including the Office of Health Standards Compliance). The commitment to a purchaser-provider split was also restated. However, while a range of financing options was outlined, none has been finalised, nor is there evidence of consensus between the Departments of Health and Treasury, despite the modest adjustment to medical scheme tax credits introduced in the 2018 Budget.15

The second phase of NHI implementation is intended to run from 2017 to 2022, and focus on “development of the NHI legislation and amendments to other legislation”. A first step is the establishment of a range of institutions that would “be the foundation for a fully functional NHI Fund”. In July 2017, the terms of reference and composition of the following institutions were spelled out: National Tertiary Health Services Committee; National Governing Body on Training and Development; National Health Pricing Advisory Committee; Ministerial Advisory Committee on Health Care Benefits for National Health Insurance; National Advisory Committee on Consolidation of Financing Arrangements; Ministerial Advisory Committee on Health Technology Assessment for National Health Insurance; and the National Health Commission.17 Despite nominations having been called for in August 2017, no appointments have been made yet. The purpose of these “institutions” is relatively clear from their names, with the possible exception of the last institution; the primary objective of the National Health Commission is to “ensure optimal health and development outcomes for South Africa through implementation of health in all policies and an all-inclusive approach to the prevention and control of Non-Communicable Diseases”.

In his Budget Speech on 15 May 2018, the Minister of Health announced that an NHI Bill would be presented to Cabinet for approval in the following week, and published for comment together with a linked Medical Schemes Amendment Bill.18 The subsequent publication of these two draft Bills was followed closely by the release of the provisional findings and recommendations report by the Competition Commission’s Market Inquiry into the Private Healthcare Sector on 28 June 2018. Although a process of stakeholder engagement will be needed before the final report is issued, the findings and recommendations clearly have bearing on the draft Bills published for comment and on the ongoing process of implementing the NHA.

Health Market Inquiry

The Competition Commission’s Market Inquiry into the Private Healthcare Sector has been far more protracted and contested than originally envisaged. The provisional findings described the private healthcare sector as “characterised by high and rising costs”, “highly concentrated funders’ and facilities’ markets”,...
“dismempowered and uninformed consumers”, and a “lack of accountability”. In particular, the report alleged that the failure to implement an effective licensing process for private hospitals and other facilities had enabled supplier-induced demand and thus driven unwarranted utilisation and costs. In particular, it noted continued failure to implement the certificate of need provisions in the NHA (sections 36, 37, 39 and 40). However, the report went beyond merely recommending implementation as provided for in the NHA, calling instead for the creation of a dedicated, independent Supply Side Regulator for Healthcare (SSRH). The proposed SSRH would consist of four units: a Health Establishment Licensing Unit, an Economic Value Assessment Unit, a Health Services Monitoring Unit, and a Health Services Pricing Unit. The phased introduction of an Outcomes Measurement and Reporting Organisation (OMRO) was also proposed. It is clear that many of these structures would require co-ordination or reconsideration in the light of plans for NHI. The report also noted the need to revisit ethical rules published by the Health Professions Council of South Africa (HPCSA) which currently hamper the development of multidisciplinary practice, reliance on global fees, and the employment of medical practitioners.

Draft National Health Insurance Bill, 2018

The keenly anticipated draft National Health Insurance Bill was published for comment on 21 June 2018. The Bill focuses predominantly on the structural elements of the proposed NHI Fund and its governance board and relationship with other structures, but also includes proposed amendments to the NHA and nine other Acts.

The Bill enables the creation of an NHI Fund, as a national public entity, governed by a Board. Unlike with other such structures (including the OHSC and SAHPRA), the appointment of the entity, governed by a Board. Unlike with other such structures

Draft Medical Schemes Amendment Bill, 2018

In a co-ordinated release, the draft Medical Schemes Amendment Bill was also published for comment on 21 June 2018. Although not overly reliant on the outcome of the Health Market Inquiry (HMI), the Bill does traverse common territory, and also anticipates the impact of the NHI Fund. To an extent, though, the Bill can also be seen as a “spring-cleaning” exercise, addressing individual problem areas in the current functioning of the private insured market. New chapters have been proposed dealing with admission of beneficiaries and cancellation of members, and re-iterating the application of community rating.
Emergency services at mass gathering events, 24 emergency medical bodies, tissue, blood products and gametes, 23 the provision of Other final Regulations have amended the controls over human a stock control system, and ensuring availability of medicines and compliance with the Pharmacy and Medicines Acts, the provision of logistics, access and safety measures, including measures to protect licensed in accordance with the Pharmacy Act, with systems for functional structure with clearly defined roles and responsibilities”, pharmaceutical services in every health establishment, calling for “a meaningful enforcement of quality standards. 22 For example, the preceding drafts, and may prove to be too vague to enable issued in February 2018 are less extensive and detailed than those offered by the Fund. As with the NHI Bill, an extensive system of appeals has been proposed, with an Appeal Board (in the case of the NHI Fund, referred to as the Appeals Tribunal). Regulations issued in terms of the National Health Act Extensive draft and final Regulations have been issued in terms of the NHA, and some of its structures have been put to the test and have demonstrated their resilience and independence. Others can still be regarded as works-in-progress. Final Regulations stipulating norms and standards for health establishments were urgently needed in order to enable the functioning of the OHSC, and in time the accreditation of providers to be contracted by the NHI Fund. The final Regulations issued in February 2018 are less extensive and detailed than the preceding drafts, and may prove to be too vague to enable meaningful enforcement of quality standards. 22 For example, the draft Regulations proposed an extensive set of requirements for pharmaceutical services in every health establishment, calling for “a functional structure with clearly defined roles and responsibilities”, licensed in accordance with the Pharmacy Act, with systems for logistics, access and safety measures, including measures to protect users against medication errors. The final version reduces this to compliance with the Pharmacy and Medicines Acts, the provision of a stock control system, and ensuring availability of medicines and medical devices.

Other final Regulations have amended the controls over human bodies, tissue, blood products and gametes, 23 the provision of emergency services at mass gathering events, 24 emergency medical services, 25 and forensic pathology services. 26 As regards the latter, the final version was published in March 2018 following the draft version in December 2017, an apparent haste that was striking. Likewise, an extensive set of Regulations on the surveillance and control of notifiable medical conditions was published for comment in June 2017 and finalised in December 2017. 27 This set of Regulations appears to implement the WHO’s International Health Regulations (IHR), obviating the need for a separate Act of Parliament (as originally drafted in 2013). The Regulations create four categories of notifiable medical conditions, with different reporting obligations, ranging from those requiring “immediate reporting by the most rapid means available upon clinical or laboratory diagnosis followed by a written or electronic notification to the Department of Health within 24 hours of diagnosis by health care providers, private health laboratories or public health laboratories” [category 1], to those requiring “written or electronic notification to the Department of Health within 1 month of diagnosis by private and public health laboratories” (category 4). Listeriosis is included in category 1, as are the viral haemorrhagic fevers, while healthcare-associated infections or multidrug-resistant organisms of public health importance are listed in category 4. Regulations dealing with human gamete banks are yet to be finalised. 28

Policy guidelines – reacting to a crisis Other instruments issued in terms of the NHA appear to be crisis-engendered. In March 2018, policy guidelines on the licensing of residential and/or day care facilities for persons with mental illness and/or severe or profound intellectual disability were issued by the Minister. 29 The intention is to regulate facilities that are not psychiatric hospitals or rehabilitation centres, but that can be described as day care facilities, group homes, or half-way houses. Draft policy guidelines had, in fact, been published by the Director-General for comment in May and June 2017, referencing the Mental Health Care Act (17 of 2002) (MHC) and the National Mental Health Policy Framework and Strategic Plan 2013-2020. 30, 31 However, the limitations of such regulatory approaches were exposed cruelly by the Gauteng Mental Health Marathon Project (GMHMP), commonly referred to as the Life Esidimeni tragedy. 144 mental healthcare users died after being transferred from long-stay residential facilities to under-regulated and unlicensed facilities after October 2015. Another 1 418 survivors suffered trauma. The tragic outcome of the GMHMP was the first major case referred to the Office of the Health Ombud, established within the OHSC in terms of the 2013 amendment to the NHA. The Ombud’s report was issued in February 2017, and found “prima facie evidence, that certain officials and certain NGOs and some activities within the Gauteng Marathon Project violated the Constitution and contravened the NHA, and the MHC, (17 of 2002)”. 32 The Ombud found that the NGOs to which patients were transferred “had neither the basic competence and experience, the leadership/managerial capacity nor ‘fitness for purpose’ and were often poorly resourced”. On the eve of the release of the report, the Gauteng MEC for Health resigned. Subsequently, the Head of Health and Director of Mental Health have been suspended and face disciplinary action. One of the recommendations of the report was to establish an arbitration process. The final arbitration award was made by former Deputy Chief Justice Moseneke on 19 March 2018; it ordered that each claimant be paid R20 000 for funeral expenses, R180 000 for shock and psychological trauma, and R1 000 000 for constitutional damages, as compensation for what were described as “unjustifiable and reckless breaches” of the law. 33
The entire GMHMP crisis, portrayed as an egregious case of “death by maladministration”,
also an object lesson of the consequences of blurred boundaries between governance (in the sense of political oversight) and management by the responsible civil servants. Senior managers appeared unable to resist the pressure felt from political office bearers, despite being legally and professionally responsible. The MEC for Health was held accountable, but even the arbitrator could not discern her motivations: “All we can hope for is that one day, the true reason for the conception and implementation of the Marathon Project will see the light of day”. This tragedy highlighted the abject failure of accountability of elected public representatives, and the lapse in the independence of structures that are accountable to political actors. However, what cannot be gainsaid is that the Office of the Health Ombud was seen to act without fear or favour.

Statutory health councils

Most of the statutory health councils have continued to issue subordinate legislation related to the regulation of scope of practice, registration and qualifications for specific professions. The lack of updated regulatory instruments from the South African Nursing Council is of concern. There is an urgent need to update the Regulations to accompany section 56(6) of the Nursing Act (33 of 2005), and thus extend prescribing privileges to include Schedule 5 and 6 medicines. No regulatory instruments were identified from the South African Dental Technicians Council or the Traditional Health Practitioners Council. Only instruments of particular interest, or those that regulate controversial aspects, are described below.

Health Professions Council of South Africa

Continued effort to regularise the situation with regard to dental support personnel has been of particular interest. The name of the responsible professional board has been changed to the Professional Board for Dental Assisting, Dental Therapy and Oral Hygiene;35 amended qualifications for registration of dental assistants have been proposed;36,37 and the scope of practice of oral hygienists was published in draft form and then finalised.38 Unlike the problematic prescribing privileges accorded to clinical associates (highlighted in the 2017 Review39 and yet to be corrected), the scope of practice for dental hygienists clearly links the provision of topical and local anaesthesia with the relevant section (sections 22A(4)(a)(v)(a)) of the Medicines and Related Substances Act (101 of 1965). Before this provision can be brought into effect, however, necessary listings will need to be made in the Schedules to the Medicines Act. Coordination of this step still appears to be a barrier to practice.

South African Pharmacy Council

As the certificate of need implied in the NHA is not yet in operation, pharmacies remain the only health establishments that require an operating licence from the Department of Health. In December 2017, the Director-General published amended guidance on the issuing of such licences for comment.40 The proposed guidance differentiates between community pharmacies located in rural and urban areas, and those in various size shopping centres. It expresses the norm that there should be “at least one community pharmacy in every sub-district or place”, with a ratio of one pharmacy per 5 000 population (but one per 2 500 in rural sub-districts).

The Council has issued draft competency standards for pharmacists,41 finalised extensive Good Pharmacy Education Standards,42 and continues to update and amend the Good Pharmacy Practice standards.43 Draft changes which would allow for the indirect supervision of post-basic pharmacist’s assistants at pharmacy-linked distribution points (as opposed to PHC clinics) have yet to be finalised.44 The Council also continues to update the list of services for which pharmacists may levy a fee and the guidelines for such fees, even though it is unclear whether or not these are uniformly implemented.45

Allied Health Professions Council of South Africa

The Allied Health Professions Council has instituted professional board examinations for graduates in Chinese medicine and acupuncture, naturopathy, phytotherapy and Unani-Tibb,46 and introduced a highly regulated continuing professional development process for all allied health professions.47 There is a well-recognised problem with the way in which the Medicines and Related Substances Act regulates prescribing by allied health practitioners. The potential conflicts between that Act and the draft scopes of practice of chiropractors and osteopaths are therefore difficult to resolve.48

A striking number of the Board Notices issued by the Council in the last year have dealt with practices declared “unprofessional”, such as the issuing of death certificates by any allied health practitioner,49 injection therapy by chiropractors and osteopaths,50 and the prescribing of bio-identical hormones by homeopaths.51

Medicines and Related Substances Act

Implementing the South African Health Products Regulatory Authority

The President issued a proclamation notice in May 2017 bringing the Medicines and Related Substances Amendment Act (72 of 2008) into effect on 1 June 2017.52 The linked 2015 Amendment Act (14 of 2015) therefore came into effect on the same day, allowing the Minister to appoint the Board for the South African Health Products Regulatory Authority (SAHPRA).53 As SAHPRA only became operational once the Board met, this allowed time for the General Regulations to the Act to be extensively revised, and issued in final form in August 2017.54 Among the many changes are: enabling provisions to allow for electronic prescribing (Regulation 33), potential online access to professional information (Regulation 11), and the requirement for barcodes on the labels of manufactured medicines (Regulation 10). With regard to the latter, the Department of Health has requested comment on its intention to prescribe the inclusion of a specific type of barcode (GTIN-14 Datamatrix) on all medicines supplied on state tender.55

The first meeting of the SAHPRA Board occurred on 1 and 2 February 2018. The MCC ceased to exist on 31 January 2018, ending more than 50 years of reliance on this body. The change of name is far from cosmetic, with a complete transformation initiated in the decision-making model for medicines and medical device regulation.

There is still confusion surrounding section 2(5) of the Act, which states that “The Authority acts through its Board”. While this may be interpreted as requiring all decisions to be taken by the Board, that is not the intention. Decision-making power is intended to be vested in the CEO and delegated personnel, with fiduciary oversight by the Board. The CEO is also enabled to appoint advisory committees,
which are expected to replace the previous MCC expert committees. These changes do, nonetheless, bring the issue of transparency in the regulatory function to the fore. Vawda and Gray have critically examined section 34 of the Act relating to the “preservation of secrecy” and have concluded that “such a blanket provision barring access to information would not pass muster as a ‘limitation that is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom’”. 56 They have accordingly recommended that the provision “be amended in an appropriate manner to accommodate the fundamental right to access to information”. The issue of regulatory transparency has also received attention in the European Union (EU). Pari Pharma sought to challenge the European Medicines Agency’s approval of the disclosure of similarity and superiority reports on an orphan medicine. The Court found against the applicant, signalling a clear preference for transparency.

Numerous challenges confront SAHPRA, some inherited from the MCC (backlogs in the approval process, constraints on capacity), as well as an imperative to transform the regulator into a highly efficient professional organisation.

**Medicine pricing and marketing**

In addition to the routine annual single exit price adjustment and adjustments to the maximum dispensing fees charged by pharmacists and licensed practitioners, the Minister has issued yet another revised set of Regulations dealing with bonus and incentive schemes.57 A previous version was never finalised, although no reason was given. A new complication has been introduced, in that section 18A of the Act has been made applicable to the sale of “any medicine, medical device or IVD” (referring to in vitro diagnostics). It is unclear whether this is in fact the intention, or whether the inclusion of medical devices and IVDs was a drafting error.

Section 18C now calls for the Minister to make Regulations relating to the marketing of medicines, medical devices or IVDs, including Codes of Practice for each of these industries, “after consultation with the relevant industries and other stakeholders”. No such regulation has been issued since the 1997 Amendment Act came into effect in 2003. With particular regard to the advertising of medicines, the reach and powers of the Advertising Standards Authority (ASA) has been in contention for some time. Recently, the Supreme Court of Appeal heard the ASA’s appeal against a High Court finding, namely that as a voluntary association the ASA’s decisions are not binding on non-members and it cannot compel participation of such persons in its processes, and that the ASA may not issue any instruction, order or ruling against non-members.58 An order of court was made by consent declaring that the ASA has no jurisdiction over non-members but may publish rulings on non-members to members in order for them to determine if they “should accept any advertisement before it is published or should withdraw any advertisement if it has been published”. The order also directed the ASA to indicate this in a standard letter to non-members. This will have the effect of compelling even non-members to be mindful of and compliant with the Advertising Code or risk having their advertisements rejected or withdrawn if they have already been published, with the attendant consequences to their reputation.

With reference to the health technology assessment focus under NHI, the Director-General has invited comment on the existing guidelines for pharmaco-economic assessment of medicines.59

**Health-related jurisprudence**

A common complaint from political office bearers and senior health managers is that their budgets are being eroded by the marked increase in malpractice suits and subsequent awards by the courts. The question has been asked: when a court awards damages for wrongs, can the liable party ask to make payments to service providers as and when the expenses are incurred, instead of as a lump-sum settlement, as is routinely ordered? This matter came before the Constitutional Court in MEC, Health and Social Development, Gauteng v DZ,60 which concluded that notwithstanding an instance where a court had awarded damages to be paid in instalments,61 this precedent had not been followed, it was doubtful that the court had jurisdiction to grant such an order, and the MEC’s contention must fail. However, the legislation is likely to be amended drastically to accommodate payment in instalments, as in a meeting on 23 May 2018 Cabinet approved the introduction to Parliament of the State Liability Amendment Bill, 2018. This Bill intends to amend the State Liability Act (20 of 1957) by altering the lump sum payments for wrongful medical treatment of persons by servants of the State, to an alternative settlement structure.62 While ostensibly aimed at increasing the financial resources of state hospitals in order to provide healthcare services, this legislative attempt in no way addresses the fundamental issue of professional negligence that gives rise to the proliferation of malpractice suits.

**Other policies with an impact on the health sector**

For the past five years, government has been reviewing the impact of pharmaceutical patents on high prices, and consequently the difficulty of ensuring access to medicines.39 Following on the publication of its Intellectual Property Consultative Framework in 2016,63 the Department of Trade and Industry released another policy document in 2017, the Draft Intellectual Property Policy of the Republic of South Africa Phase I 2017.64 In this phase of the development of the policy, the focus is on “IP and public health, coordination in international forums, and the implementation of commitments undertaken in international agreements”. Phase 1 priorities have been identified on the basis of South Africa’s development objectives, supplemented by research, analysis, and experience, as well as assessments of existing capacity to implement the measures outlined. While panned by the pro-IP lobby,65 the policy has been lauded by other experts,66,67 and despite being approved by Cabinet in May 2018,68 no indication has yet been given of the process for amendment of the Patents Act (57 of 1978).

**Conclusion**

The tragedy of GMHMP can be viewed as a litmus test for the NHA, the Office of Health Standards Compliance, and the Health Ombud in that it tested the efficacy and fitness for purpose of these instruments and institutions. While it has exposed major deficiencies in both governance and management, it has also focused attention on the gap between policy and implementation, and between intentions and consequences. What is clearly needed is a sea change in the culture of service in certain sectors of the country’s health services, as well as stringent adherence to, and enforcement of, constitutional obligations by all service providers. The arbitration award has set an important precedent in terms of accountability and the impact of the Constitution on the rights of citizens and their families, particularly...
in the award of constitutional damages for violation of human rights. Although not binding on the courts, the last award will have strong persuasive authority. However, the extent to which weaknesses in the implementation of policy and legislation have been exposed cannot be ignored. South Africa cannot be satisfied with world-class policies and laws “on paper”, and yet continue to fail to deliver a responsive, quality, affordable health service to all.

The critical issues of the GMHMP, National Health Insurance, and SAHPRA raise fundamental concerns about the health of our institutions, policies and our ability to deliver on the vision of universal health coverage that is effective, accessible, affordable and respectful of human dignity. The halting progress we have made continues to delay full realisation of the social compact promised in our Constitution.
References


58 The Advertising Standards Authority v Herbex (Pty) Ltd. (902/16) [2017] ZASCA 132 (29 September 2017)


61 Wade v Santam Insurance Company Ltd 1985 1 PH J3 (C).


