Health Policy and Legislation

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In 2013, Parliament passed only one Act tabled by the Minister of Health, the National Health Amendment Act (12 of 2013). However, this Act was fundamental to the creation of an independent Office of Health Standards Compliance, a key building block for the eventual introduction of National Health Insurance. However, the expected White Paper on National Health Insurance was not published, nor did the National Treasury issue the expected discussion document on the financing options. Only one draft health Bill was published: the draft International Health Regulations Bill. The Medicines and Related Substances Amendment Bill was approved by Cabinet, but was not tabled as expected. There was also confusion surrounding the proposed Control of Marketing of Alcohol Beverages Bill. The production of secondary legislation continued apace, with final Regulations issued in terms of the National Health Act dealing with the management of human remains. Draft Regulations on health research were also issued. Secondary and tertiary legislation was also finalised, or issued in draft for comment, by most of the statutory health councils. Of note were the amendments to the General Regulations issued in terms of the Medicines and Related Substances Act (101 of 1965), particularly those dealing with the regulation of complementary medicines. There was considerable interest in the potential health-related implications of the Draft National Policy on Intellectual Property. Though not specific to health, the Protection of Personal Information Act (4 of 2013) will require close attention to practices in all health facilities.

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Introduction

Parliament has amended one of the laws for which the Minister of Health bears responsibility in 2013, in the form of the National Health Amendment Act (12 of 2013).[1] However, that does not alter the list of laws as catalogued in the corresponding chapter of the *South African Health Review* of 2011.[2] The 2012–2013 Annual Report of the National Department of Health (NDoH) also provides an extensive listing of the non-health-related legislation with which the NDoH (and, by extension, the health system) is expected to comply.[3] One additional Bill has been published for comment, but not yet tabled in Parliament.[4]

In addition to describing the changes to the National Health Act, this chapter also focuses on health-related legislative instruments at the national level that have been the subject of change since 2012, 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.

Given the centrality of intellectual property law to access to medicines and other health technologies, the proposed intellectual property policy is covered in some detail.

One new piece of health-related jurisprudence, dealing with traditional health practitioners, is also covered. A court challenge to an element of the South African Pharmacy Council's regulation of pharmacy premises was also decided in late 2013.

In terms of new policy, attention is still firmly focused on the promised White Paper on National Health Insurance (NHI). However, some national policy documents have been released, relating to mental health and to the implementation of the National Drug Master Plan. Changes are also being made to medicines regulatory practice, some of which are detailed in guidelines issued by the Medicines Control Council. However, two major policy developments that were expected to progress in 2013 remain stalled – the issuing of the final White Paper on National Health Insurance, and the creation of the South African Health Products Regulatory Authority.

National legislation related to health

National Health Act

The National Health Amendment Act (12 of 2013) was assented to by the President in July 2013, and brought into effect (save for sections 2 and 3) on 2 September 2013.[5,6] Sections 2 and 3 deal with the planned removal of the responsibility for port health services from provincial departments of health, and its relocation at a national level. The balance of the Amendment Act deals with the creation of the Office of Health Standards Compliance (OHSC) as an independent structure outside of the Department of Health. The OHSC has been created to monitor compliance with norms and standards for the provision of health services in both the public and private sectors. It will also advise the Minister of Health on the development of such norms and standards. The OHSC has been created as a juristic person, to be funded through money appropriated by Parliament and fees received for services rendered. The OHSC is to be headed by a Chief Executive Officer (CEO), to be appointed by the Board in consultation with the Minister of Health. The Board itself is to be appointed by the Minister, and is to consist of at least seven members with pre-specified expertise and nominated in different ways. Five of the members are expected to have expertise in "medicine, pharmacy, reproductive and maternal health, nursing, paediatrics, surgery, clinical governance and risk management, occupational health and safety, infection control, and public health", and are to be nominated by "institutions of higher learning". The balance (one member per category) are expected to have expertise in the law, economics and financial matters or accounting, the private health care sector, public health care and public administration, and quality assurance. Two additional members will represent organised labour and "civil society or the community". A call for nominations was issued in September 2013.[7] Parliamentary oversight of the Office has been ensured by requiring the Minister to table a copy of the annual report, financial statements and audit report within a specified time of receiving such documents from the CEO. Once tabled in Parliament, these documents will also be made public. Nonetheless, the CEO and Board are accountable, primarily, to the Minister. Whether these measures will suffice to ensure the appropriate level of independence of the Office of Health Standards Compliance remains to be seen. Provision has also been made for an Ombud, to be appointed by the Minister, but expected to act independently, impartially and "without fear, favour, bias or prejudice" (section 81B). The Ombud will be able to investigate complaints relating to norms and standards, but also to launch such investigations on his or her own initiative. The OHSC is expected to be a critical element in the proposed system of accreditation for the purposes of National Health Insurance.

One additional set of final Regulations has been issued in terms of the National Health Act in 2013. On 22 May 2013, an extensive set of Regulations dealing with the management of human remains was gazetted in final form.[8] This set of Regulations governs the activities of funeral undertakers, mortuaries, the conveyance of human remains, burial and cremation, exhumations and reburials. While unremarkable in their content, these Regulations do represent one more step in the process of consolidating public health regulation in terms of the National Health Act, and hence in accordance with the new shape and functioning of the national health system.

In May 2012, the Minister had approved the Policy Framework for the Ethics Approval and Endorsement of Health Research by the National Department of Health, which summarised the various ethical and regulatory approvals required for clinical trials and other research.[9] On 29 May 2013, a further set of draft Regulations relating to "Research with Human Subjects" was gazetted for public comment.[10] The draft Regulations clarify the meaning of a number of terms including "best interests of the child" used in section 71(2) of the National Health Act in relation to therapeutic research involving minors. The term is hence defined as follows: "significant decisions affecting a minor's life should aim to promote amongst others the minor's physical, mental, moral and emotional welfare". In the same vein, where section 71(2) of the Act refers to "a significant improvement in the understanding of the minor's condition or disorder", the term "condition" is defined as "physical and psycho-social characteristics shown to affect health". While the term "human subject" was not defined in the Act (section 71 of the Act makes reference to "research or experimentation on a living person"), the term is now defined as "a living person about

whom an investigator obtains data or specimens of identifiable private information through intervention or interaction with that person". Another lacuna in the Act relates to the term "minimal risk", which is now defined as "the probability or magnitude of harm or discomfort anticipated in the research is not greater in itself than that ordinarily encountered in daily life including routine medical, dental or psychological tests or examinations". "Non-therapeutic research" is defined as "research that does not hold out the prospect of direct benefit to the participant but holds out the prospect of generalizable knowledge", while "therapeutic research" is defined as "research that holds out the prospect of direct benefit to the participant". The term "significant risk" is defined as meaning "substantial risk of serious harm".

The Regulations spell out the key principles of health research, including relevance; a basis in valid scientific methodology, protection of the rights of participants to dignity, privacy, bodily integrity and equality; informed consent; and the need for independent ethical review. They impose additional obligations on researchers, including submission of research proposals for ethical review, consultation with relevant authorities, and ensuring the availability of compensation for research-related injury. In addition to the usual requirements for informed consent, the regulations require that research participants be informed of "their freedom to decline or withdraw from the research without prejudice".

Importantly, in relation to non-therapeutic research to be conducted with minors, the Regulations provide for an application process for ministerial consent to such research. Although these Regulations have helped to clarify the normative framework for a broad range of research activities, some weaknesses in the overall framework have been identified.[11] Strode has pointed to the "over-bureaucratisation of ethics", citing as an example the requirement to obtain institutional approval from both the user's healthcare provider and the head of establishment when applying for permission to conduct research into experimental health services at health establishments. She also points to the anomalous situation whereby healthcare workers conducting record reviews are not required to obtain ethical review, whereas other researchers are required to obtain authorisation from an ethics committee.

In September 2013, the Director-General of Health issued draft norms and standards relating to environmental health, as required by section 21(2)(a)(ii) of the National Health Act.[12] Only one month was allowed for comment in the notice, which was issued by the Minister. The intent of these Regulations is to "provide a national approach in ensuring the standardization of functions and activities in the delivery of environmental health services". The norms and standards will form the basis for the monitoring of compliance by the OHSC. Environmental health services are predominantly to be delivered by local authorities, with malaria control and the control of hazardous substances delineated as provincial competencies, and port health as a national competency.

International Health Regulations Bill

A draft Bill providing for the repeal of the International Health Regulations Act (28 of 1974), and incorporating the International Health Regulations of 2005 into domestic law, was gazetted for comment in October 2013. The International Health Regulations (IHR) were adopted by the World Health Assembly in 2005 and came into effect in 2007. They constitute a legally binding agreement and provide a "framework for the coordination of the management of events that may constitute a public health emergency of international concern".[13] Accordingly, the Bill provides for the establishment of a "National IHR Focal Point", the designation of points of entry (including inland container depots), and the application of the IHR in relation to persons, baggage, cargo, containers, ships, aircraft, road vehicles, goods and postal parcels. The notification by World Health Organization of an event which may constitute a "public health emergency of international concern" is based on the following criteria:

"(a) seriousness of the public health impact of the event;

(b) unusual or unexpected nature of the event;

(c) potential for the event to spread internationally; and/or

(d) the risk that restrictions to travel or trade may result because of the event".

In order to ensure compliance with the IHR, the intention to shift port health services from provincial to national control had already been signalled by the National Health Amendment Act (12 of 2013), though not yet implemented.[5,6]

Mental Health Care Amendment Bill

Although tabled in 2012, the Mental Health Amendment Bill (39 of 2012), has yet to be passed by Parliament. Bill 39B, reflecting the changes made by the Select Committee on Social Services of the National Council of Provinces, was issued in March 2013.[14] The Parliament website reflects this Bill as serving before the National Assembly. 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. Among the powers that cannot be delegated are those enabling the designation of facilities for the provision of mental health services.

The National Health Council adopted the Mental Health Policy Framework (MHPF) for SA and the Strategic Plan 2013–2020 in July 2013.[15] As described in the editorial to the local medical journal, the MHPF has eight key objectives: "district-based mental health services and primary healthcare re-engineering; building institutional capacity; surveillance, research and innovation; building infrastructure and capacity of facilities; mental health technology, equipment and medicines; intersectoral collaboration; human resources for mental health; advocacy, mental health promotion and prevention of mental illness". However, the contents of the policy document are no longer accessible on the National Department of Health website, which is undergoing redesign.

Health Professions Act

No fundamental changes to the Health Professions Act have been made during the year under review.

In March 2013, the Health Professions Council of South Africa (HPCSA) amended the ethical rules applicable to practitioners registered with the Council, in order to effect tighter control of the practices of "canvassing" and "touting".[16] Other rule amendments dealt with the registration of additional qualifications for medical practitioners and dentists.[17,18]

In October 2013, the Minister published final Regulations defining the scope of practice of the profession of oral hygiene.[19] Importantly, oral hygienists may only practise independently after a year under

the supervision and control of a dentist, dental therapist or another oral hygienist. Those who qualified before 2001 are also required to have completed additional training before engaging in independent practice.

In November 2013, the HPCSA issued a media statement warning medical practitioners and the public not to participate in or use the telemedicine service "Hello Doctor".[20] While not being specific about what elements of "Hello Doctor" were considered "unethical", the HPCSA's notice characterised the telemedicine service as discouraging "face-to-face consultations between the patient and practitioner". The Council indicated that revised Telemedicine Guidelines were being considered by the professional boards and would be issued in due course.

Nursing Act

In March 2013, the Minister published a raft of Regulations and Notices relating to the registration and education and training of various categories of nursing personnel.[21-24] Other Regulations deal with appeals against decisions of the South African Nursing Council (SANC).[25] On the same day, the Minister issued a notice, in terms of the Nursing Act (33 of 2005), creating the category of "staff nurse".[26] Disappointingly, there has been no progress in creating the category of prescribing nurses envisaged by section 56(1) of the Nursing Act. This continues to hamper the development of authorised prescribing nurses as provided for in the Medicines and Related Substances Act (101 of 1965), and the listing of substances to be prescribed by such nurses in the Schedules. It also prevents, according to some interpretations, the dispensing of prescriptions written by nurses holding either section 38A or 56(6) permits by pharmacists or pharmacist's assistants.

In July 2013, the Minister made minor changes to the Regulations governing disciplinary inquiries conducted by the SANC.[27]

The Regulations regarding the scope of practice of nurses and midwives were issued in draft form in October 2013, with comments being invited within three months of this date.[28]

Pharmacy Act

Despite repeated signals from the South African Pharmacy Council (SAPC), the promised Regulations relating to continuing professional development (CPD) for persons registered in terms of the Pharmacy Act have yet to be gazetted in final form. As a consequence, amendments to Council rules (including the ethical rules) and other Regulations (such as those relating to the maintenance of the registers) have not yet been made. Without these Regulations, the mandatory recording of CPD activities by registered persons cannot be enforced.

On 20 December 2013, the SAPC issued two Board Notices relating to Good Pharmacy Practice (GPP) standards. The first provided new minimum standards relating to the supervision of pharmacy support personnel.[29] The second, a draft for comment, proposed the amendment of a range of GPP standards, including those for the provision of HIV tests in pharmacies (removing the ban on the sale of home-testing kits), requiring all community and institutional pharmacies to either provide a 24-hour service or clearly display the contact details of the on-call pharmacist, covering the procurement, storage and distribution of thermolabile medicines, and stipulating minimum standards for courier pharmacies and the use of automated dispensing units.[30]

Allied Health Professions Act

Only two minor Board Notices were issued by the Allied Health Professions Council of South Africa in 2013, both correcting previous Notices.[31,32] However, as is outlined in relation to the Medicines and Related Substances Act, practitioners registered in terms of this Act will be affected markedly by changes to the registration of complementary medicines. The Medicines and Related Substances Act allows for the designation of "practitioners" (being those registered in terms of the Allied Health Professions Act) as "authorised prescribers", but only in respect of the substances listed for that purpose in the Schedules. This mechanism, which is intended to recognise exceptions rather than norms, seems inappropriate when dealing with complementary products that are within the core competency of specific allied health professions, such as homeopathy. It is as yet unclear, though, how complementary medicines will be incorporated into the existing Schedules.

Medical Schemes Act

Although no new legislation, either primary or secondary, has been issued in relation to the Medical Schemes Act (131 of 1998), the Treasury has released a statement about the complex process of finalising Regulations clearly delineating the boundaries between medical schemes and health insurance products.[33] It was envisaged that a revised second draft of the Regulations would be published for a further comment period by the end of 2013, or after the enactment of the Financial Services Laws General Amendment Bill (29 of 2012), which is currently before Parliament. This Bill introduces an amendment to the definition of a medical scheme in the Medical Schemes Act, as follows (where, as usual, words in bold type in square brackets indicate omissions from existing enactments, and words underlined with a solid line indicate insertions in existing enactments):[34]

'''business of a medical scheme'' means the business of undertaking, **[liability]** in return for a premium or contribution **[-]**, the liability associated with one or more of the following activities:

(a) **[to make provision]** providing for the obtaining of any relevant health service;

(b) **[to grant]** granting assistance in defraying expenditure incurred in connection with the rendering of any relevant health service; **[and]** or

(c) **[where applicable, to render]** rendering a relevant health service, either by the medical scheme itself, or by any supplier or group of suppliers of a relevant health service or by any person, in association with or in terms of an agreement with a medical scheme."

The Treasury summarised the policy stance as follows: "The revised second draft Regulations will acknowledge that while health insurance products have a role in the marketplace, these products must operate within a framework whereby they complement medical schemes and support the social solidarity principle embodied in medical schemes."

In relation to the amended definition, the Treasury explained that: "The revised second draft Regulations will provide for the conditions under which certain health insurance policies will be excluded from the definition of a *"business of a medical scheme"*. The conditions will include, but are not limited to, product standards that define the benefit offering; enhanced product disclosure/marketing requirements; alignment of broker commission between health insurance and medical schemes products; and closer regulatory reporting and monitoring requirements. These conditions are designed to prevent health insurance policies from undermining the business of a medical scheme." Overall, the intention is to allow for the continued sale of Gap Cover and Hospital Cash Plan insurance products, but with enhanced scrutiny of such products.

However, the lack of progress in relation to policy interventions previously signalled but not finalised (and perhaps now abandoned) has been noted.[35] These include the issue of risk equalisation and mandatory scheme membership for those employed above a certain income level.

Foodstuffs, Cosmetics and Disinfectants Act

In March 2013, far-reaching Regulations limiting the inclusion of sodium in certain foods were gazetted in final form.[36] Guidelines for monitoring irradiated foodstuffs were also enabled in terms of the Foodstuffs, Cosmetics and Disinfectants Act (54 of 1972).[37]

Medicines and Related Substances Act

Although a draft of the proposed Medicines and Related Substances Amendment Bill was published for comment in March 2012, this Bill has not been issued in final form, nor does it appear to have been tabled in Parliament, despite being approved by the Cabinet on 18 September 2013.[38,39] Without the passage of this enabling Bill, or the promulgation of the 2008 Amendment Act, the creation of the South African Health Products Regulatory Authority (SAHPRA) cannot proceed.[40] The reasons for the delay of this Bill, which appears now to be somewhere between the tagging mechanism and the First Reading stage before referral to the National Assembly Portfolio Committee on Health, are unclear. To some extent, it may merely be a casualty of the run-up to the 2014 election, but there remain concerns about the viability of the proposed regulatory structure. One of the key definitions in the proposed Bill is that of a "health product", which is defined as "a medicine, Scheduled substance, medical device, IVD, cosmetic or foodstuff". The 2008 Act had defined "IVD" as an "in vitro diagnostic medical device", meaning "a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes". The circular reference would indicate that the 2008 Act will also need to be promulgated. However, more importantly, the definition of a "health product" shows the breadth of the regulatory scope envisaged for the new regulatory authority.

The regulatory approach to complementary medicines has been highly contested for many years, not least since the publication of the 2002 notice by the Medicines Control Council (MCC), which was referred to by some as a "call-up" notice, with a much abbreviated requirement for information, and by others as merely an information-gathering exercise.[41] In November 2013, the Minister finally published amendments to the General Regulations to the Medicines Act, which promised to provide much-needed clarity in this regard.[42] The Regulations, which came into effect on the date of publication, defined complementary medicines (CMs) in relation to three elements, all of which would need to be met: "complementary medicine" means any substance or mixture of substances that (a) originates from plants, minerals or animals; (b) is used or intended to be used for, or manufactured or sold for use in assisting the innate healing power of a human being or animal to mitigate, modify, alleviate or prevent illness or the symptoms thereof or abnormal physical or mental state; and (c) is used in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (63 of 1982)". At the same time, the Medicines Control Council published final guidelines on the assessment of complementary medicines in relation to quality, safety, and efficacy.[43] Two additional draft guidelines were published for comment at the same time, dealing with the fees to be charged for complementary medicine applications and the use of the electronic Common Technical Document (eCTD) for such applications.[44,45] Some weeks later, a rather dated document entitled "Roadmap for registration of complementary medicines" was also placed on the MCC's website.[46] One of the clearer statements in that document related to the status of the 2002 notice: "On 22 February 2002 the Council published a notice in Government Gazette No. 7282, R. 204 solely for the purpose of an audit of products already on or about to enter the market at that time, for a period of 6 months. The intention was that the audit should have been completed in respect of those products available on the market by 22 August 2002. Nevertheless, submissions dealing with the subject matter of the 2002 notice continue to be made to the Medicines Control Council". Further, it made the intention clear: "The 2002 notice has led to much uncertainty amongst importers, manufacturers, wholesalers, retailers and consumers regarding the legal status of these products, as companies who submitted such applications were often under the misconception that these submissions were serving as applications for registration rather than simple notifications. Government Gazette Notice R. 870 of 15 November 2013 calls for the legislative control of all these complementary or alternative medicines".

Importantly, the regulation of complementary medicines did not entail an amendment of the Act itself, but relied on the current provisions in sections 14 and 15, and the standard approach to assessing quality, safety and efficacy. In the same way that the specific requirements for data vary between new chemical entities (which are assessed on all three criteria) and generic medicines (which are only assessed on quality, with an additional requirement to show interchangeability), a specific set of criteria has been established for medicines that meet the definition of "complementary medicines". Critically, these would be restricted to medicines "associated with those disciplines regulated by the Allied Health Professions Council of South Africa (AHPCSA). These are commonly known as Homeopathic medicines, Western Herbals, Traditional Chinese medicines, Ayurvedic medicines, Unani-Tibb and Aromatherapeutic medicines/oils". Specific reference sources and lists of substances were prescribed for each complementary category. One of the pressing tasks will be to identify products that are on the market currently, which may have a registry number issued in terms of the 2002 audit, but do not fit the new definition of a CM, and should therefore either be registered as medicines or removed from the market.

A risk-based approach, differentiating between high-risk and low-risk health claims has been adopted. Examples of "high-risk" claims listed include "Treats/cures/manages any disease/disorder", "Prevention of any disease or disorder", "Reduction of risk of a disease/disorder", "Aids/assists in the management of a named symptom/disease/disorder", "Relief of symptoms of a named disease or disorder", and "Treatment of proven vitamin or mineral deficiency diseases". In order to justify such a claim, applicants would be required to submit clinical data, drawn from at least two of the following four sources: recognised Pharmacopoeiae, recognised monographs, three independent written histories of use in the classical or traditional medical literature, or citations from other *in vivo* or *in vitro* studies, case reports or other sources. Lower requirements have been stipulated for low-risk claims, defined as "General health enhancement without any reference to specific diseases or conditions", "Health maintenance, including nutritional support", or "Relief of minor symptoms (not related to a disease or disorder)". This statement from the guideline is self-evident, but may prove difficult to apply: "The evaluation of high-level claims (i.e. for the use of medicines for serious illnesses) requires an assessment of the differential between the benefits of a medicine and the risks of its use. There is no simple measure for this: the acceptable level of risk varies with the nature of the benefits, the risk from taking the medicine and the risks of untreated (and undiagnosed) diseases. Generally, the more serious and life threatening the untreated disease and the greater the benefit, the higher is the level of acceptable risk. The benefit-risk profile is also affected by the availability of accepted (proven) treatments, the risk profile of those accepted therapies, and the risks of foregoing treatment where such a medically acceptable option is available. A benefit-risk profile should be determined for every complementary medicine – even for so-called "minor conditions".

However, regardless of the specific requirements in terms of safety and efficacy, all CMs will be subject to compliance with current Good Manufacturing Practice. Detailed guidance on the approach to assessing the quality of CMs is provided.

As with the implementation of the initial Act from 1967 onwards, this process will take years to implement. The new General Regulations therefore stipulate that all CMs that are as yet unregistered must include the following disclaimer on their labels: "This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease".

Unusually, the amended General Regulations also included a risk-based set of deadlines. Those related to labelling, package inserts and patient information leaflets would come into operation three months from the date of publication of the amendment. With specific reference to the CM category (the new Category D medicines), those which fell in the pharmacological classifications of antiviral agents, oral hypoglycaemics, cardiac medicines and cytostatic agents would be called up immediately for registration. Accordingly, any CM in such categories that was already on the market would need to have an application for registration submitted within six months from the date of publication of the Regulations. Any new CM in such pharmacological classifications that was brought to market after the same date would first need to be registered. Delayed application of the same rules was specified for other pharmacological categories: by 24 months for CMs in the pharmacological classification slimming preparations, male sex hormones, female sex hormones and androgen-oestrogen combinations claiming sexual stimulation and sexual dysfunction benefits; and by 30 months for any CMs claiming immune stimulation (or similar expressions), medicines acting on the muscular system, and vitamins claiming to be sport supplements and exceeding the upper limits for vitamins and minerals as published by the MCC. Finally, it was stated that the entire process, for all remaining pharmacological classifications, would be completed no later than December 2019. Although vitamins were mentioned in relation to sports supplements, they did not appear to meet the definition of complementary medicines. This view was further supported by the inclusion of new inscriptions for both vitamins and probiotics in amended Schedules published by the Minister in February 2014.[47]

Although this regulatory scheme does not deal with the very challenging issue of African Traditional Medicines, it would appear to provide the means to tackle the ever-expanding and out-of-control CM market, using a risk-based approach that draws on the experience of a number of other regulators, notably the Australian Therapeutic Goods Authority. Whether the MCC inspectorate (or its successor in the form of SAHPRA) has the means, capacity and will to implement these Regulations remains to be seen. Three workshops were arranged in February 2014 to enable the regulator to explain the new guidelines to the CM industry.[48]

The existing provisions of the Act were nonetheless sufficient to declare an unregistered product claiming to be an effective anti-malarial (Nordman Artemesia Anti-malaria Capsules) as undesirable.[49]

In addition to the vexed issue of CMs, the amended General Regulations addressed a number of problems that had emerged since the last set was published in 2003. Some were simply typographical errors, such as tidying up the requirements for registers to be kept by all sellers of specified Schedule 5 substances. Others addressed areas of concern, such as the requirement that anyone entering or leaving the country could only do so with 30 days' supply of medicines for personal use. This was replaced with a three-month quantity for those entering the country only. In addition, the control over clinical trials was extended to those involving animals.

Without much fanfare, an important concession was granted in relation to holders of dispensing licences in October 2013.[50] Provided that the holders of such licences paid the annual fee, they would remain valid until suspended or revoked by the Director-General, instead of being renewable every three years. By contrast, licences to manufacture and to act as a wholesaler or distributor of medicines would remain valid for only five years.

The Medicines Act also includes the regulation of prices in the private sector. In January 2013, the Minister stipulated that single exit prices in the private sector could be increased by a maximum of 5.8%.[51] On 1 February 2013, the Director-General issued final guidelines on the submission of pharmacoeconomic analyses in relation to medicines, but their application remains voluntary until further notice.[52] It is unclear whether any such submissions have yet been submitted, or whether the Department has made any determinations on the basis of such submissions. The degree to which the medical schemes will accept or act upon such determinations has also been questioned.[53] In September 2013, the Minister of Health issued a notice calling for submissions in relation to the single exit price increase for 2014, also providing a hint at the

weighting to be applied in relation to local consumer price inflation and the exchange rates relative to the Euro and US dollar.[54] One of the unintended consequences of the single exit price system has been the apparent ban on any donation programmes in the private sector. In that regard, an MCC notice of section 36 exclusions issued in June 2013 was significant.[55] It exempted a particular product from the application of section 22G(3)(a) of the Act and General Regulation 6, but "solely for the sale at no cost to one A Vahed at the prescribed dose of his treating Physician". This is a clumsy and time-consuming solution to the problem, requiring a unanimous recommendation from the MCC for reaching a decision. In May 2013, the Registrar used the same mechanism to extend the exemption of Schedule 0 medicines from the transparent pricing system, including the ban on bonusing, for a further three years.[56] In January 2014, the Minister of Health stipulated that the maximum increase in the single exit price for 2014 would be 5.82%, and the Director-General published the requirements for applying for such an increase.[57,58] The low maximal increase in the single exit price was immediately criticised as not taking ongoing exchange rate fluctuations into account, which elicited a response from the Department indicating that extraordinary increases in 2014 might be considered and that the formula for determining such increases might be reconsidered.[59] However, allowing more than one increase in a single exit price cycle would require a change in the Regulations.

In September 2013, two sets of Schedules to the Medicines Act were issued by the Minister.[60,61] The first of these was significant, as it listed substances in each of the schedules to be prescribed by various categories of emergency personnel, dental therapists and optometrists. These were the first such listings in the Schedules, allowing for the application of Section 22A of the Medicines and Related Substances Act, as had been in place since 2003. However, while other applications for similar listings were in progress, no movement had yet been made in relation to nurses, the most common non-medical prescribers in the health system. A draft guideline for such applications was published by the MCC in October 2013.[62]

Other health-related legislation

Although not under the direct auspices of the Minister of Health, two additional pieces of legislation with health-related consequences were passed or published in draft form in 2013.

Protection of Personal Information Act

The Protection of Personal Information Act (4 of 2013), assented to in November 2013, is a progressive piece of legislation that seeks to give effect to the constitutional right to privacy by protecting citizens' personal information held by public and private bodies, through the regulation of the possession of personal information, and to enforce these measures through the mechanism of an Information Regulator.[63]

In the Act, "personal information" is defined broadly as information relating to identifiable, living natural (or juristic) persons, concerning their race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth. Significantly, such information also includes a person's medical history and biometrics. The bodies identified may handle such information (lawful processing) under stringent conditions stipulated in the Act, and subject to the rights of the individual being protected, which conditions include the principles of accountability, lawfulness, minimality, consent, justification and objection. Further safeguards include security, data subject participation and correction of personal information. In addition, there is a prohibition on the processing of special personal information such as "the religious or philosophical beliefs, race or ethnic origin, trade union membership, political persuasion, health or sex life or biometric information" of an individual. The prohibition relating to an individual's health or sex life does not apply to processing by certain exempt categories: medical professionals, healthcare institutions or facilities or social services (for the purposes of treatment, care or administration), insurance companies or medical schemes (for the purposes of assessing risk to the company or scheme), and a host of other bodies.

The Act has significant implications for the healthcare sector. It bolsters the privacy provisions in the common law, the Constitution[64] and the National Health Act.[65] It does so by requiring the adoption, by public and private bodies, of security measures on the integrity and confidentiality of personal information in their possession or control. This is to be achieved by taking appropriate and reasonable measures to prevent the loss of, and unlawful access to, such information. Breaches are to be visited with both penalties under the Act, as well as civil claims for damages resulting from negligent disclosure of personal information.

A notable exception is the processing of such information "solely for the purpose of journalistic, literary or artistic expression to the extent that such an exclusion is necessary to reconcile, as a matter of public interest, the right to privacy with the right to freedom of expression". It thus appears to sanction the disclosure of medical records, provided it can be established that it would be in the public interest to do so. This is in sharp contrast to the approach adopted by legislators in respect of the 'Secrecy Bill', which does not appear to have struck the same acceptable balance between secrecy and the public interest.[66]

Draft Mine Health and Safety Amendment Bill

In November 2013, the Minister of Mineral Resources issued a draft version of the Mine Health and Safety Amendment Bill, 2013, for comment.[67] The memorandum explains that it seeks to strengthen the setting, monitoring and enforcement of health and safety standards in mines, and the operations of the Mine Health Inspectorate.

Health-related policy

The pre-eminent policy process relating to health should be the introduction of National Health Insurance. However, while there has been some attention paid to the "piloting" of NHI in various districts, the White Paper has yet to be issued.[68,69] The promised discussion document on the financing options for NHI has also not yet been issued by the National Treasury, though academic endeavours to explore the various possibilities continue.[70] Think-tanks within South Africa have also continued to issue analyses of the potential impact of policy changes on the existing private sector.[71]

Of direct relevance to this effort, the Terms of Reference for the market inquiry into the private healthcare sector were issued in final form

in late November 2013.[72] Importantly, the Terms of Reference have been extended to include the "relationship between pharmaceutical manufacturers, logistics services, health professionals, hospitals and hospital groups, doctors and retail pharmacy as systemic cost drivers", as well as "the influence of the Government's tender processes on product prices in the private health sector". The pricing of new medicines and health technologies will also be considered, which tie in with the pharmacoeconomic submissions now requested by the Department of Health. Nonetheless, as pointed out by SECTION27, much remained unclear about the process of the inquiry, which was expected to commence on 6 January 2014 and reported by 30 November 2015.[73] The names of the members of the panel were announced in January 2014.[74]

In 2013, the National Department of Health continued to issue technical policy documents in order to guide healthcare practice. These included the updated contraception guidelines,[75,76] various guidelines to aid the implementation of the Mental Health Care Act,[77] and the Mini Drug Master Plan (2011/12–2013/14).[78] As with the 2012 contraception guidelines, the 2013 guidelines on the management of type 2 diabetes at primary care level did not appear to have been aligned explicitly with the Standard Treatment Guidelines and Essential Medicines List developed by the ministerially appointed National Essential Medicines List Committee, which inform the procurement of medicines in the public sector.[79] Where such uncoordinated policymaking occurs, delays in the procurement of the necessary health products (such as contraceptive implants) may delay implementation of the policy.

While no policy document has yet been issued, the Minister of Health has clearly signalled an intention to address alcohol usage by means of restrictions on the marketing of such products. It has been pointed out that alcohol taxes in South Africa are currently regressive, with the tax on sorghum beer the most regressive.[80] Notably, the Department of Health has issued Terms of Reference for the call for proposals to conduct an independent regulatory impact assessment on the proposed Control of Marketing of Alcohol Beverages Bill.[81] In a statement made on 20 September 2013, the Minister of Social Development stated that the Bill would seek "to contribute to the reduction of alcohol-related harm and the protection of public health and community well-being by limiting the exposure of the public to alcohol marketing by (a) Restricting the advertisement of alcoholic beverages, (b) Prohibiting any sponsorship associated with alcoholic beverages (excluding donations), and (c) Prohibiting any promotion of alcoholic beverages".[82] However, a month later, the media reported that no Bill had been published, and that there appeared to be disagreement in Cabinet about the process to be followed.[83] It is unclear whether the Bill would first be subjected to a regulatory impact assessment (as outlined in the Department of Health's notice) or published for public comment.

Other policies with an impact on health

Draft National Policy on Intellectual Property

The Draft National Policy on Intellectual Property, 2013 was released for public comment by the Minister of Trade and Industry on 4 September 2013.[84] As indicated in the last edition of the *Review*, the broad aim of this policy is to empower South Africans and promote development. While there are some differences, the 2013 Draft National Policy is substantially the same as its predecessor. Significantly, the policy again devotes extensive sections to access to public health and medicines. In particular, it has been described as: "grounded in a developmental approach appropriate to our country, and seeks to eliminate the many perverse outcomes of IP protection which are detrimental to the broader society".[85]

The Draft Policy contains strong recommendations with regard to the following issues:

- the establishment of a substantive system for the search and examination of patents;
- the incorporation of flexibilities in the World Trade Organizations's Trade-Related Aspects of Intellectual Property Rights Agreement (1994), and the Doha Declaration on TRIPS and Public Health (2001);
- amendment of the Patents Act in order to be amenable to public health concerns;
- the inclusion of such flexibilities as pre- and post-grant opposition to patent applications, and the use of parallel importation and compulsory licensing;
- a decision not to enter into bilateral trade agreements that negate the gains attained in multilateral agreements regarding flexibilities; and
- the protection of clinical trial and other data, but not data exclusivity.

However, while the policy refers to the use of flexibilities, in particular in order to enhance access to affordable medicines, it is found wanting in the following respects:

- the lack of the requirement of strict patenting standards with explicit proscription of new use and new formulation patents to prevent patent "ever-greening" ("the submission of a new application for an ostensibly novel product, which is in fact only very slightly different from the one which is about to lose its patent protection. The 'new' product can then receive a further 20 years of patent protection.");[86]
- provision for full disclosure in patent applications, including International Non-proprietary Name;
- provision for parallel importation under an explicit international exhaustion regime;
- provision for simplified procedures for compulsory licensing, including expanded grounds for grant, and remuneration guidelines limiting extensive royalties;
- provision for compulsory licences on the grounds of anti-competitive conduct;
- extensive early working exceptions, as well as other exceptions for educational, scientific and research purposes;
- exclusion of diagnostic, therapeutic and surgical methods, plants, animals and genetic material; and
- broad exceptions to patent rights for research and education.

The impact of intellectual property (IP) protection is clearly evident in the field of tuberculosis (TB). With the prices of first-line antiretrovirals (ARVs) having plummeted in the past decade as a result of generic competition,[87] the spotlight has increasingly been turned on the issue of medicines for tuberculosis, second-line ARVs, and medicines used to treat cancer. A recent study indicates that funding for TB

research and development has declined, primarily as a result of private sector cutbacks on spending.[88] IP protection on key drugs to treat TB further compounds the problem. One example is linezolid, which has been used in treating drug-resistant TB. Pfizer currently markets the drug at the unaffordable price of R676 per tablet in the private sector. A generic version manufactured in India is sold in that country for as little as R10 per tablet, but South Africa cannot import this cheaper option because of Pfizer's patent.[89] An improved pathway to government use licensing or compulsory licensing would ease access to this and other needed essential medicines.

Although the Minister of Health had not previously appeared to be particularly engaged with the Draft National Policy on Intellectual Property, this changed dramatically with the publication in the media of a proposal from an American lobbying firm to the Innovative Pharmaceutical Association South Africa (IPASA), the body representing transnational pharmaceutical manufacturers.[90] The proposal, entitled "Campaign to Prevent Damage to Innovation from the Proposed Draft National IP Policy in South Africa" was rejected by IPASA, but the reputational damage was sufficient to see two member companies leave IPASA. The document, and the Minister's characterisation of the planned lobbying effort, drew international attention and was also referred to by the Director-General of Health in her address to the World Health Organization Executive Board in February 2014.[91] The Director-General drew immediate parallels with the 1998 attempt to prevent the promulgation of the Medicines and Related Substances Amendment Act (59 of 1997): "Chair, the recent leak by the multinational pharmaceutical industry of the strategy written by Public Affairs Engagement to undermine South Africa's efforts to reform its Intellectual Property policies is unfortunate. One of the objectives of this policy is to contribute towards the protection and promotion of public health, and access to medicines in particular. This is not the first time that South Africa has been under such an attack, even in the face of the most devastating HIV/AIDS and TB co-morbidities. The first time was when Nelson Mandela was the first respondent to the legal challenge". Although the Draft National Policy on Intellectual Property is not restricted to medicines-related issues, it appears that, as in 1998, access to medicines will provide the battleground over which the technical issues are fought.

Jurisprudence

Few court decisions with marked impact on the delivery of health care in South Africa have been delivered in 2013. However, two stand out.

In the matter of *Kievits Kroon Country Estate v Mmoledi*, the Supreme Court of Appeal (SCA), when considering an unfair dismissal, grappled with the issue of whether a traditional healer's certificate may be equated with a medical certificate for the purposes of sick leave.[92] The employee concerned had requested sick leave and provided a letter from a traditional healer to the effect that she was being treated for having "visions" of ancestors, which required her to undergo training with the traditional healer to deal with her condition. Having failed to report to work for the period requested, she was dismissed after an internal disciplinary inquiry found her guilty of misconduct for disobeying an instruction to report for duty and being absent without permission. This decision was overturned by the Commission for Conciliation, Mediation and Arbitration (CCMA), and subsequently confirmed by the Labour Court, the Labour Appeal Court and the SCA. In essence, the CCMA found, after hearing her uncontroverted evidence, that her absence was caused by circumstances beyond her control, and ordered her reinstatement. The Court referred to the "cultural chasm" between the opposing world views of the employer and employee, citing the decision in *Department of Correctional Services v Popcru* in support of the view that "employees' sincerely held cultural beliefs were constitutionally protected".[93] While the *Kievits* decision appears to place the recourse to traditional healers on par with "mainstream" medical practitioners in respect of medical certificates and treatment options, it remains to be seen how widely it will be implemented in practice. In this regard, appropriate regulation of the traditional medicines sector will go a long way towards providing clarity.

In December 2013, the North Gauteng High Court delivered a judgment in the case brought by MediRite (Pty) Ltd, a corporate pharmacy owner, challenging the South African Pharmacy Council's amended Good Pharmacy Practice (GPP) standards relating to the demarcation of a pharmacy located within another business.[94] The GPP standard was changed in 2012 to require that "[t]he demarcation must be permanent, solid and closed at all times, which demarcation may be, inter alia, brick and mortar, aluminium, steel, glass, dry wall or wood partition". The GPP standard also required the demarcation to extend "from the floor to the ceiling height" and to incorporate all areas attached to the pharmacy. This was deemed by the applicant to be excessive and impractical in relation to a pharmacy located in a supermarket, and thus a threat to its viability. The application was dismissed, with costs, as the Pharmacy Council's actions were found to be reasonable with regard to the requirements of the Promotion of Administrative Justice Act (3 of 2000).

Conclusion

Although 2013 did not see release of the much-anticipated White Paper on National Health Insurance, there has been movement in some important areas of health legislation and policy. Of note, the enabling provisions for the independent Office of Health Standards Compliance are now in place and the process of nomination of members of the Board of that structure has commenced. The prospects of progress in relation to the regulation of complementary medicines seem at last to be positive, though the possibility of court action to delay or frustrate the implementation of the new Regulations cannot be dismissed. Although the major changes to national health legislation have been put in place, in particular in the form of the National Health Act (61 of 2003), the challenges of implementing such changes in every sphere of government, at every health facility, and across the persistent public-private divide cannot be underestimated. The enabling nature of much of South African health law requires the development and maintenance of detailed secondary legislation in the form of Regulations and statutory council notices. Though each may seem minor in content, they all contribute to the shaping of the national health system, and to the progressive realisation of the right to health envisaged by the Bill of Rights.

Finally, like all others who use personal information protected in terms the new Act, healthcare providers will need to carefully consider the demands of new legislation on their practices.

Update

After finalisation of this chapter, a number of new developments of relevance to health policy and legislation were noted. These are described in brief:

- On 18 February, notice of intention to table a private members' Bill and inviting comment on the Medical Innovation Bill was gazetted. This Bill, tabled by Mario Oriani-Ambrosini, MP is intended to "make provision for innovation in medical treatment and to legalise the use of cannabinoids for medical purposes". [General Notice No. 100 of 2014, Government Gazette No. 37349, 18 February 2014]
- On 20 February, the explanatory summary for the Medicines and Related Substances Amendment Bill (6 of 2014), was published. However, no public hearings have yet been held in relation to this Bill. [General Notice No. 117 of 2014, Government Gazette No. 37361, 20 February 2014]
- On 28 February 2014, the Minister of Health issued draft Regulations proposing criteria for the licensing of pharmacy premises. Although this licensing scheme is operated in terms of the Pharmacy Act (53 of 1974), it closely mirrors the proposed certificate of need. [Government Notice No. R.151, Government Gazette No. 37399, 28 February 2014]
- On 31 March 2014, the President issued a promulgation notice, setting 1 April 2014 as the date on which sections 36 to 40 of the National Health Act (61 of 2003) would come into operation. Section 36(1) states that "A person may not – (a) establish, construct, modify or acquire a health establishment or health agency; (b) increase the number of beds in, or acquire prescribed health technology at, a health establishment or health agency; (c) provide prescribed health services; or (d) continue to operate a health establishment or health agency after the expiration of 24 months from the date this Act took effect, without being in possession of a certificate of need". The implementation of the certificate of need will require the development of extensive Regulations. [Government Notice No. 21 of 2014; Government Gazette No. 37501, 31 March 2014]
- On 23 April 2014, the Minister of Health published the National Health Normative Standards Framework for Interoperability in eHealth. [Government Notice No. 314 of 2014, Government Gazette No. 37583), 23 April 2014]
- On 2 May 2014, the President issued a promulgation notice, bringing some sections of the Traditional Health Practitioners Act (22 of 2007) into operation. [Government Notice No. 29 of 2014, Government Gazette No. 37600, 2 May 2014]
- On 23 May 2014, the Minister of Health issued draft Regulations regarding healthcare waste management, in terms of the National Health Act. [Government Notice No. R.375, Government Gazette No. 37654, 23 May 2014]

References

1 Republic of South Africa. National Health Amendment Act (12 of 2013). Cape Town: Government Gazette No. 367, 24 July 2013.
URL: http://www.gov.za/documents/download.php?f=195193

2 Gray A, Vawda Y, Jack C. Health policy and legislation. In: Padarath A, English R, editors. South African Health Review 2011. Durban: Health Systems Trust; 2011.

3 National Department of Health. Annual Report 2012-2013. Pretoria: National Department of Health; 2013.

4 Minister of Health. International Health Regulations Bill, 2013. General Notice No. 1020. Cape Town: Government Gazette No. 36931, 14 October 2013.
URL: http://www.gov.za/documents/download.php?f=200955

5 Republic of South Africa. National Health Amendment Act (12 of 2013). Government Notice No. 529. Cape Town: Government Gazette No. 36702, 24 July 2013.
URL: http://www.gov.za/documents/download.php?f=195193

6 President of the Republic of South Africa. Commencement of the National Health Amendment Act (12 of 2013). Proclamation No. 37. Cape Town: Government Gazette No. 36787, 30 August 2013.
URL: http://www.gov.za/documents/download.php?f=197816

7 Minister of Health. Notice of nominations for members of the Board of the Office of Health Standards Compliance. Government Notice No. R.672. Cape Town: Government Gazette No. 36836, 9 September 2013.
URL: http://www.info.gov.za/view/DownloadFileAction?id=198407

8 Minister of Health. Regulations relating to the management of human remains. Government Notice No. R.363. Cape Town: Government Gazette No. 36473, 22 May 2013.
URL: http://www.gov.za/documents/download.php?f=190587

9 National Department of Health. Policy Framework for the Ethics Approval and Endorsement of Health Research by National Department of Health. Approved by the Minister on 24 May 2012.

10 National Department of Health. Regulations relating to research with human subjects. Government Notice No. R.387. Cape Town: Government Gazette No. 36508, 29 May 2013.
URL: http://www.gov.za/documents/download.php?f=190997

11 Strode AE. The parameters of the current legal framework for health research: forms of health research which are regulated and obligations imposed on researchers. SAJBL 2013; 6(2): 69-71.

12 Minister of Health. National norms and standards relating to environmental health in terms of National Health Act (61 of 2003). General Notice No. 943, Government Gazette No. 36849, 20 September 2013.
URL: http://www.gov.za/documents/download.php?f=199222

13 World Health Organization. The International Health Regulations (2005). IHR Brief No. 1.
URL: http://www.who.int/ihr/publications/ihrbrief1en.pdf

14 Minister of Health. Mental Health Care Amendment Bill (39B of 2012).
URL: http://www.gov.za/documents/download.php?f=200445

15 Stein D. A new mental health policy for South Africa. S Afr Med J 2014; 104(2): 115-116.
URL: http://www.samj.org.za/index.php/samj/article/viewFile/7938/5796

16 Health Professions Council of South Africa. The ethical rules of conduct for practitioners registered under the Health Professions Act, 1974: amendment. Board Notice No. 26. Cape Town: Government Gazette No. 36083, 1 March 2013.
URL: http://www.gov.za/documents/download.php?f=185153

17 Health Professions Council of South Africa. Rules relating to the registration by medical practitioners and dentists of additional qualifications: amendment. Board Notice No. 163. Cape Town: Government Gazette No. 36707, 2 August 2013.
URL: http://www.gov.za/documents/download.php?f=195714

18 Health Professions Council of South Africa. Rules relating to the registration by medical practitioners and dentists of additional qualifications: amendment. Board Notice No. 31. Cape Town: Government Gazette No. 36225, 15 March 2013.

19 Minister of Health. Regulations defining the scope of the profession of oral hygiene. Government Notice No. R.800. Cape Town: Government Gazette No. 36944, 17 October 2013.
URL: http://www.gov.za/documents/download.php?f=201257

20 Health Professions Council of South Africa. Media statement: Doctors and public warned against use of Hello Doctor Services. 19 November 2013.
URL: http://www.hpcsa.co.za/downloads/press_releases/press_release_2013/hpcsa_med_rel_telemedicine_nov_2013.pdf

21 Minister of Health. Regulations relating to the approval of and minimum requirements for education and training of learners leading to registration in category auxiliary nurse. Government Notice No. R.169. Cape Town: Government Gazette No. 36230, 8 March 2013.
URL: http://www.gov.za/documents/download.php?f=185957

22 Minister of Health Regulations relating to the approval of and minimum requirements for education and training of learners leading to registration in category staff nurse. Government Notice No. R.171. Cape Town: Government Gazette No. 36232, 8 March 2013.
URL: http://www.gov.za/documents/download.php?f=185958

23 Minister of Health. Regulations relating to the approval of and minimum requirements for education and training of learners leading to registration in categories professional nurse and midwife. Government Notice No. R.174. Cape Town: Government Gazette No. 36235, 8 March 2013.
URL: http://www.gov.za/documents/download.php?f=185956

24 Minister of Health. Regulations relating to the particulars to be furnished to the Council for keeping the register for nursing practitioners; the manner of effecting alterations to the register; and certificates that may be issued by the Council: amendment. Government Notice No. R.175. Cape Town: Government Gazette No. 36236, 8 March 2013.
URL: http://www.gov.za/documents/download.php?f=190097

25 Minister of Health. Regulations regarding an appeal against decisions of South African Nursing Council. Government Notice No. R.172. Cape Town: Government Gazette No. 36233, 8 March 2013.
URL: http://www.gov.za/documents/download.php?f=185955

26 Minister of Health. Notice regarding the creation of categories of practitioners in terms of section 31(2) of the Nursing Act, 2005. Government Notice No. R.176. Cape Town: Government Gazette No. 36237, 8 March 2013.
URL: http://www.gov.za/documents/download.php?f=185953

27 Minister of Health. Regulations relating to the conducting of inquiries into alleged unfitness to practice due to disability or impairment of persons registered in terms of the Nursing Act, 2005. Government Notice No. R.490. Cape Town: Government Gazette No. 36671, 15 July 2013.
URL: http://www.gov.za/documents/download.php?f=194349

28 Minister of Health. Nursing Act: Regulations regarding the scope of practice of nurses and midwives. Government Notice No. R.786. Cape Town: Government Gazette No. 36935, 15 October 2013.
URL: http://www.gov.za/documents/download.php?f=201101

29 Registrar of the South African Pharmacy Council. Rules relating to good pharmacy practice: Minimum standards: Amendments. Board Notice No. 271, Government Gazette No. 37193, 20 December 2013.
URL: http://www.gov.za/documents/download.php?f=206321

30 Registrar of the South African Pharmacy Council. Rules relating to good pharmacy practice: Amendments and additional minimum standards: draft. Notice No. 272. Cape Town: Government Gazette No. 37193, 20 December 2013.

31 Allied Health Professions Council of South Africa. Registration of trainers and/or lecturers at public and private institutions of education and training in allied health professions. Board Notice No. 30. Cape Town: Government Gazette No. 36225, 15 March 2013.
URL: http://www.gov.za/documents/download.php?f=190100

32 Allied Health Professions Council of South Africa: Paragraph 3.1 amendment. Board Notice No. 149. Cape Town: Government Gazette No. 36682, 26 July 2013.
URL: http://www.gov.za/documents/download.php?f=195216

33 National Treasury. Process for the release of the envisaged revised draft regulations on the demarcation between health insurance policies and medical schemes. 15 October 2013.

34 Minister of Finance. Financial Services Laws General Amendment Bill (29B of 2012).
URL: http://www.gov.za/documents/download.php?f=202141

35 Bateman C. Universal coverage possible – with private sector support. S Afr Med J 2014; 104(1): 8-9

36 Minister of Health. Regulations relating to the reduction of sodium in certain foodstuffs and related matters. Government Notice No. R.214. Cape Town: Government Gazette No. 36274, 20 March 2013.
URL: http://www.gov.za/documents/download.php?f=186474

37 Minister of Health. Regulations governing irradiated foodstuffs: amendment. Government Notice No. R.366. Cape Town: Government Gazette No. 36484, 24 May 2013.
URL: http://www.gov.za/documents/download.php?f=190908

38 National Department of Health. Publication of Medicines and Related Substances Amendment Bill, 2012. General Notice No. 216. Cape Town: Government Gazette No. 35151, 15 March 2012.
URL: http://www.gov.za/documents/download.php?f=161875

39 Government Communications and Information Services. Statement on the Cabinet meeting of 18 September. 23 September 2013.
URL: http://www.gcis.gov.za/content/newsroom/media-releases/cabinet-statements/statement-cabinet-meeting-18Sept2013

40 Republic of South Africa. Medicines and Related Substances Amendment Act (72 of 2008). Government Notice No. 434. Cape Town: Government Gazette No. 32148, 21 April 2009.
URL: http://www.info.gov.za/view/DownloadFileAction?id=99562

41 Registrar of Medicines. Call up notice for medicines frequently referred to as complementary medicines in terms of the Medicines and Related Substances Act (101 of 1965). Government Notice No. R.204 Cape Town: Government Gazette No. 23128, 22 February 2002.

42 Minister of Health. General Regulations made in terms of the Medicines and Related Substances Act (101 of 1965): amendment. Government Notice No. R.870. Cape Town: Government Gazette No. 37032, 15 November 2013.
URL: http://www.gov.za/documents/download.php?f=203571

43 Medicines Control Council. Complementary medicines: quality, safety and efficacy. November 2013.
URL: http://mccza.com/genericDocuments/7.01_CAMs_QSE_Dec13_v2.pdf

44 Medicines Control Council. Fees payable to the Registrar for complementary medicines. November 2013.
URL: http://mccza.com/genericDocuments/17.04_Fees_CAMs_Nov13_v1.pdf

45 Medicines Control Council. Complementary medicines – use of the ZA-CTD format in the preparation of a registration application. November 2013.
URL: http://mccza.com/genericDocuments/7.03_CAMs_ZACTD_Nov13_v1_draft.pdf

46 Medicines Control Council. Roadmap for registration of complementary medicines. November 2013.
URL: http://mccza.com/genericDocuments/7.02_Roadmap_for_CAMs_Dec13_v1.pdf

47 Minister of Health. Medicines and Related Substances Act: Schedules. Government Notice No. R.104. Cape Town: Government Gazette No. 37318, 11 February 2014.
URL: http://www.gov.za/documents/download.php?f=209487

48 Registrar of Medicines. Workshops between the regulator and industry on registration of complementary medicines. December 2013.
URL: http://mccza.com/genericDocuments/9.50_CAMs_workshops_Dec13_v1.pdf

49 Registrar of Medicines. Medicines and Related Substances Act (101/1965) as amended: medicines that have been declared undesirable. Government Notice No 916. Cape Town: Government Gazette No. 37075, 27 November 2013.

50 Minister of Health. Medicines and Related Substances Act (101 of 1965). General regulations: amendment. Government Notice No. R.766. Cape Town: Government Gazette No. 36929, 14 October 2013.
URL: http://www.gov.za/documents/download.php?f=200950

51 Minister of Health. Annual adjustment of single exit price of medicines and scheduled substances for the year 2013. Government Notice No. 35. Cape Town: Government Gazette No. 36087, 22 January 2013. URL: http://www.gov.za/documents/download.php?f=182386

52 Director-General of Health. Publication of the guidelines for pharmacoeconomic submissions. Government Notice No. R.68. Cape Town: Government Gazette No. 36118, 1 February 2013. URL: http://www.gov.za/documents/download.php?f=183162

53 Stander MP, Bergh M, Miller-Jansön H. A first step towards transparency in pricing of medicines and schedules substances – publication of guidelines for pharmaco-economic submissions. A Afr Med J 2014; 104(1): 10-11.

54 Minister of Health. Regulations relating to a transparent pricing system for medicines and scheduled substances: annual adjustment of single exit price of medicines and scheduled substances for the year 2014. Government Notice No. R.705. Cape Town: Government Gazette No. 36863. URL: http://www.gov.za/documents/download.php?f=199694

55 Registrar of Medicines. Exclusion of certain medicines from operations of certain provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965). Government Notice No. R.409, Government Gazette No. 36551, 10 June 2013. URL: http://www.gov.za/documents/download.php?f=191896

56 Registrar of Medicines. Exclusion of certain medicines from operation of certain provisions of the Medicines and Related Substances Act (101 of 1965). Government Notice No. R.377. Cape Town: Government Gazette No. 36507, 29 May 2013. URL: http://www.gov.za/documents/download.php?f=190994

57 Minister of Health. Medicines and Related Substances Act: Annual adjustment of single exit price of medicines and scheduled substances for 2014. Government Notice No. R.68. Cape Town: Government Gazette No. 37292, 31 January 2014. URL: http://www.gov.za/documents/download.php?f=208725

58 National Department of Health. Medicines and Related Substances Act: Information to be furnished by manufacturers and importers of medicines and scheduled substances when applying for single exit price adjustment in 2014. Medicines and Related Substances Act: Annual adjustment of single exit price of medicines and scheduled substances for 2014. Government Notice No. R.69. Cape Town: Government Gazette No. 37292, 31 January 2014. URL: http://www.gov.za/documents/download.php?f=208724

59 Kahn T. Local drug makers getting pick-me-up. BDLIve, 6 February 2014. URL: http://www.bdlive.co.za/business/healthcare/2014/02/06/local-drug-makers-getting-pick-me-up

60 Minister of Health. Medicines and Related Substances Act: Schedules. Government Notice No. R.674. Cape Town: Government Gazette No. G 36827, 13 September 2013. URL: http://www.gov.za/documents/download.php?f=198817

61 Minister of Health. Medicines and Related Substances Act: Schedules. Government Notice No. R.690. Cape Town: Government Gazette No. 36850, 20 September 2013. URL: http://www.gov.za/documents/download.php?f=199230

62 Registrar of Medicines. Scheduling of substances for prescribing by authorised prescribers. October 2013. URL: http://mccza.com/genericDocuments/2.37_Scheduling_for_prescribing_by_authorised_prescribers_Oct13_v1_for_comment.pdf

63 Republic of South Africa. Protection of Personal Information Act (4 of 2013). Government Notice No. 912. Cape Town: Government Gazette No. 37067, 26 November 2013. URL: http://www.gov.za/documents/download.php?f=204368

64 Republic of South Africa. The Constitution of the Republic of South Africa Act (108 of 1996).

65 Republic of South Africa. National Health Act (61 of 2003).

66 Minister of State Security. Protection of State Information Bill (6H – 2010).

67 Minister of Mineral Resources. Mine Health and Safety Amendment Bill: Draft. General Notice No. 1103. Cape Town: Government Gazette No. 37027, 15 November 2013. URL: http://www.gov.za/documents/download.php?f=203481

68 Matsoso MP, Fryatt R. National Health Insurance: the first 18 months. S Afr Med J 2013; 103(3): 156-158.

69 Ogunbanjo G. What is the status quo of South Africa's National Health Insurance pilot project? SA Fam Pract 2013; 55(1): 301.

70 Okorafor OA. National Health Insurance reform in South Africa. Estimating the implications for demand for private health insurance. Appl Health Econ Health Policy 2012; 10(3): 189-200.

71 Econex. The South African Private Healthcare Sector: Role and Contribution to the Economy. Research Note 32, December 2013. URL: http://www.econex.co.za/index.php?option=com_docman&task=doc_download&gid=106&Itemid=60 (the full report is at http://www.econex.co.za/index.php?option=com_docman&task=doc_download&gid=104&Itemid=60)

72 Competition Commission of South Africa. Terms of reference for market inquiry into the private health sector. General Notice No. 1166. Cape Town: Government Gazette No. 37062, 29 November 2013. URL: http://www.gov.za/documents/download.php?f=204560

73 SECTION27. Press Statement: SECTION27 welcomes the release of the final Terms of Reference for the Competition Commission's health inquiry. URL: http://www.section27.org.za/2013/12/03/press-statement-section27-welcomes-the-release-of-the-final-terms-of-reference-for-the-competition-commissions-health-inquiry/

74 Competition Commission. Media release: Commission appoints healthcare inquiry panel. 30 January 2014. URL: http://www.compcom.co.za/assets/Uploads/AttachedFiles/MyDocuments/Commission-appoints-healthcare-inquiry-panel-media.pdf

75 National Department of Health. National Contraception Clinical Guidelines. Pretoria: National Department of Health; 2012.

76 National Department of Health. National Contraception and Fertility Planning Policy and Service Delivery Guidelines. Pretoria: National Department of Health; 2012.

77 These were accessible at http://www.doh.gov.za/list.php?pageNum_rsList=1&totalRows_rsList=96&type=Policy%20Documents

78 National Department of Health Mini Drug Master Plan (2011/12-2013/14).

79 National Department of Health. Updated management of type 2 diabetes in adults at primary care level. 2013.

80 Ataguba JE. Alcohol policy and taxation in South Africa. An examination of the economic burden of alcohol tax. Appl Health Econ Health Policy 2012; 10(1): 65-76.

81 National Department of Health. Terms of Reference for the call of proposals to conduct an independent regulatory impact assessment on the proposed Control of Marketing of Alcohol Beverages Bill. 2013.

82 Minister of Social Development. Statement by the Minister of Social Development, Ms Bathabile Dlamini during a media briefing on the Control of Marketing of Alcohol Beverages Bill. 20 September 2013.
URL: http://www.info.gov.za/speech/DynamicAction?pageid=461&sid=39918&tid=122603

83 Paton C. Cabinet in disarray over bill banning alcohol adverts. BDlive, 16 October 2013.
URL: http://www.bdlive.co.za/national/2013/10/16/cabinet-in-disarray-over-bill-banning-alcohol-adverts

84 Minister of Trade and Industry. Draft National Policy on Intellectual Property, 2013. General Notice No. 918. Cape Town: Government Gazette No. 36816, 4 September 2013.
URL: http://www.gov.za/documents/download.php?f=198116

85 Schonwetter T, Vawda YA et al. Joint Submission by Academics on Draft National Policy on intellectual Property of South Africa. 17 October 2012.
URL: http://ip-unit.org/wp-content/uploads/2013/10/IP-Policy-Academics-Submission_final171013.pdf

86 Jackson E. Law and the Regulation of Medicines. Oxford: Hart Publishing; 2012. p. 81.

87 Médicins Sans Frontières. Untangling the Web of Antiretroviral Price Reductions. 16th Edition – July 2013.
URL: http://d2pd3b5abq75bb.cloudfront.net/2013/09/11/10/25/44/896/MSF_Access_UTW_16th_Edition_2013.pdf

88 Frick M, Jimenez-Levy E. Tuberculosis Research and Development. 2013 Report on Tuberculosis Research Funding Trends, 2005-2012. November 2013. Treatment Action Group.
URL: http://www.treatmentactiongroup.org/sites/g/files/g450272/f/201310/TAG_TB_2013_8.5.pdf

89 Low M. Patents Must serve the Public Interest. 23 October 2013. Treatment Action Campaign Blog.
URL: http://www.fixthepatentlaws.org/?p=793

90 De Wet P. Motsoaledi: Big pharma's 'satanic' plot is genocide. Mail and Guardian, 17 January 2014.
URL: http://mg.co.za/article/2014-01-16-motsoaledi-big-pharmas-satanic-plot-is-genocide

91 South African Director-General of Health. Intervention at the 134th session of the World Health Organization's Executive Board under agenda item 9.7 on Access to essential medicines.
URL: http://keionline.org/node/1913

92 Kievits Kroon Country Estate v Mmoledi and Others (875/12) [2013] ZASCA 189, 29 November 2013.

93 Department of Correctional Services v Popcru 2013 (4) SA 176 SCA.

94 MediRite (Pty) Ltd v South African Pharmacy Council and the Minister of Health. North Gauteng High Court. Case No. 50309/12. 20 December 2013. Unreported.