

# South African Health Review 2014/15



*Jabulani 14*



# South African Health Review 2014/15



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# Foreword

As an accredited annual journal of research on health policy development, reform, implementation and intervention for systemic improvement, the *South African Health Review* (SAHR) represents and expresses Health Systems Trust's vision of building health for all in our country through strengthened health systems.

Generated in the context of partnership with policy-makers, planners, health managers, researchers, and health and development organisations – both locally and abroad – who constitute the sources and the audience of the Review's content, the knowledge encapsulated in this publication enlightens regional and international thought and action around people-centred health care.

Flanked by the standard chapters on health policy and legislation and on health and related indicators, this 18th edition of the SAHR presents material that reflects the wide scope of important topics in the contemporary terrain of health systems strengthening. The issues covered range from the specificity of needs-based rural health resource allocation, a call to integrate disability in equitable care, and the structure of medical schemes' benefit options, to understandings of roles, participation, knowledge and implementation within the realm of public mental health services as well as the nursing profession. There are also incisive texts on key aspects of health management, such as the nature and use of information for decision-making at facility level, leadership development among frontline managers, and capacitating community participation in primary health care.

On behalf of the Board, I commend the host of dedicated professionals whose commitment and expertise have borne fruit in this enterprise: the accomplished authors whose data and analytical perspectives form the grist of this edition's content; the eminent academics who served as peer reviewers; the members of the SAHR Editorial Advisory Committee for their invaluable guidance through selection and refinement processes; and HST's diligent editorial team and administrative staff.

We are perennially grateful to the National Department of Health for supporting the production of the Review, thus enabling a sustained contribution to the realisation of a healthy life for all.



Dr Maureen Tong

Chairperson of the Board of Trustees,  
Health Systems Trust





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Ashnie Padarath, Judith King and René English

## Project Co-ordinator

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## Editorial Advisory Committee

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This publication was supported by a grant from the National Department of Health.

## Cover art

The cover art for the 2014/15 *South African Health Review* is an oil-on-canvas painting by Jabulani Douglas Cele, entitled "Long Ride 1". Born and raised in KwaZulu-Natal Province, Cele is a self-taught artist who has secured notable commissions and exhibited in established galleries. His work is inspired by ordinary people's responses to adverse situations and depicts their efforts to survive and thrive.

Seen in the context of the Review, this image illustrates the significant progress made along the road to optimal health service delivery. The portion of the road ahead being in shadow signifies uncharted terrain, but the purposeful determination of the woman moving into the future, so to speak, is stirringly optimistic and motivational.



# Editorial

The 2014/15 *South African Health Review* (SAHR) consists of 15 chapters that explore the range and depth of shifts in equity, efficiency and quality – both unfolding and neglected – in South Africa's public health arena.

The topography of this content is elevated with factual information on policy and legislative changes, progress reports on initiatives to transform and improve the health system, and accounts of innovative approaches applied at facility and district level that contain salutary lessons for scale-up and replication across the country.

Scanning the road already travelled in the journey of health system transformation, it is immediately apparent that our discourse has evolved from 'how to effect change' to 'how change has been experienced and understood'. Our health system is maturing, and numerous historical initiatives are bearing fruit, particularly when viewed in the light of recent policy decisions; a key example of this is the health sector component of the Negotiated Service Delivery Agreement 2010–14 (NSDA), which ushered in a series of reforms geared towards preparing the health system for the introduction of National Health Insurance.

The release of this 18th edition of the Review occurs a month after the adoption of the global 2030 Agenda for Sustainable Development, which is described by UN Secretary-General Ban Ki-moon as embodying "the yearnings of people everywhere for lives of dignity on a healthy planet". This synchronicity affords a viewing of South African health reform and innovation over a wider continental and international vista. Lessons learnt from South Africa's health reforms emerge as a worthy contribution to the vision of "a long and healthy life for all" – not only for South Africans, but for the entire global family.

This edition is compiled along seven thematic pathways that traverse this vision of healthy nationhood:

- Health policy
- Policy implementation
- Attaining equitable health systems
- Strengthening human resources
- Private sector
- Emerging Public Health Practitioner Award
- Tracking progress

## Health policy

In Chapter 1, Andy Gray and Yousuf Vawda reflect on developments – and in some cases, the lack thereof – in South Africa's health policy and legislation charted over the past year, noting that despite the non-appearance of the White Paper on National Health Insurance, the development of national secondary legislation informing the implementation of the National Health Act is continuing. Only one health-related Act was passed in 2014/15: the Mental Health Care

Amendment Act (12 of 2014), and no progress has been made with the Medical Innovation Bill, one of the few Private Member's Bills to be considered by Parliament. Gray and Vawda outline the substance of several court challenges to the Minister and statutory councils, particularly that calling for legislation to decriminalise physician-assisted suicide (with a landmark ruling in its favour having been made especially poignant after the death of the appellant, Advocate Robin Stransham-Ford, of natural causes due to terminal illness).

## Policy implementation

To strengthen health system effectiveness, the Primary Health Care Re-engineering and eHealth Strategies, among others, were introduced as part of the NSDA in 2010. More recently, the Ideal Clinic initiative was introduced to ensure standardisation of high-quality healthcare delivery at facility level. The chapters included in this section describe progress in implementing the Ideal Clinic Realisation and Maintenance (ICRM) Initiative, implementation of the eHealth Strategy, as well as initial implementation of the District Clinical Specialist Teams as one component of the three-streamed PHC Re-engineering Strategy. Such implementation is crucial to the success of the envisaged NHI as a means of universal health coverage.

In Chapter 2, Robert Fryatt and Jeanette Hunter provide an account of developments made in the Ideal Clinic Realisation process from June 2013 to March 2015. The Ideal Clinic initiative is steered under Operation Phakisa – South Africa's adaptation of Malaysia's 'Big, Fast Results' strategy that is designed to fast-track the implementation of solutions for national key priority areas – to devise a detailed, costed implementation plan, clear persistent bottlenecks in clinics, test responses, make required modifications for scale-up, secure the needed resources, provide the necessary training, and build the knowledge needed to maintain the desired ideal clinic status. Eleven elements, known as transversal levers, are needed to accelerate the attainment of fully functional PHC facilities, including the development of a standard structure for the District Health Management Office with standard job profiles; development and implementation of a change management model; and ensuring integrated chronic disease management, encompassing the full value chain of continued care and support, patient record storage and retrieval to shorten excessive waiting times.

Implementation of the Ideal Clinic concept will see this model as the fulcrum of a community-based PHC service, including school health, ward-based outreach and environmental health. An important need is that of an effective service delivery platform for national strategic programmes such as the integrated plan for HIV and TB, family planning, and maternal and child health services.

Eight work-streams with crosscutting and complementary expertise were formed to focus on specified activities and outputs (i.e. service delivery, waiting times, infrastructure, human resources for health, financial management, supply chain management, institutional

arrangements, and scale-up and sustainability), and to prepare a final report after six weeks. All 10 components of the Ideal Clinic Realisation and Maintenance framework were fitted into these eight work-streams along with the transversal levers. Costing was done across all eight work-streams, each of which addressed the case for change, South Africa's aspirations for the Ideal Clinic, the issues hampering optimal health care and the root causes thereof, and how these could be resolved through specified solutions and initiatives.

Representing a broad range of authors including government and non-governmental organisations, Chapter 3 provides an update on the steps being taken in collaboration with NGOs to execute reference implementation of the eHealth Strategy for South Africa in PHC facilities. Here, Milani Wolmarans and colleagues present the valuable lessons learnt through using the 700 facilities in the NHI facilities as pilot sites for this implementation process. Among these is the recognition that a cohesive patient administration system – including reducing the number of registers in these facilities from 54 to six – is the foundation needed for ensuring a rationalised process of patient access to healthcare facilities, which in turn supports quality health information services and effective facility management while improving patient experience.

Using a Theory of Change approach, Oboirien and colleagues, in their chapter *Understanding roles, enablers and challenges of District Clinical Specialist Teams in strengthening primary health care in South Africa*, explore the perceptions and experiences of the initial stages of implementation of the District Clinical Specialist Teams (DCSTs) in three districts to better understand organisational and behavioural characteristics influencing PHC strengthening. Their findings show that implementation was under way in all three districts, and the key enablers of DCST implementation related to the relative strengths of existing capacity and systems; the use of local or individual discretion and strategies when implementing the policy, thus enabling implementation despite existing challenges; trust-building mechanisms between the various actors; actors' abilities to leverage knowledge of local contexts and systems; and the roles of leaders and champions.

Key challenges encountered in all districts revolved around poor communication of the policy and its implementation at various levels; difficulty in expanding coverage due to recruitment (resulting in teams not being fully constituted according to the guidelines); financial constraints; and geographical access barriers, mainly due to transport issues in rural and remote areas. Other problems included resistance at the frontline as the role of the DCSTs was viewed with suspicion, but these are reported to be changing. Important future considerations are to address these challenges and, as the authors posit, to decide: "whether it is still justifiable to have a homogenous team given the differences in population size, number of facilities and rural context of the districts that DCSTs are supporting". The implications of these different contexts must be considered in future evaluations.

### Attaining equitable health systems

Equity in health remains a focal topic for South Africa, where for many decades, healthcare service provision was divided along racial lines. More than 20 years into democracy, challenges in redressing this inequity prevail, despite political will and commitment. The four chapters presented in this section of the Review explore ways of confronting inequity within the district health system using a specific

emphasis on mechanisms for shifting resources – human, financial and otherwise – to the lowest levels. Each of the four chapters respectively addresses decentralisation, task-shifting in public mental health services, better integration of disability services into the PHC platform, and an approach developed for assessing equity in public health resource allocation that accounts for rural contextual needs.

In Chapter 5, Hendricks and colleagues embark on a conceptual and practice-focused expedition into the implementation of a coherent decentralisation system that responds to the health needs of the population. After an overview of other nations' forms of decentralisation, they assiduously package the important lessons, caveats and issues that should be factored into the country's passage towards further decentralisation; this discussion covers the potential role of the National Department of Health in a new decentralised environment, and a set of criteria to phase and steer the decentralisation process is offered. The authors conclude that while decentralisation is not without its disadvantages, it could have an extraordinarily positive impact on the quality of and access to health services for our most vulnerable populations. As a means of advancing the successful implementation of the envisaged NHI-funded health system, the decentralisation process would require ongoing monitoring and evaluation against set targets.

The high prevalence of mental health disorders and their associated psychological and physical disabilities are highlighted by Maxine Spedding, Dan J. Stein and Katherine Sorsdahl in Chapter 6: *Task-shifting psychosocial interventions in public mental health: A review of the evidence in the South African context*. Informed by international documentation and literature, they propose that task-shifting from specialised to non-specialised health workers of psychosocial interventions to treat common mental disorders would be a worthwhile consideration for South Africa. To this end, they reviewed data on nine task-shifted interventions to address mental disorders in the local public mental health setting, and thematically analysed this evidence in the context of the new mental health policy that seeks to make health services more equitably accessible.

They report that locally, task-shifting studies have primarily focused on depression and substance-abuse, with fewer focusing on pregnant women and a paucity of research in the area of children and adolescents. In all the studies, various categories of health workers were employed to deliver a range of evidence-based interventions, and most studies supported the effectiveness of task-shifting to non-specialised health workers as an approach to improving primary care mental health service delivery. The authors highlight the need to further assess the costs and future sustainability of this process and to explore the best methods for implementation and scale-up. They also recommend that greater attention be paid to delineating human resource cadres – along with each category's duties and tasks, characteristics, skill sets and education levels – for conceptualising mental health service delivery interventions and ensuring adequately competent service providers.

Kate Sherry urges policy-makers to consider integrating disability when planning for health services delivery in her chapter *Disability and rehabilitation: Essential considerations for equitable, accessible and poverty-reducing health care in South Africa*. Given its poor inclusion in health, current inequitable health outcomes, and limited access to care for people with disabilities, she makes a case for their right to health to be realised through the inclusion of rehabilitation

as a core component of PHC. Specifically, she advocates for improved access to general health care, strengthening the voices of people with disabilities in policy-making, planning and service provision, and building an evidence base on disability, health and rehabilitation. Importantly, if disability is not addressed, the effectiveness of other programmes focusing on both communicable and non-communicable diseases may be negatively affected.

Despite widespread efforts, SA faces persistent structural inequities in resourcing and delivery of care, notably with regard to resource allocation from provinces to districts and facilities that is not necessarily needs-based. In Chapter 8, Daygan Eagar and colleagues explore an approach to accounting for need in the assessment of equitable resourcing of the country's public health system, and present a concept for creating a rural index that specifically elucidates differences between rural and urban contexts, including demographic, geographic and socio-economic factors. They report "tentative evidence suggesting that within rural provinces, funds tend to flow disproportionately to districts and facilities located in urban areas". Their findings show that while the rural index was useful in distinguishing between urban and rural district hospitals in KwaZulu-Natal Province, its value as an approach lies within its facilitation of rural factors being accounted for in resource allocation models that focus on quality improvement in service delivery rather than on mere efficiency. They propose that such an index be incorporated into performance management frameworks that seek to "not only address issues of equity (between rural and urban settings) but also efficiency and effectiveness as an outcome of resource allocation processes."

### Strengthening human resources

Nurses are the 'backbone' of the health system and those workers who provide services at the frontline of the health system are key to ensuring translation of relevant policies into practice at primary health care level. The four chapters that make up this section illuminate this territory's features and flaws. Chapter 9 investigates the numerous challenges that typify the nursing profession and impact on its viability; Chapter 10 documents a programme that aims to enhance the leadership abilities of nurse managers heading up clinic operations; Chapter 11 analyses data from a series of case studies that unpack how nurse managers make decisions; and Chapter 12 considers how community participation in the public health system at sub-district level can be enhanced, including the key enablers and barriers to effective participation of this kind.

In *A profession in peril? Revitalising nursing in South Africa*, Laetitia Rispel and Judith Bruce provide an analytical perspective of nurses and nursing in South Africa, and of the key issues that require attention in order to revitalise the profession. They conclude that nursing in South Africa is a profession at risk of being harmed or destroyed, and that immediate and significant action is needed in the areas of policy implementation, improving nurse practice environments, and nurse education. They call for key policy actors operating at national levels who are responsible for the leadership and management of nursing to address weaknesses in the area of policy capacity. Nurses should be capacitated and given opportunities to participate in policy development, implementation and feedback, and their training should enhance their political, policy and planning competencies. Focused leadership and development programmes are also required. The resource, administrative and quality-of-care

aspects of their nursing practice environments should be addressed, and several aspects of nursing education, as well as continuing professional development for nurses, should be strengthened. These revitalisation efforts require high-level buy-in and support from key national actors.

Tim Wilson, Sarah Davids and Anna Voce present the Wellness for Effective Leadership (WEL) programme, and capacity-development intervention implemented through a series of workshops designed to support groups of frontline managers through facilitated positive shifts, spanning personal and interpersonal aspects and leadership practice and service delivery. Their chapter *Frontline managers matter: Wellness for Effective Leadership* highlights that personal and interpersonal contexts and existing organisational cultures are shown to be key contexts in which frontline managers are constrained in their daily activities and general functioning. This limits the efficacy of these nurses' leadership, despite their laudable sense of commitment to their work. The participants' responses indicate that many of these managers are bearing buried emotional trauma, stemming from growing up during the apartheid era, and that these factors have negative consequences on their personal and work relationships.

Vera Scott and colleagues, in Chapter 11 entitled *Operational health service management: Understanding the role of information in decision-making*, explore the nature of PHC facility-level decision-making in human resources management and quality improvement, and demonstrate its importance in terms of facility and health system performance. Using an in-depth multi-study approach, they describe the use of different types of information in decision-making, concluding that "local information and experience-based knowledge supports managers in adapting and innovating locally to ensure successful policy implementation, and formal information supports greater accountability in service delivery". Using an adaptation of Ortiz Aragón's 'Systemic Theories of Change' framework for purposeful capacity development, they explore the relationships between the hardware and both the tangible and intangible software of the health system. With Health Management Information System (HMIS) data development being uneven in South Africa, in that important HR data are not as available for decision-making as are other forms of routinely collected data, operational managers need access to and assimilation of a broad range of information including informal sources for decision-making. Good interpersonal and people-management skills are essential leadership attributes required for this function.

Chapter 12 is entitled *Re-imagining community participation at the district level: lessons from the DIAHLS collaboration*, in which Susan Cleary and colleagues report on the outcomes of a series of sub-district engagements to understand and strengthen community participation using a number of approaches. These included a multi-stakeholder health risks and assets mapping activity; 'Local Action Group' initiatives; a capacity development initiative; and reflective sessions with service colleagues. Using a framework of collective capacity, the authors sought particularly to identify the enablers of community participation at sub-district level. This project forms part of the broader study in which Scott et al. participated (see Chapter 11), and hence Ortiz Aragón's framework is also applied in this piece of work.



The authors identify that budgetary and resource allocations, and infrastructure and technology for community participation are important to support these activities (hardware). In terms of software, the key role played by certain members of the sub-district health provision team was also highlighted through this work – exemplified by that of the environmental health practitioners and their ability to foster dialogue among local communities, given their placement within the sub-district. Other factors included organisational systems, knowledge and skills, and the ability to facilitate participatory engagements. These, combined with a ‘relational skillset’ of ‘intangible software’ such as values, power and communication, are important for fostering better community participation. Cleary et al. also assert that their work has “provided an example of how a participatory approach can powerfully enable change when stakeholders are brought into conversation around a common cause”.

### Private sector

Sparked by the Council of Medical Schemes’ (CMS) stated intention of maximising access to good-quality medical scheme cover while working in the best interest of the consumer, Josh Kaplan and Shivani Ranchod, in their chapter *Analysing the structure and nature of medical scheme benefit design in South Africa*, articulate the design of 118 benefit options available in the open market to at least 30 000 beneficiaries who are offered at least four registered benefit options. They provide an overview of the nature and structure of these market options, highlighting that the most recent regulatory change affecting benefit design in South Africa occurred more than 10 years ago. Differences were identified between the demographics of the beneficiaries they serve and the corresponding contribution rates. The analysis also revealed that the incomplete regulatory environment within which the schemes are created and offered enables medical scheme providers’ use of benefit designs to ‘cherry-pick’ members and to form them into homogenous groups. The authors argue that “medical benefit design in South Africa requires significant attention in order to facilitate equitable access to medical scheme cover in South Africa”, and that under these circumstances, the industry is not likely to fulfill the requirement of ‘Treating Customers Fairly’. In questioning the industry’s commitment to deliver value to the customer, they call for medical aid schemes to reduce the complexity of choice that burdens each customer and for more transparency when marketing their benefit options.

### Emerging Public Health Practitioner Award

Verusia Chetty, a doctoral student and lecturer in the Discipline of Physiotherapy at the University of KwaZulu-Natal in Durban, is this year’s recipient of the Emerging Public Health Practitioner Award for her chapter entitled *A model of care for the rehabilitation of people living with HIV in a semi-rural South African setting* (Chapter 14). Chetty presents a model of care developed with the aim of feasibly addressing the demand for rehabilitation arising from the dramatic extension of the life-span of people living with HIV, along with HIV-related disabilities, co-morbidities and side effects of medication. Using an Integrated Learning in Action approach, the model is gauged for its usefulness in integrating patient-centred, evidenced-based rehabilitation practice into South Africa’s response to HIV, and for its relevance in terms of policies that guide the country’s rehabilitation practice. This entailed several sub-studies in a semi-rural healthcare setting in the province of KwaZulu-Natal, conducted

in three phases and involving the multidisciplinary healthcare team at the site, affiliated non-governmental organisation representatives, service users and experts in the field. Phase 1 focused on a review of international rehabilitation models; the second phase constituted an enquiry into the perspectives of key stakeholders, and the final stage of work was directed towards reaching consensus among the experts on the framework guiding the model of care.

### Tracking progress

A reliable means of navigation and orientation is needed for any journey, and especially for forays beyond expected parameters. The steadfast *Health and Related Indicators*, composed by Candy Day and Andy Gray as Chapter 15, represents just such an instrument, packing reflective thought around the capture, extraction and analysis of health data to answer considerably more than ‘where are we now?’. Plotting our bearings at the turnstile between the close of the target cycle for the Millennium Development Goals and the debut of the Sustainable Development Goals agenda, the authors position South Africa among the global actors striving for progress in the health-related MDGs, and simultaneously draw this chapter’s health statistical profiles inward to refocus on gains and losses made in regions and districts across the country.

They echo the call by international scholars for investment of resources to support more accurate and nuanced reporting of progress towards global goals, through standardised data, methods and models for estimating rates and levels of incidence, prevalence, illness and death. While acknowledging the South African National Department of Health’s foresight in planning for a more efficient health management information system, they also note the need to formulate quantifiable national targets, so that future measurements and comparisons, based on precision and reasonable coverage, can inform the most appropriate decisions and effective implementation.

Shod with evidence, fuelled by a sense of justice, and spurred by collective action – our health system is powering forward. As this edition of the *South African Health Review* demonstrates, accuracy, imagination, diligence and resolve can take us into “lives of dignity on a healthy planet”.

**Ashnie Padarath, Judith King and René English**

Health Systems Trust









# Health Policy and Legislation

## Authors:

Andy Gray<sup>i</sup>

Yousuf Vawda<sup>ii</sup>

**D**espite the non-appearance of the White Paper on National Health Insurance, the development of national secondary legislation informing the implementation of the National Health Act continues apace. Regulations in draft and final form have been issued by the Minister of Health. There are still steps to be taken before the independent Office of Health Standards Compliance is fully operational. However, the process of implementing chapter 6 of the National Health Act remains uncertain, after the premature promulgation of a section of this chapter was reversed by the Constitutional Court.

Only one health-related Act was passed in 2014/15 – the Mental Health Care Amendment Act (12 of 2014). The Medicines and Related Substances Amendment Bill (6 of 2014) is still being debated, and will require each provincial legislature to develop a clear mandate in line with its section 76 status. No progress has yet been made with the Medical Innovation Bill, one of the few Private Member's Bills to be considered by Parliament.

Increasingly, the Minister of Health and the statutory councils have been the subject of court challenges. These have included challenges to: the Good Pharmacy Practice standard set by the South African Pharmacy Council; the way in which the Medicines Control Council has attempted to regulate medical devices; and the prescribed minimum benefit (PMB) Regulations in terms of the Medical Schemes Act. Changes to the PMB Regulations have been published for comment, as have guidelines for the design of low cost benefit options. The issue of physician-assisted suicide was also addressed by the courts, which expressed a desire that specific legislation be developed in this regard. Although there are no current legal challenges to the medicine pricing interventions, some may still be launched if the Minister proceeds to issue final regulations dealing with perverse incentives and/or international benchmarking.

*The development of national secondary legislation informing the implementation of the National Health Act continues apace.*

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## Introduction

The current Strategic Plan 2014/15 – 2018/19 of the National Department of Health outlines the legislative mandate of the Department.<sup>1</sup> It describes the Constitutional mandates and lists the specific legislation which fall under the Minister of Health's portfolio. The Strategic Plan also identifies targets for legislative reform in the period covered. Among the targets identified for the 2014 to 2019 period are:

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

This list includes two of the three planned policy initiatives described in more depth in the Strategic Plan. The first of these is to facilitate implementation of National Health Insurance (NHI). What is described, though, does not mention the long-awaited White Paper on National Health Insurance. There have been many intimations during the period under review that release of the White Paper, or at least of the Treasury document outlining the funding options for NHI, is imminent. However, to date, no document has been published. Cabinet approval is eagerly awaited.

The second refers to the establishment of the Office of Health Standards Compliance, the process for which is described in more detail in the next section.

The third planned policy initiative refers to the establishment of the South African Health Products Regulatory Authority (SAHPRA). This process is dependent on the passage of the Medicines and Related Substances Amendment Bill 6 of 2014), which is still before the National Assembly Portfolio Committee on Health.<sup>2</sup> The process being followed in relation to this Bill is described in more detail later in this chapter. The Medicines Amendment Bill is also expected to make some changes to medicine pricing processes, but such changes rely more on subordinate legislation, as described. Parliament is also in the process of discussing the Medical Innovation Bill (Private Member's Bill 1 of 2014).<sup>3</sup>

The pace of health legislation in Parliament again slowed down in 2014/15, with only a single Act being passed.<sup>4</sup> Despite the International Health Regulations Bill having been published for comment in 2013, this Bill has yet to be tabled in Parliament.<sup>5</sup> The draft Bill provides for the repeal of the International Health Regulations Act (28 of 1974), and the incorporation of the International Health Regulations (IHR) of 2005 into domestic law. The IHR are a "framework for the coordination of the management of events that may constitute a public health emergency of international concern".<sup>6</sup> The need for effective implementation of such Regulations was underscored by the Ebola outbreak in West Africa in 2014/15. There has, nonetheless, been some progress in relation to shifting Port Health Services from provincial to national control, with the promulgation of sections 2 and 3 of the National Health Amendment Act (12 of 2013).<sup>5,6</sup> This change would be required in order to comply with the IHR.

This chapter focuses on health-related legislative instruments at the national level that have been the subject of change since 2014, 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. In the case of each law or statutory council, important health-related jurisprudence is also described.

As intellectual property policy is crucial to many efforts to improve access to health technologies, such as medicines, progress in this regard is also covered.

## National legislation related to health

### National Health Act

As indicated in the National Department of Health's Strategic Plan, the establishment of the Office of Health Standards Compliance (OHSC) as an independent structure outside of the Department of Health is receiving high priority. The appointment of members of the Board of the OHSC was gazetted in January 2014.<sup>7</sup>

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. The creation of such norms and standards is therefore key to its functioning. These documents are voluminous, and cannot therefore be accommodated in the usual Government Gazette format. In February 2014, notice has been issued in the Government Gazette of the publication, in terms of the National Health Act, of Norms and Standards Guidelines in relation to Building Engineering Services, Infrastructure Design for Waste Management in Healthcare Facilities and Emergency Centers.<sup>8</sup> Readers were directed to an online repository for the actual documents. However, at the time of writing, this repository could not be accessed. The website stated that "This account has been suspended". The notice also stated that "A further process for extracting the essential criteria from the guidelines for inclusion as health regulations will follow". Further notices of this nature, covering a wide range of services and health infrastructure types, were issued in June 2014 and May 2015.<sup>9,10</sup> Both of these notices also included a statement to the effect that "The guidelines should not be seen as requirements necessitating the alteration and upgrading of all existing healthcare facilities". A draft set of Norms and Standards Regulations was published for comment in February 2015.<sup>11</sup> These draft Regulations are intended to apply to all public sector hospitals, clinics and community health centres, as well as all private sector acute hospitals and primary health clinics. The drafts have been criticised for being vague and poorly drafted, and for potentially duplicating or conflicting with provincial legislation. An example will suffice to show how imprecise drafting may cause confusion: Sub-regulation 32(2)(b) states that a health establishment must "Ensure that all medicines are in stock, in accordance with the essential medicines list or applicable formulary". It is unclear which "essential medicines list" is referred to, as there is no single nationally mandated list applicable in both the public and private sectors. The National Essential Medicines List could be considered



to be a 'model', which may be varied by the provinces. It also varies by level of care, with Primary, Adult Hospital, Paediatric Hospital and tertiary/quaternary versions. In the private sector, 'formularies' vary considerably. A small change from "the essential medicines list" to "an essential medicines list" might introduce the necessary flexibility.

Draft Regulations were also issued in the same Gazette in February 2015 to describe the functioning of the OHSC.<sup>12</sup> As with the Norms and Standards Regulations, comment was requested within three months. The Procedural Regulations are a critical building block which will need to be finalised before the OHSC can be functional. For instance, the draft Regulations state that consent to enter and search any health establishment must be obtained in advance, but that where such consent cannot be obtained, a warrant may be obtained instead. Nonetheless, an OHSC inspector will be able to enter and search any premises without a warrant, "if there are reasonable grounds to believe that, if applied for, a warrant for entry and search would be issued and that the delay in obtaining a warrant would defeat the object of the warrant". The draft Regulations also specify the process for issuing compliance notices. However, draft Regulation 21 states that "The Office must develop an enforcement policy which sets out the Office's approach to enforcing compliance". This creates yet another layer of policy and detail, which is still lacking. Such a policy will need to be gazetted, after approval by the Board. Importantly, the draft Regulations call for a "progressive" approach to enforcement, taking into account such factors as the "nature and severity of non-compliance with prescribed norms and standards and the consequences thereof", "the compliance history of the health establishment", the "frequency of transgressions in relation to prescribed norms and standards" and "any mitigating or aggravating factors". The OHSC will need not only to demonstrate impartiality and independence, but will also need to be appropriately transparent to the public. Accordingly, it is refreshing to note the very specific reporting requirements in these draft Regulations: the OHSC will be required to, on a quarterly basis, publish on its website or in any other publication a report covering:

- inspections conducted with name and location of establishments;
- compliance certificates issued with name and location of establishments;
- hearings conducted with name and location of establishments and outcome;
- recommendations made to relevant authorities in terms of section 79(1)(e); and
- complaints received and resolved, by category.

On an annual basis, it will also have to "publish on its website or in any other publication a report covering the compliance status of all health establishments and compliance notices achievement record."

Another set of Regulations in terms of the National Health Act was issued in draft form in July 2014, and then in final form in May 2015.<sup>13</sup> This is a very detailed set of Regulations, governing every element of the provision of emergency medical services by not only the public and private sectors, but also by the South African Military Health Services "when providing a service within the civilian environment to non-military patients". There is a process

for licensing, for inspection, and for the creation of an Emergency Medical Service Advisory Committee. During a "major incident or disaster" (which are not specifically defined, so would take their dictionary-derived meanings), responsibility for the co-ordination of the emergency response is vested in the provincial Emergency Medical Services. Any service that was operational before the commencement of the Regulations is allowed to continue for a maximum of one year, but thereafter must be licensed in accordance with these Regulations.

The necessary Regulations to allow for the implementation of section 71 of the National Health Act were issued in final form in September 2014.<sup>14</sup> One of the areas of concern in relation to the control of research with human participants was the requirement for ministerial consent for non-therapeutic research with minors. The final Regulations provided not only a clear application form and criteria for the consideration of such applications, but also for the delegation of this responsibility. The delegated authority may consider such applications only after their scrutiny by a registered health research ethics committee. The prescribed form asks applicants to:

- "Describe the scientific justification for the enrolment of minors. Explain why this research must be done with minors as participants."
- "Describe how the research might, or aims to, advance knowledge affecting the health and welfare of minors as a class. Note that 'condition' is defined in the Regulations as 'physical and psycho-social characteristics understood to affect health' allowing that this research does not only involve children with an illness."
- "Describe how consent to the research will be in line with public policy or would be acceptable, for example, show how the research poses acceptable risks and promotes the rights of minors."
- "Describe how the potential risks from the research procedures and/or intervention to minor participants will be minimized and describe any possible benefits from the research to society in the form of knowledge."

In May 2014, draft Regulations describing the processes for managing health waste in health establishments were issued for comment.<sup>15</sup> Two elements in this draft deserve attention: the first is the inclusion of the principle of "green procurement", defined as "selection for purchase of products and services that minimizes the impact of the products and services on the environment". The second is the reliance, in many parts of the draft Regulations, on South African National Standards which are published by the South African Bureau of Standards (SABS). This reliance on existing standards avoids duplication, but also provides such standards with legislative backing. Failure to comply can result in a fine or imprisonment for not more than two years, or both such fine and imprisonment. Enforcement of the Regulations will be assigned to the environmental health practitioners of the municipal area/district in which each health facility is located.

The National Health Act has also been used to underpin the National Health Normative Standards Framework for Interoperability in eHealth.<sup>16</sup> The Minister has also gazetted draft Regulations to establish a Ministerial Advisory Committee on eHealth.<sup>17</sup>

The most controversial aspect related to the implementation of the National Health Act was the issuing of a Promulgation Notice, bringing section 36 to 40 of the Act into effect, which was issued by the President on 31 March 2014.<sup>18</sup> Sections 36 to 40 deal with the certificate of need for health establishments. Read together, the sections criminalised the provision of health services without a properly issued certificate of need. In the absence of Regulations, it was unclear how these provisions would be implemented. By July 2014, the Director-General of Health was indicating that the Department would delay implementation in order to craft such Regulations.<sup>19</sup> Despite such assurances, the South African Dental Association and the Hospital Association of South Africa brought the issue to the attention of the Presidency, noting that the promulgation was premature. The President then approached the Constitutional Court directly to declare the Proclamation invalid in terms of section 172(1)(a) of the Constitution. The applicants maintained that the decision to bring the sections into operation was as a result of a bona fide error, and was thus irrational in law. The respondents supported the relief sought. The unanimous court granted direct access, as well as the relief to set the Proclamation aside, as the legislative process to remedy the situation would have been lengthy and burdensome.<sup>20</sup> The court held that the premature decision to issue the Proclamation was not rationally connected to the implementation of a national regulatory scheme for healthcare, or any other governmental objective, echoing its earlier decision on a similar issue in *Pharmaceutical Manufacturers Association of SA and Another: In re Ex Parte President of the Republic of South Africa and Others* [2000] ZACC 1. There have been no draft Regulations issued since then that would provide clarity on how exactly the Department of Health intends to apply those parts of chapter 6 of the National Health Act that are still not operative.

## Mental Health Care Act

The Mental Health Care Amendment Act (12 of 2014) was assented to by the President in May 2014.<sup>4</sup> 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. The Amendment Act has yet to be promulgated.

Nonetheless, implementation of the 2002 principal Act has been addressed by the issuance of draft amendments to the General Regulations in November 2014.<sup>21</sup> In September 2014, the Minister of Health also issued final Regulations establishing a Ministerial Advisory Committee on Mental Health, and in October 2014 called for nominations.<sup>22,23</sup>

## Health Professions Act

No fundamental changes to the Health Professions Act have been made during the year under review. However, the Minister and the Health Professions Council of South Africa continue to issue a steady stream of subordinate legislation in the form of Regulations and Rules (either draft or final) relating to qualifications (and additional qualifications) held by particular health professionals, where such qualifications may be earned, the registration of students and practitioners, and the scopes of practice of such professions. These have related to medical practitioners and dentists,<sup>24-27</sup> dental therapists and oral hygienists,<sup>28-30</sup> medical technicians (in the category tuberculosis),<sup>31</sup> medical laboratory scientists,<sup>32</sup> environmental health officers,<sup>33-35</sup> optometrists,<sup>36</sup> speech-language

therapists and audiologists,<sup>37-41</sup> psychologists,<sup>42</sup> and various categories of emergency care practitioners.<sup>43-56</sup>

An area that is often ignored is the classification and certification of tests that can be used only by registered psychologists. The Professional Board for Psychology issued an updated list of such tests in August 2014.<sup>57</sup>

The description of scopes of practice for health professionals other than medical practitioners and dentists, or specifically those with additional qualifications, may include statements about their competence to prescribe medicines. However, in order to gain access to prescribing privileges, the medicines that may be prescribed by each group must be listed for that purpose in the Schedules to the Medicines and Related Substances Act (101 of 1965). Such lists have been gazetted for categories of emergency medicine practitioners and dental therapists.<sup>58</sup> Discussions between the Medicines Control Council and the Health Professions Council of South Africa are ongoing in respect of such lists of medicines to be prescribed by podiatrists and optometrists. However, despite this procedure being well described and used, the Health Professions Council issued a draft scope of practice for clinical associates in May 2015, which included the following statement about their right to prescribe:

Prescribing medicines for common and important conditions according to the primary health care level Essential Drugs List (EDL) and up to schedule IV, except in emergencies when appropriate drugs of higher schedules may be prescribed. The prescription must contain the name of the supervising registered medical practitioner. In the case of drugs not on the EDL the prescription must be countersigned by a registered medical practitioner.<sup>59</sup>

While no doubt pragmatic in intent, this attempt at a short-cut would cause significant problems, especially for pharmacists who are presented with prescriptions written by clinical associates, the first cohort of whom have graduated and entered practice.

In terms of jurisprudence, a recent Supreme Court of Appeal (SCA) decision deserves close attention.<sup>60</sup> Medical negligence claims continue to rise in the public sector, and the SCA has ruled that such claims must succeed if there is sufficient evidence giving rise to an inference of negligence by hospital staff. In this case, Ms Goliath appealed a decision of the Eastern Cape High Court which dismissed her claim for damages arising from the failure of hospital staff to remove all surgical swabs from her abdomen at the conclusion of her surgery. The High Court held that she had failed to discharge the onus of establishing negligence, relying on the decision of the majority judgment in *Van Wyk v Lewis* [1924 AD 438] which rejected the application of the *res ipsa loquitur* (the case speaks for itself) maxim in medical negligence claims. In this matter, save for a denial that any of his employees was negligent, the respondent did not adduce any evidence to controvert the testimony of the appellant and her expert witness. The SCA found that the trial judge

appears to have allowed himself to be diverted from the obvious inference of negligence dictated by the evidence in this case by virtue of his heightened focus on the applicability of the maxim *res ipsa loquitur* to cases based on alleged medical negligence.

It accordingly granted judgment in favour of the appellant for R250 000 and other relief. It has been argued that the implementation of the *res ipsa loquitur* approach “could facilitate a more equitable legal platform for the plaintiff”, and be in line with the requirements of the Constitution.<sup>61</sup>

## Nursing Act

As was noted in previous editions of the Review, the lack of a similar listing of medicines to be prescribed by various categories of specialist nurses, as envisaged by section 56(1) of the Nursing Act, continues to prevent, 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. Progress in this regard has been glacial. In May 2014, the Minister issued a notice creating the categories of nurse specialist and midwife specialist, as required by section 31(2) of the Nursing Act (33 of 2005).<sup>62</sup> The South African Nursing Council has also placed a generic competency framework and a number of “competency statements” for advanced nurse practitioners on their website ([http://www.sanc.org.za/professional\\_practice.htm](http://www.sanc.org.za/professional_practice.htm)). The categories listed are:

- Critical Nurse Specialist (Adult)
- Forensic Nurse
- Midwife Specialist
- Nephrology Nurse Specialist
- Occupational Health Nurse Specialist
- Ophthalmic Nurse Specialist
- Orthopaedic Nurse Specialist
- Paediatric Nurse Specialist
- Primary Care Nurse Specialist

However, while there is some mention of prescribing, the process of engagement with the Medicines Control Council to enable scheduling for this purpose has yet to start. For example, the competency statement for the primary care nurse specialist states:

Prescribes relevant medication as per applicable legislation and protocols, taking into account prescriber’s responsibility and accountability (Rational drug prescribing)... Prescribing according to competency level and authorization, and... Keeps and stores medication as per specific drug instructions.

There is no reference to the requirements of the Medicines and Related Substances Act (101 of 1965), and in particular section 22A (in relation to prescribing) and 22C(1)(a) (in relation to dispensing licences).

In October 2014, the Minister issued final Regulations regarding the disciplinary powers of the Nursing Council, as well as appeals against decisions of the Council.<sup>63,64</sup> The latter involves the use of a standard ministerially appointed appeals committee, as is done with other statutory health councils.

Draft Regulations relating to the training of midwives were also published for comment in October 2014.<sup>65</sup>

## Pharmacy Act

As was noted in the previous issue of the Review, there has been an inexplicable delay in the finalisation of Regulations relating to continuing professional development (CPD) for persons registered in terms of the Pharmacy Act. Without these Regulations, the mandatory recording of CPD activities by registered persons cannot be enforced. No reasons for the delay have been advanced by either the Ministry or the Department of Health.

The South African Pharmacy Council continues to update the Good Pharmacy Practice (GPP) standards, which are legally binding on all practitioners, whether in the public or private sectors. Some of the changes previously published for comment were finalised in February 2015.<sup>66</sup> The issues covered were those related to the handling of thermolabile medicines and the use of automated dispensing units. However, there has been concern that the GPP standards are overly elaborate and detailed, and are straying from the intended purpose of prescribing an absolute minimum. There was evidence, nonetheless, that concerns raised about previous drafts had been taken into account, specifically in relation to the proposed requirement that institutional pharmacies all offer a 24-hour service. The draft GPP standards published in February 2015 will need to be reviewed carefully for practicality.<sup>67</sup> The areas covered in these draft standards are:

- minimum standards for community or institutional pharmacies providing mobile pharmaceutical services;
- minimum standards for community or institutional pharmacies operating internet sites; and
- minimum standards relating to the collection and the delivery of medicines to patients from a community or institutional pharmacy.

The last of these may have serious implications for the chronic dispensing models currently being explored in NHI pilot districts as well as for the antiretroviral adherence clubs that have been successfully implemented by non-governmental organisations in a number of sites.<sup>68</sup>

The Pharmacy Council also issued draft Good Pharmacy Education Standards for comment, in December 2014.<sup>69</sup> These standards also use the terms “pharmacy technical assistant” (PTA) and “pharmacy technician” (PT), which are expected to replace the categories of basic and post-basic pharmacist’s assistants. The implementation of this change has been convoluted. In June 2015, the Council informed the profession, through its *e-Pharmaciae* newsletter, as follows:

On 1 July 2011 the South African Pharmacy Council published Board Notice 123 of 2011 in Government Gazette No 34428 which Board Notice identified Council’s intentions to introduce two new cadres of pharmacy support personnel into the registers: these cadres being the Pharmacy Technical Assistant and the Pharmacy Technician. In 2012, Council requested the Medicines Control Council to propose an amendment to Section 22A of the Medicines and Related Substances Act, 101 of 1965, to replace the term pharmacist’s assistant with pharmacy support personnel. Almost four years later, the first pharmacy technical assistants and pharmacy technician graduates are entering the world

of pharmacy amidst legislative challenges surrounding their registration and access to medicines.<sup>70</sup>

In addition, the Council noted that amendments to the necessary Regulations had not been published by the Minister of Health, so the new cadres of pharmacy support personnel had no defined scopes of practice. Until such time as these two pieces of legislation (the Medicines Act and the Regulations to the Pharmacy Act) were amended, the Council proposed to register the new PTAs and PTs as pharmacist's assistants (post-basic).

Given the apparent lack of co-ordination between the Pharmacy Council and the Ministry/Department of Health, the Council's publication of draft scopes of practice and qualifications for specialist pharmacists in December 2014 also raises concerns.<sup>71</sup> The first sentence states that "the South African Pharmacy Council intends to request the Minister of Health" to amend Regulations, thus updating some existing specialist categories (radiopharmacist and pharmacokineticist) and creating new categories (clinical pharmacist and public health pharmacy and management). As with the GPP standards, a one-size-fits-all approach is evident in these drafts, which is overly prescriptive to the universities that would be expected to provide specialist qualifications. Recognition of existing qualifications that could meet the minimum requirements and procedures for recognition of prior learning are also lacking.

Pharmacies are among the few health facilities that require anything like a certificate of need before they can be opened, moved or altered. The publication of proposed criteria for the issuing of licences for pharmacy premises in February 2014 was therefore heavily contested.<sup>72</sup> The process involves licensing by the Department of Health, and then recordal by the Pharmacy Council. However, apart from compliance with the "need" component, as adjudged by the Department, the applicant must also comply with GPP standards. As was reported in the previous edition of the Review, the application of these GPP standards had been unsuccessfully challenged in the North Gauteng High Court by Medirite. Medirite's appeal was decided by the SCA in March 2015.<sup>73</sup> The case concerned the position of pharmacies that are independently operated in supermarkets and other business premises. The court set out the organisation of the appellant pharmacy within the business premises as follows:

- the pharmacy consists of a dispensary in which scheduled medicines are stored and kept out of the public's reach;
- members of the public deal with the pharmacist over the counter, and are provided privacy by the placement of partitions that create a booth-like structure;
- the space between the counter and the dispensary is fitted with a retractable and lockable vertical shutter;
- there is a waiting area situated in front of the service counter as well as a 'front-shop'; and
- schedule 0 medicines such as headache tablets are kept in the front-shop. Initially, one of the GPP rules required that the pharmacy premises had to be clearly demarcated and identified from the business premises, but the Council proposed an amendment to the rule to require additional requirements for demarcation to be complied with, such as the erection of a wall. Despite representations made by the appellant, the Council proceeded with publishing the amendment. The appellant requested reasons for the decision taken, in terms of the Promotion of Administrative Justice Act (3 of 2000)

(PAJA). The Council replied that the separate identification and demarcation of the pharmacy from the host business was imperative – third parties would be able to know exactly where the pharmacy was located; further, it assisted with confidentiality, access to scheduled substances, access to the pharmacy, and stock control.

The appellant then challenged the decision to amend the rule. The court decided the issue based on reviewability of administrative action under the Promotion of Administrative Justice Act (3 of 2000) (PAJA), and found that while the original rule also required the pharmacy to be clearly identified and demarcated, the Council had not previously found the appellant in breach of this rule. The court held that this leads to the inference that the appellant's premises were in fact clearly identifiable and demarcated. The Council had not indicated the inadequacies of the original rule justifying the amendment when it published the proposed amendment. The court also considered the findings of the task team instituted by the Council on the various aspects of pharmaceutical practice. The recommendation was that there should be a white line demarcation separating the pharmacy from the rest of the business. There was no suggestion of a permanent enclosure being erected. The court found that there was no legitimate justification for the amendment, and the reasons provided by the Council were inadequate. It was unclear how the erection of a floor-to-ceiling wall would be the only effective method of achieving the purposes of identification and demarcation of the pharmacy. This was not the least invasive means to achieving the desired result of a demarcation. In the absence of an explanation of relevant considerations it had taken into account and an adequate justification for its decision, the court found the Council's decision to be arbitrary and irrational, and further, that the Council had failed to indicate why it felt that a less onerous demarcation would not have sufficed. The conduct of the Council was therefore unreasonable. The court set aside the decision of the Council to amend the rule on the basis that it was irrational and unreasonable. This judgment will have important implications for all the GPP standards, including the new standards that have been published for comment.

### Allied Health Professions Act

In October 2014, the Allied Health Professions Council of South Africa issued a draft code of ethics for comment, which included guidelines for good practice and for advertising.<sup>74</sup> The definitions distinguish between a 'practitioner' ("means a person registered as an acupuncturist, ayurveda practitioner, Chinese medicine practitioner, chiropractor, homeopath, naturopath, osteopath, phytotherapist or Unani-Tibb practitioner") and a 'therapist' ("means a person registered as a therapeutic aromatherapist, therapeutic massage therapist or therapeutic reflexologist"). In terms of the Medicines and Related Substances Act (101 of 1965), 'practitioners' may, if deemed competent by their statutory health council, gain access to the right to prescribe medicines listed for that purpose in the Schedules. No such complementary medicines have yet been listed in the Schedules. Illogically, the Medicines Act also requires such practitioners to have a dispensing licence. The draft scope of practice, as published, states that a practitioner may "prescribe or dispense medicine", without qualifying the term "medicine" in any way. The draft code of ethics states that the following acts are not permitted:



"Subject to the provisions of Section 32A(f)<sup>a</sup> of the Act a practitioner in active practice may not –

(a) In any way distribute, sell, advertise or promote any medicine or medical device as defined in terms of the Act or as defined in the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), or any other activity which amounts to trading in medicines or medical devices, other than those used in the course of the practitioner's practise or prescribed for patients; or

(b) engage in or advocate the preferential use or prescription of any medicine or medical device, if any valuable consideration is derived from such preferential use or prescription: Provided that the provisions of this subparagraph shall not prohibit a practitioner from owning shares in a listed public company manufacturing or marketing medicines or medical devices, or, subject to the provisions of the Pharmacy Act, 1974, from being the owner or part-owner of a pharmacy, or, whilst in the fulltime employment of a pharmaceutical concern in any particular capacity, from performing such duties as are normally in accordance with such employment; or prohibit a practitioner from partaking for educational purposes in lecturing on any medicine or medical device to persons registered in terms of the Act, the Health Professions Act, Nursing Act or the Pharmacy Act as the case may be."

The Regulations to the Pharmacy Act prohibit any authorised prescriber from owning or having a beneficial interest in either a community pharmacy or an institutional pharmacy in the private sector. This is yet one more example of the complex inter-relationships between existing and proposed legislation which will require careful management.

An Allied Health Professions Council of South Africa (AHPCSA) Board Notice, initially issued in October 2014, which restricted the use of professional titles, was rescinded in April 2015, without any reasons being recorded.<sup>75,76</sup> In the same Gazette, proposed Continuing Professional Development requirements were published.<sup>77</sup>

## Medical Schemes Act

A key design element of the medical schemes environment is the designation of prescribed minimum benefits (PMBs) in terms of Regulation 8 to the Medical Schemes Act (Act 131 of 1998). The existing Regulation 8 has been challenged in the Western Cape High Court by Genesis Medical Scheme (Case No. 15268/14). Although this action was initially launched by Genesis and Samwumed, the latter has withdrawn. However, a number of other actors have indicated that they should have been co-respondents (Medical Schemes Council and Registrar), or have applied to be admitted as *amici curiae* (the Hospital Association of South Africa, the South African Private Practitioners Forum, the Multiple Sclerosis Society of South Africa, the Infertility Awareness Association of South Africa, a psychiatrist, and B Braun Avitum, a medical equipment supplier).<sup>78</sup> The Minister of Health was reported not to be opposing

the application, indicating that he would abide by the decision of the court, and to be at an advanced stage in the drafting of an amendment to Regulation 8. In July 2014, a draft set of amendments to Regulation 8 were indeed published for comment.<sup>79</sup> It was proposed that medical schemes would be liable to pay either an amount based on the 2006 National Health Reference Price List tariff, adjusted for inflation (using the consumer price index), or a tariff negotiated with the provider, "for which no co-payment of deductible is payable by the member".

In September 2015, coinciding with the release of its annual report, the Council for Medical Schemes released guidelines for low cost benefit options (LCBOs), which would enable a scheme to apply for exemption in terms of section 8(h) of the Act.<sup>80</sup> The exemption would allow the scheme leeway in terms of the requirements for open enrolment, PMB coverage and/or broker remuneration. The accompanying guidelines listed which services would be required in relation to each of the chronic diseases (CDL) listed as PMB, including only diagnosis for some (such as HIV and tuberculosis), and only treatment in accordance with the CDL algorithms for others (such as asthma and diabetes). The guidelines also included a proposed limited medicines list, though without specifying the basis for the choices made.

## Foodstuffs, Cosmetics and Disinfectants Act

In September 2014, The Minister of Health issued draft amendments to the Regulations dealing with health messages on container labels of alcoholic beverages.<sup>81</sup> These minor amendments, which are intended to come into effect after 18 months, are yet to be finalised.

## Medicines and Related Substances Act

Medicines-related legislation remains highly contested, with the Medicines and Related Substances Amendment Bill (6 of 2014) currently before Parliament.<sup>2</sup> For reasons that have not been explained, this Bill, though initially tabled as a section 75 Bill (an ordinary Bill not affecting the provinces) was tagged as a section 76 Bill (an ordinary Bill affecting the provinces).<sup>b</sup> This means that the Bill will need to be debated in each of the provincial legislatures, perhaps after public hearings, before a mandate can be issued to each provincial delegation to the National Council of Provinces (NCOP). The NCOP must pass, amend or reject a section 76 Bill, but if the Bill was introduced in the National Assembly (as Bill 6 was), the National Assembly can override the NCOP decision with a two-thirds majority of its Members. As a result, however, passage of the Bill in the current year is uncertain. In anticipation of the creation of the South African Health Products Regulatory Authority (SAHPRA), which is provided for in both Bill 6 of 2014 and in the Medicines and Related Substances Amendment Act (72 of 2008), the current Medicines Control Council (MCC) has been appointed for a period of five years or until the establishment of the Authority, whichever comes first.<sup>82</sup> Once Bill 6 of 2014 is passed and assented to, it will need to be promulgated together with Act 72 of 2008, and accompanied by extensive new regulations and guidelines.

Bill 6 of 2014 reverses the introduction of the term "product" (which Act 72 of 2008 defined as "means a medicine, a Scheduled

<sup>a</sup> This section states that it is an offence if any person "supplies or offers to supply to any person not registered under this Act, the Health Professions Act, 1974 (Act 56 of 1974), or the Nursing Act, 1978 (Act 50 of 1978), any instrument or appliance which can be used, or is claimed to be effective, for the purpose of diagnosing, treating or preventing physical or mental defects, illnesses or deficiencies in man, knowing that such instrument or appliance will be used by such unregistered person for the purpose of performing for gain an act which such unregistered person is in terms of the provisions of this Act or the Health Professions Act, 1974, or Nursing Act, 1978, prohibited from performing for gain."

<sup>b</sup> A concise explanation of the difference in procedure for section 75 and section 76 Bills can be accessed at <https://pmg.org.za/bills/explained/>.



substance or a cosmetic or foodstuff which contains a scheduled substance”), returning to the terms “medicines, Scheduled substances, medical devices or IVDs” (IVDs being *in vitro* diagnostic devices). The Bill provides for a Board of the Authority (comprising not more than 15 persons, of whom not more than 10 persons shall have expertise in the fields of medicine, medical devices, IVD, pharmacovigilance, cosmetics and foodstuffs regulation, clinical trials, good manufacturing practice, public health or epidemiology; one with knowledge of the law; one with knowledge of good governance; one with knowledge of financial matters and accounting; one with knowledge of information technology; and one person with knowledge of human resource management), which mixes both governance and technical aspects. Although the Board is entitled to appoint committees “to assist it with the performance of its functions”, it is unclear whether these will be same as the current expert committees of the MCC. The Board, after consultation with the Minister, will appoint the Chief Executive Officer (CEO). Act 72 of 2008 replaced section 4 of the principal Act (dealing with the terms of office of the Council) with a section describing an advisory committee (“to advise or act as a consultative body for the Minister and the Authority on matters concerning corporate governance of the Authority”). However, Bill 6 of 2014 repeals section 4. This is but one example of the complex outcomes that will result from the simultaneous promulgation of both Amendment Acts. The essence of the entire reform package is that decision-making power will be vested in the Authority, not in a Council made up of part-time appointees. The Authority will be “established as an organ of state within the public administration but outside the public service.”

Although the Bill was introduced in the National Assembly on 24 February 2014, the Department briefed the Portfolio Committee on Health only on 3 September 2014, and the first public hearings were held only on 29/31 October and 5 November 2014. However, in a most unusual move, the Portfolio Committee entertained additional submissions from the Traditional and Natural Health Alliance on 25 February 2015. The only indication thus far of the intention of the Portfolio Committee seems to be a desire to introduce an additional amendment to section 18A, to read as follows:

(1) No person shall supply any [product] medicine, medical device or IVD according to a bonus system, rebate system or any other incentive scheme.

(2) Notwithstanding subsection (1), the Minister may prescribe acceptable and prohibited acts in relation to subsection (1) in consultation with the Pricing Committee referred to in section 22G.

These changes appear to be in line with the request made by the chairperson of the Pricing Committee during the first set of public hearings. However, this minimal change also underscores the reluctance of the Portfolio Committee to make wholesale changes to the Bill, which is itself evidence of the reluctance of the Minister and his legal advisers to make significant changes to Act 101 of 1965, even where such changes have been identified as necessary. The Pharmacy Council’s plea for amendments to section 22A of the Act is a case in point.

The lengthy list of “prohibited acts” referred to in section 18A was published for comment in August 2014, but has yet to appear in final form.<sup>83</sup> The draft included this list of “incentive schemes” which would, among others, be prohibited: discounts; rebates; unaccept-

able advertising fees; unacceptable credit payments; unacceptable data fees, but excluding data fees paid to an independent firm that specialises in the provision of data to the health care industry; unacceptable fees paid to induce and / or encourage biased sale of a particular medicine or scheduled product; unacceptable marketing fees or co-marketing fees; formulary listing payments; inducements; loyalty fees or similar fees, enrichment or benefit for purchasing or prescribing a particular medicine, or purchasing or prescribing a certain volume of a medicine; shelf space fees; directors fees, honoraria and similar compensation paid to a HCP or any person who is in a position to potentially influence medicine choice, where such professional or other person actually do (sic) not perform any services or work for which he or she is purportedly being remunerated, or which are in excess of a reasonable fee, honoraria or compensation which would be negotiated on an arm’s length commercial basis; and fees, enrichment of or benefit provided to a HCP, administrative staff or any business enterprise or health care establishment in the health care sector which fee, enrichment or benefit is provided on the understanding that the health establishment or professional will give preference to, or encourage the purchase, sale, prescription, dispensing, use or recommendation of a particular medicine or medicines in return for such fee, enrichment or benefit” (where HCP is a health care practitioner).

It is alleged that some of these fees, such as shelf fees, co-marketing fees and data fees, are being routinely paid at present, and have compensated for the low dispensing fees negotiated by medical schemes (within the maxima stipulated by the Minister on an annual basis).

In May 2014, the Minister also published further draft Regulations dealing with the methods for international benchmarking of medicines prices for comment.<sup>84</sup> A two-phase approach was proposed: in phase 1 the benchmark price would be the average of prices in the country basket (initially to include Australia, Canada, New Zealand and Spain), if this were lower than the South African ex-manufacturer price; in phase 2, the lowest price in the country basket would apply. The benchmark methodology would only apply to originator products, not generic medicines. Neither the perverse incentive nor the benchmarking interventions have been implemented to date, but the normal process of operating the pricing system has continued, with the maximum increase in single exit prices set at 7.5% in 2015,<sup>85</sup> and the dispensing fee for pharmacists updated and the next update process commenced.<sup>86-88</sup> The process for updating the dispensing fee for licensed dispensing practitioners (non-pharmacists) has commenced.<sup>89,90</sup>

SAHPRA will be expected to extend effective regulation from medicines (including complementary medicines) to medical devices. In preparation for this extension, draft Regulations dealing with medical devices and *in vitro* diagnostic devices were published for comment in April 2014.<sup>91</sup> Extensive comment was received, resulting in a complete revision of the proposed regulatory approach. A new set of draft Regulations, to be published again for a brief comment period, is expected to be published shortly. The need for urgent action in this regard has been underlined by two recent High Court judgments, in which the current MCC’s ability to regulate products that may be deemed to be medical devices has been successfully challenged.

The first of these challenges involved a dermal filler product range.<sup>92</sup> Following the seizure of its products on the basis that they were not registered in terms of the Medicines and Related Substances Act (101 of 1965), the applicant sought an order declaring that medical devices are not subject to registration in terms of the Act. The principal issue was whether a dermal filler containing a small quantity of lidocaine (a local anaesthetic) was a medical device in terms of the Act, or whether it should be registered as a medicine because it contained a substance which is registrable. The applicant's expert asserted that lidocaine was added to the dermal fillers for the sole purpose of ensuring comfort during the injection of the filler, and as such the product was a medical device. The court considered a recommendation made to the MCC by a member of the Expert Clinical Committee to the effect that the product be registered as a medicine because of its side effects. The court regarded this as a recommendation which had not been ratified or approved by the Minister or the MCC. It held that the mere fact that the product contained a small amount of a registrable substance did not in itself make the device a medicine. The court further found that the purpose of the product was not achieved through chemical, pharmacological, immunological or metabolic means (as per the definition of "medical device" in the Act), and was therefore a medical device. The court also considered whether the applicant was entitled to apply for a declaratory order as to whether medical devices, as defined in the Act, are not subject to registration. The respondents submitted that the court should be slow to make a declaratory order as it was not for the court but for the MCC to determine whether a product is a medicine or not. The court took the view that if the MCC wanted the product to be registered as a medicine, it ought to have followed the procedure set out in the Act which required the Minister, in consultation with the MCC, to make regulations to that effect. It found that this procedure was not followed and therefore granted the declaratory order, holding that the products were medical devices. The wording of the judgment went beyond the specific product concerned in a way that could be construed as 'overreach'. It declared that "In the absence of the promulgation of appropriate regulations in terms of section 35(1) (xxvii) of the Medicines Act the first respondent and/or the second respondent are not empowered to deal with authorizing, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, exportation, storage, transportation, sale or use of any medical device or class of medical devices in respect of safety, quality and efficacy in the Republic".

The impact of this broad prohibition was soon evident in another case, which dealt with a range of ophthalmic preparations (the Optive® range).<sup>93</sup> The court followed the reasoning in the Gelderma decision and ruled that these products were medical devices and not subject to registration, in the absence of any specific regulations. It accepted the applicant's contention that the mode of action of the chemical substance used in the Optive® products is "based on it (sic) physical properties which provide a lubricating effect and prolonged residence time in the eye", to be distinguished from artificial tears, which were regarded as medicines under the Act. Both of these judgments cited the decision in *Treatment Action Campaign and Another v Matthias Rath and Others* [2008] 4 All SA 380 (C) (TAC), in which it was held that it was not for the MCC to decide whether a product was a medicine, but rather that such a decision was to be made by the court. The Rath decision has important implications for the extent of the authority of the MCC, and in time,

that of SAHPRA. While the courts' reasoning appears to have been consistently applied, the MCC's cause was not advanced by the poorly presented evidence and argument in the *Allergan* case.

As was covered in detail in the previous issue of the Review, the MCC has also embarked on a process to bring complementary medicines under effective regulation. In October 2014, an important step was taken to re-establish control over products containing more than the stipulated amounts of a range of vitamins and minerals.<sup>94</sup> Products, other than foodstuffs, containing more than the stipulated daily doses were declared to be subject to registration as Category A medicines, regardless of whether a medicinal claim is made or not. The resolution applies to products already on the market as well as those that would become available after the date of the notice. The Scheduling status of probiotics was also amended in updates to the Schedules published in May 2014 and March 2015.<sup>95,96</sup> In September 2014, draft amendments to the General Regulations were published for comment, which proposed a change to the definition of a complementary medicine.<sup>97</sup> The existing definition would be replaced with "'complementary medicine' means any substance or mixture of substances that –

- (a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by Council, and
- (b) is used or purporting to be suitable for use or manufactured or sold for use –
  - (i) in maintaining, complementing, or assisting the innate healing power or physical or mental state, or
  - (ii) to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state, of a human being or animal, and
- (c) is used –
  - (i) as a health supplement, or
  - (ii) in accordance with those disciplines as determined by Council, or
- (d) is declared by the Minister, on recommendation by the Council, by notice in the Gazette to be a complementary medicine."

The key change here would be introduction of the concept of a "health supplement", which would not be a product in line with one of the complementary disciplines regulated by the AHPCSA. Examples of categories to be included were pre- and probiotics, minerals, fats, oils, fatty acids, carotenoids, bioflavonoids, aminosaccharides and saccharides. However, a less easily explained addition was "animal extracts, products and derivatives". These changes have yet to be issued in final form.

It is difficult to track progress with the implementation of the complementary medicines regulatory scheme introduced in 2014. There have been reports of planned court challenges from the complementary medicines industry. The MCC has issued no public reports on progress or any challenges being encountered.

Declarations in terms of section 23 of the Medicines and Related Substances Act, in terms of which substances are declared undesirable, are rare. In August 2014, the MCC declared all medicines containing phenylbutazone, whether registered or not, to be undesirable.<sup>98</sup>

## Traditional Health Practitioner Act

In May 2014, the President issued a promulgation notice bringing some sections of the Traditional Health Practitioners Act (22 of 2007) into operation.<sup>99</sup> Progress in this regard has been slow as the planned Traditional Health Practitioners Council faces serious challenges, not least relating to initial set-up funding, but also in relation to contacting and recording the large number of traditional health practitioners of various categories who are already in practice.

## Medical Innovation Bill

The purpose of this Bill, introduced by the late Mario Oriani-Ambrosini MP, is to make provision for “innovation in medical treatment” and to legalise the use of cannabinoids for medical purposes and beneficial commercial and industrial uses.<sup>3</sup> The Bill was also the subject of a Constitutional Court challenge to the interpretation of Parliamentary Rules by the Speaker.<sup>100</sup>

The justification for the Bill, according to its proponents, is as follows: “Under current legislation, medical practitioners are being legally prevented from prescribing and administering effective and harmless treatments, including those involving the use of cannabis, with respect to several life-threatening diseases, including cancer, because such treatments have not been approved in terms of presently legally required double-blind in vivo clinical studies. However, such clinical studies are often economically unviable, as the treatment or the substances used for it, such as bicarbonate of sodium or cannabis, are in the public domain and not capable of been patented, thereby preventing any relevant party from recouping the costs of such studies from future profits. This results in unnecessary human suffering and death on a mass scale, with consequent immense social and economic costs.”

The objectives of the Bill are “to establish one or more research hospitals where “medical innovation” can take place, especially with regard to the treatment and cure of cancer, and to legalise the medical, commercial and industrial use of cannabis in accordance with emerging world standards”. The Bill would create a special legal dispensation, which would apply only in research pilot hospitals authorised by the Minister of Health, where medical practitioners would be granted greater professional discretion to administer “innovative and alternative medical treatments” on the basis of the patients’ informed consent. The Bill also seeks to enable a medical practitioner who believes that it is not possible or appropriate to make an evidence-based decision in determining how to treat a patient’s condition, because in the medical practitioner’s opinion there is no research or other evidence available in relation to the condition or alternative treatments thereof, or the available research or other evidence is insufficient or uncertain to, subject to this Act, administer or prescribe a treatment other than a generally accepted or legally authorised one. The medical practitioner would be required to consider various factors in making the determination to so prescribe and administer, such as the reasons for the insufficiency of relevant research; the relative risks associated with the proposed treatment; the relative likely success rates of the proposed treatment compared to other treatments; and, in the medical practitioner’s reasonable judgement, the relative likely consequences of applying, or failing to apply, the proposed treatment. Also to be considered are: opinions or requests made by, on behalf of, or in relation to, the

patient; and the informed consent of the patient, guardian or other legally authorised person. Subject only to the Constitution, the Bill would indemnify such medical practitioner from negligence for the pre-existing range of acceptable treatments for a condition, when taking the decision to innovate in this regard.

Subject only to the Constitution, the Bill also proposes to decriminalise the growing, processing, distributing, using, advertising or otherwise dealing with or promoting cannabinoids for purposes of treatment, and commercial or industrial uses or products identified by the Minister of Trade and Industry by the appropriate proclamation.

The Parliamentary Portfolio Committee on Health heard submissions from various legal and medical experts, including the Medical Research Council (MRC), on 27 May 2015. The MRC commended Parliament for bringing attention to issues of medical cannabis, but stated that it could not support the Bill in its current form. It recommended that a full Cochrane Review be undertaken by the MRC, to evaluate the quality and strength of evidence for use of cannabinoids/cannabis for both palliative care and therapeutic use. It also suggested that the MCC would need to consider the evidence before registering cannabinoids/cannabis in South Africa. The MRC proposed that it should take the leading role in co-ordinating further research and clinical trials on the use of medical cannabis. The MRC also proposed that it should monitor the possible influences of medical cannabis use on non-medical use, especially among adolescents.

It seems highly unlikely that this Bill will be legislated any time soon. The Bill fails to recognise existing provisions in the Medicines and Related Substances Act, which allow for access to substances in Schedule 7 (such as cannabis) for research purposes, or for the management of a specific patient. The evidence for beneficial effects of medical cannabis and cannabinoids was recently subjected to a comprehensive systematic review.<sup>101</sup> The review found “moderate-quality evidence to support the use of cannabinoids for the treatment of chronic pain and spasticity”, but only “low-quality evidence suggesting that cannabinoids were associated with improvements in nausea and vomiting due to chemotherapy, weight gain in HIV infection, sleep disorders, and Tourette syndrome”. The findings in relation to HIV were consistent with those previously reported in a Cochrane Review.<sup>102</sup>

## Other health-related legislation and jurisprudence

Although not under the direct auspices of the Minister of Health, the Criminal Law (Sexual Offences and Related Matters) Amendment Bill (18 of 2014) has some relevance for health professionals.<sup>103</sup> The aim of the Bill is to amend the Criminal Law (Sexual Offences and Related Matters) Amendment Act, 2007, so as to ensure that children of certain ages are not held criminally liable for engaging in consensual sexual acts with each other. The amendments are consequent upon two separate judgments of the Constitutional Court in the case of *Teddy Bear Clinic for Abused Children v the Minister of Justice and Constitutional Development and Others* [2013] ZACC 35, and the case of *J v the National Director of Public Prosecutions and Others* [2014] ZACC 13. In the *Teddy Bear* case, the Court found that sections 15 and 16 of the Act infringe on the rights of adolescents in terms of sections 10 (human dignity), 14 (privacy) and 28(2) (best interest of a child) of the Constitution of the Republic

of South Africa, 1996. The Court determined that sections 15 and 16 are unconstitutional insofar as they criminalise consensual sexual conduct between adolescents. In the *J* case, the Court dealt with Section 50(2)(a) of the Act which places an obligation on a court to order that the particulars of a convicted person or a person in respect of whom the court has given a direction in terms of the Criminal Procedure Act, 1977, must be included in the National Register for Sex Offenders. As the provisions of section 50(2)(a) are also applicable to persons who were children at the time of the commission of the sexual offences, the Court questioned the constitutional validity of section 50(2)(a), with specific reference to the “best interest of the child” principle, as reflected in section 28(2) of the Constitution. The Court found that the limitation of the right of child offenders in section 50(2)(a) of the Act is not justified in an open and democratic society.

The Bill thus proposes to make the relevant amendments which have the effect of decriminalising consensual sexual acts between two adolescent persons, and decriminalising consensual sexual acts between a 16- or 17-year-old person and an adolescent person where the age gap between the two persons is not more than two years. This will enable health professionals to provide much-needed sexual and reproductive health services to adolescents without the obligation to report such consensual sex acts.

The implementation of amendments to the Births and Deaths Registration Act (51 of 1992), which prevent the sharing of cause of death notification data between Statistics SA and local health authorities, has been blamed for blocking effective public health interventions in the Western Cape.<sup>104</sup> A review of the entire vital registration process is underway, which may lead to improved data-sharing in the interests of public health.

In May 2015, the Department of Traditional Affairs invited comment on a Draft Policy on the Customary Practice of Initiation in South Africa.<sup>105</sup> The draft policy envisages the creation of a National Initiation Oversight Committee (NIOC) and a series of Provincial Initiation Co-ordinating Committees (PIOCs), drawing on the provisions of the National Health Act, the Children’s Act and the Traditional Health Practitioners Act (for instance, in terms of relying on registered traditional surgeons). Among the objectives of the policy are to “provide for the protection of life, the prevention of injuries and the prevention of all forms of abuse experienced by initiates before, during and after initiation”.

The issue of physician-assisted suicide in terminally ill patients occupied centre-stage during the year with the High Court application of Robert Stransham-Ford.<sup>106</sup> The applicant had been diagnosed with stage 4 prostate cancer, and was expected to live for only a few weeks, when he approached the court for an order to allow a medical practitioner to end his life or to enable him to end his life by administering or providing him with some or other lethal agent. He also requested that such medical practitioner not be subsequently held liable in criminal or civil law. The application was opposed by the Minister of Justice and Correctional Services, the Minister of Health, the Health Professions Council of South Africa, and the National Director of Public Prosecution. The court agreed with the applicant that dying with dignity is a fundamental human right. It addressed the question of the infringement of the right to dignity, taking the view that as a practical necessity, regard must be given to the subjective views and the condition of a person who

claims that his constitutional rights have been affected. It had to be determined whether his complaint was justified and, in this case, the court held that there was no doubt that any reasonable reader or physician would regard the applicant’s complaint as justifiable. There was a close relationship between dignity and other rights such as privacy, freedom and bodily integrity, and dignity required an acknowledgement of the value and worth of others. On the issue of the legality of physician-assisted suicide, in light of its duty to consider developing the common law under section 39(2) of the Bill of Rights, the court concluded that the absolute prohibition on physician-assisted suicide in common law does not accord with the rights relied upon by the applicant (as elucidated above). Section 11 of the Constitution (the right to life) cannot be relied on to argue that an individual is obliged to live, no matter the quality of his life. Relying on various authors as well as the foreign case of *Carter vs. Canada*,<sup>107</sup> the court emphasised the importance of ensuring safeguards in such cases. Based on the order made by that court, these safeguards are that: (1) the applicant is mentally competent; (2) the applicant made his request freely, voluntarily, and without undue influence; and (3) the applicant is terminally ill and suffering intractably, and has a severely curtailed life expectancy of a few weeks. The safeguards are applicable to this specific case, and each case is to be decided on its particular circumstances and merits. The court ruled that a medical practitioner who would assist the applicant in terminating his life would not be criminally liable. It held further that the crimes of murder and culpable homicide in the context of physician-assisted suicide, insofar as they provide for an absolute prohibition, unjustifiably limit the applicant’s rights to dignity and bodily and psychological integrity. Finally, the court suggested that the legislature ought to seriously consider introducing a Bill on the matter of euthanasia, regard being had to the South African Law Commission’s 1998 report on “Euthanasia and the artificial preservation of life”.<sup>108</sup> Notices of appeal against the judgment have been lodged by all the respondents on both procedural and substantive grounds. It has been pointed out that the judgment is not binding on any court, “but may be of persuasive value”.<sup>109</sup> However, support for a referendum on the subject has been expressed, noting that “limiting autonomy at the end of life... represents the last remnants of paternalism in healthcare”.<sup>110</sup>

## Health-related policy

In May 2015, the National Department of Health published its draft language policy for comment.<sup>111</sup> The Department proposes to use three languages as “official languages”: isiZulu, Sesotho sa Leboa, and English. However, for some media (such as the website), only English will be used.

In 2014/15, the National Department of Health continued to issue technical policy documents in order to guide healthcare practice. These included the 2014 version of the Primary Health care Standard Treatment Guidelines and Essential Medicines List.<sup>112</sup> Tracking the issuing of other technical policy documents has been made very difficult by yet another poorly implemented redesign of the NDoH website (which now shows no policy documents after 2013).



## Other policies with an impact on the health sector

### 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.<sup>113</sup> As indicated in the previous edition of the Review, the broad aim of this policy is to empower South Africans and promote development. However, despite considerable pressure, the policy has not been issued in final form, nor have the consequent amendments to patents legislation been commenced. A final version of the policy is expected to serve before Cabinet sometime during 2015.

The problem of patent 'evergreening' continues to plague South Africa's intellectual property landscape. This practice, where a new patent is granted for an incremental innovation which does not necessarily constitute an inventive step as required by the Patents Act, has the effect of barring generic competition and is an obstacle to affordable access. A recent case illustrates the problem.<sup>114</sup> The case involved infringement proceedings brought by Bayer as holders of a 2004 patent on the oral contraceptive sold as Yasmin®, alleging that Pharma Dynamics, a local distributor of generic medicines, had infringed the patent by importing and marketing the generic equivalent, which they had marketed as Ruby®. Pharma Dynamics denied that the patent was valid as it lacked an inventive step, and counterclaimed revocation of the patent. The Commissioner of Patents held that the patent was valid and that Pharma Dynamics had infringed it. Bayer's expert had contended that the inventive step lay in the result that good bioavailability of a poorly soluble drug is obtained by rapid dissolution using an uncoated enteric form. The Pharma Dynamics expert countered that it would have been obvious to a person skilled in the art "to try uncoated DSP, as a matter of routine, in an in vivo test" and hence did not meet the threshold for an inventive step, being a mere "counter-intuitive" discovery, which should not be afforded patent protection. The SCA agreed with Bayer's view and dismissed the appeal by Pharma Dynamics. Principally it found that firstly, "in light of the in vitro results, the in vivo experiment that eventually led to the unsuspected invention did not seem to have the slightest hope of success

before it was actually done". Further, it criticised the argument by Pharma Dynamics as lacking "any form of logical underpinning" and making no sense that "the skilled formulator would disregard the considerable costs, delays and risks associated with carrying out in vivo tests in circumstances where the formulator had no expectation whatsoever that the test might lead to any useful result". The judgment may be criticised for applying, along with earlier decisions of the Commissioner of Patents, for example, *Pfizer & Ano v Cipla Medpro & Ors* 2005 BIP 1, a very low standard of inventive step for the grant of a patent. Additionally, it did not appear to take account of the nature of the step, namely that it constituted a mere counter-intuitive discovery, and could thus be excluded from patentability in terms of section 25(2)(a) of the Patents Act. Further, it overemphasised the issue of the costs associated with testing as these have no direct bearing on the question of whether or not a patent may be granted. The long-term (20-year) protection that is granted for patents is precisely to enable an innovator to recoup its sunk costs of research and development.

## Conclusion

Yet again, this chapter has to record that, as in 2013, the much-anticipated White Paper on National Health Insurance has not been issued. Although there has been significant progress in some important areas of health legislation and policy, there are still steps to be taken before the independent Office of Health Standards Compliance is fully operational. Progress in relation to the planned South African Health Products Regulatory Authority has been desultory, and the ability of the current Medicines Control Council to regulate medical devices has been significantly hampered by a wide-ranging court decision. Each step in the process is important, from the drafting of a Bill, to its appropriate tagging, to the careful elaboration of appropriate Regulations, their finalisation and co-ordination with the step of promulgation by the President, and then effective administrative action by those responsible for implementation, be they statutory health councils or officials in national, provincial or local spheres of government.

However, the practical implications of ever more rigid regulation always need to be borne in mind, in order to avoid hampering the delivery of a quality health service.

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