

# Health Legislation and Policy

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## Abstract

*The National Health Act is the key piece of legislation in the health sector, and this chapter focuses firstly on the extent to which this Act has been brought into effect over the past year. Other important pieces of health legislation are in the process of being brought into effect, including a new Nursing Act. In general, implementation of existing laws on the statute books has been slow, but some progress has been made with the less controversial aspects of the National Health Act. The second half of 2008 has been dominated by the tabling of a number of Amendment Bills relating to health, including a National Health Amendment Bill. These are expected to be taken through Parliament in 2008, despite the truncated terms provided as a result of the looming General Election in 2009. Court decisions can also have a dramatic impact on health legislation and on the development and implementation of policy. Some of these key recent cases are also covered in this chapter. Implementation-level policies continue to be developed, and a listing of recent key documents emanating from the national Department of Health is provided. Overall, the situation continues to be characterised by conflict, particularly between the Ministry / Department of Health and various stakeholders in the health sector. The potential gains that could stem from a more inclusive and participatory policy and legislative process remain elusive, but important.*

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## Introduction

This chapter reviews progress in the implementation of the National Health Act, as well as some of the key legislative developments over the past year. It also provides an overview of current pending legislation and discusses some of the key court challenges and legal debates relating to health legislation and policy that have occurred in 2007/08.

In the national Department of Health's (NDoH) Annual National Health Plan 2007/08, the following statement is made:

*"The National Health Act of 2003, in Section 21(5) stipulates that the Director-General of the National Department of Health (NDoH) will integrate the health plans of the National Department and Provincial Departments annually and submit integrated health plans to the National Health Council (NHC). An Annual National Health Plan (ANHP) for the entire health system is therefore a legal requirement".<sup>1</sup>*

The primacy of the National Health Act of 2003 is thus clear. The extent to which this Act has been brought into effect and supplemented with the necessary subordinate legislation, and the extent to which it reflects the policy stance of the Ministry and Cabinet, are thus of major importance.

Some of the key issues were outlined by the Minister of Health in her briefing to the National Assembly Portfolio Committee on Health in February 2008. The Minister noted the following:

*"In October 2007, I convened a Private Sector Indaba to discuss my concerns about the unaffordable high costs in the private healthcare sector. At this Indaba everyone agreed that all was not well in the private health sector and that government would indeed have to take regulatory measures to ensure that the sector was sustainable".<sup>2</sup>*

Those steps have dominated debate in the latter part of 2008. At the same briefing, the Minister outlined the legislative programme for the year, noting that only the following Bills would be tabled:

- a Medical Schemes Amendment Bill;
- the South African Medical Research Council Bill;
- a National Health Amendment Bill; and
- a Medicines and Related Substances Amendment Bill.<sup>3</sup>

Initially, it was stated that the deadline for receipt of these Bills would be 29 February 2008, but the most controversial of these were only published in the Government Gazette in June 2008.<sup>4</sup> On 28 February 2008, an explanatory memorandum was published to accompany the Tobacco

Products Control Amendment Bill, 2008, which dominated the legislative space in the first part of 2008.<sup>5</sup>

The possibility of a disjuncture between plans and policy managed by the Executive and the views of the ruling party has not been a feature of the South African political landscape in the post-apartheid era. However, the 2007 Polokwane Conference of the African National Congress (ANC) produced wide-ranging resolutions under the general rubric of 'Organisational Renewal'.<sup>6</sup> Under the heading 'On Health', the following resolutions were accepted (presented here as bullet points, but numbered as items 52-68 in the original document):

- *"Education and health should be the two key priorities of the ANC for the next years.*
- *Reaffirm the implementation of the National Health Insurance System by further strengthening the public health care system and ensuring adequate provision of funding.*
- To develop a reliable single health information system.
- Government should intervene in the high cost of health provision.
- There should be health cover for Veterans of the struggle.
- We should develop a recruitment and Human Resource Development strategy for health professionals.
- Develop an MoU with foreign countries on the exodus of health professionals.
- The ANC should further consider the matter of making HIV and AIDS notifiable. In this regard a distinction should be made between the two as these are two conditions. In doing this, the ANC should also consider the negative implications of this recommendation, such as stigma.
- We accelerate the roll-out of the comprehensive health care programme, such as through the provision of ARV at all health facilities. At the same time we should strengthen capacity to monitor the side-effects of ARV.
- We accelerate programmes for hospital revitalisation including through innovative solutions that accommodate partnerships.
- We intensify our efforts to create an environment that promotes positive individual behaviour in our communities, especially amongst young people.
- There will be no need to adopt a special HIV and AIDS grant as this will be catered for by the comprehensive social security system.

- *The ANC should explore the possibility of a state-owned pharmaceutical company that will respond to and intervene in the curbing of medicine prices.*
- *More resources be allocated to programmes on sexual awareness. ANC branches must be actively involved in these programmes.*
- *Introduce a policy on African traditional medicine.*
- *Caution should be exercised when deciding on PPPs as a solution for the delivery of health services.*
- *Diseases such as TB and cancer should be given special attention”.<sup>6</sup>*

While none could be construed as signalling a major departure from existing policy, some did stimulate debate. These included the call for a state-owned pharmaceutical manufacturer and the word of caution on the use of private-public partnerships (PPPs). The extent to which they will shape health policy and legislation after 2009 remains to be seen, but the potential for some shifts in emphasis certainly exists. It was noteworthy that the Minister of Health was quoted on 15 July 2008 as stating that she would table a National Health Insurance policy at the next Cabinet meeting.<sup>7</sup> The subsequent Cabinet statement included this mention:

*“Cabinet received a progress report on the establishment of a National Health Insurance for South Africa, and noted that legislation relating to the establishment of the Risk Equalisation Fund was before Parliament”.*<sup>8</sup>

A number of key policy questions, including how this National Health Insurance System will be shaped, what the timelines for implementation will be, and how both private providers of health services and medical schemes will be engaged and involved, thus remain open.

## Legislation

This section summarises health-related legislation that has been passed, legislation tabled for consideration by Parliament and legislation currently in draft form. The three most controversial processes are dealt with first.

Attention is also paid to the implementation of important legislation passed previously. In addition, a large amount of subordinate legislation has been brought into effect or published in draft form. Space does not permit listing all of these Regulations, Board Notices and guidelines.

## The National Health Act, 2003 and the National Health Amendment Bill, 2008

The National Health Act (Act 61 of 2003) has been on the statute books for almost five years.<sup>9</sup> Although a wide range of Regulations was contemplated in the Act (see Table 1), only the following issues have been addressed since 2007.

- The process of determining the National Health Reference Price List - the information gathering process; the process of determination for 2008, and appointment of an advisory committee.<sup>10-12</sup>
- The process of enabling the National Health Research Council - draft Regulations.<sup>13</sup>
- The process of enabling the National Health Research Ethics Council - draft Regulations, and draft Regulations on the use of genetic material on research and therapeutics.<sup>14-16</sup>
- Communicable diseases - draft Regulations.<sup>17</sup>
- Pathology services - Regulations on rendering a forensic pathology service, and draft Regulations on the general control of human bodies, tissue and organs for transplantation.<sup>18,19</sup>

Once issued in final form, some of these Regulations will enable the Human Tissue Act (Act 65 of 1983, as amended) to be repealed. In addition, the establishment of a national blood transfusion service has been mandated by the promulgation of section 53 of the Act.<sup>20</sup>

A number of critical chapters and sections, however, remain enabled in their basic form (by the Act), but are not yet in operation (as the detail is still missing). These include the regulation of quality standards, to accompany the implementation of the Office of Standards Compliance (Chapter 10) and the Regulations to accompany the Certificate of Need (Chapter 6).

Instead, attention has now been diverted by the rushed publication of a draft National Health Amendment Bill.<sup>4</sup> The Bill was finally tabled as Bill 65 of 2008.<sup>21</sup> The intent, according to the published explanatory memorandum, is to “introduce a new chapter in the National Health Act, 2003, that provides for a framework for health pricing”.<sup>21</sup> The new chapter (Chapter 10A) first defines ‘prices’ as meaning “tariffs, fees or any form of reimbursement for health services rendered, procedures performed and consumable and disposable items utilised by health establishments, health care providers or health workers”.<sup>21</sup> However, it specifically states (in the proposed section 89K) that “[t]he provisions of this Chapter do not apply to the sale of medicines”.<sup>21</sup>

**Table 1: Regulations provided for in the National Health Act, 2003**

| Issues to be covered in Regulations, according to section 90 of the National Health Act, 2003 |   |
|---|---|
| ♦   | the fees to be paid to public health establishments for health services rendered;   |
| ♦   | the norms and standards for specified types of protective clothing and the use, cleaning and disposal of such clothing;   |
| ♦   | the development of an essential drugs list and medical and other assistive devices list;  |
| ♦   | human resource development;   |
| ♦   | cooperation and interaction between private health care providers and private health establishments on the one hand and public health care providers and public health establishments on the other;   |
| ♦   | returns, registers, reports, records, documents and forms to be completed and kept by the national department, provincial departments, district health councils, health care providers, private health establishments and public health establishments;   |
| ♦   | the functions of persons who render voluntary, charitable or similar services in connection with a public health establishment;   |
| ♦   | the rendering of forensic pathology, forensic medicine and related laboratory services, including the provision of medico-legal mortuaries and medico-legal services;   |
| ♦   | communicable diseases;  |
| ♦   | notifiable medical conditions;  |
| ♦   | rehabilitation;   |
| ♦   | emergency medical services and emergency medical treatment, both within and outside of health establishments;   |
| ♦   | health nuisances and medical waste;   |
| ♦   | the import and export of pathogenic micro-organisms;  |
| ♦   | health laboratory services, including the classification, accreditation and licensing of health laboratories; and setting, monitoring and enforcing quality control standards applicable to health laboratories;  |
| ♦   | non-communicable diseases;  |
| ♦   | health technology;  |
| ♦   | health research;  |
| ♦   | the national health information system contemplated in section 74;  |
| ♦   | the processes and procedures to be implemented by the Director-General in order to obtain prescribed information from stakeholders relating to health financing, the pricing of health services, business practices within or involving health establishments, health agencies, health workers and health care providers, and the formats and extent of publication of various types of information in the public interest and for the purpose of improving access to and the effective and efficient utilisation of health services;   |
| ♦   | the processes of determination and publication by the Director-General of one or more reference price lists for services rendered, procedures performed and consumable and disposable items utilised by categories of health establishments, health care providers or health workers in the private health sector which may be used by a medical scheme as a reference to determine its own benefits; and by health establishments, health care providers or health workers in the private health sector as a reference to determine their own fees, but which are not mandatory. |

Source: Republic of South Africa, 2003.<sup>9</sup>

Medicines pricing thus remains regulated by the Medicines and Related Substances Act (Act 101 of 1965, as amended).

The intent of Chapter 10A is *"to create a framework that-*

- a) enables health care providers, health establishments and medical schemes to -*
  - i) negotiate collectively on prices; and*
  - ii) bargain individually on prices; and*
- b) ensures transparency and fairness in the determination of prices".<sup>21</sup>*

The mechanism for this entails the appointment by the Minister of Health of a 'Facilitator for Health Pricing' and up

to five assistant facilitators (having invited nominations for these positions). Taken as a whole, they would be expected to have *"qualifications or experience in mediation and dispute resolution, health economics, law, commerce, health or public administration".<sup>21</sup>*

The key section (89F) reads as follows:

*"(1) The Minister must within 60 days of publication of the reference price lists (RPL) contemplated in section 90(l)(i), by notice in the Gazette, invite health care providers, health establishments and medical schemes (hereinafter jointly referred to as 'the parties') to negotiate and bargain on prices.*

(2) The parties may -

- a) negotiate collectively in instances where the parties are represented by representative organisations or associations; or
- b) bargain individually in instances where the parties represent themselves as individual entities.

(3) The parties to both collective negotiations and individual bargaining -

- a) may conduct such negotiations or bargaining separately according to their specific area of interest; and
- b) must use the RPL as a source of reference for negotiations and bargaining".<sup>21</sup>

Section 89G makes it clear that legal maximum prices will be achieved in negotiations, or by arbitration, arranged by the Facilitator, in the case that *"such prices are in respect of prescribed minimum benefits"* (defined by reference to Government Notice No. R.570 of 5 June 2000, issued in terms of the Medical Schemes Act, 1998).<sup>21</sup> The arbitrator would be appointed by the Minister of Health, after consultation with the Minister of Justice and Constitutional Development.

Finally, the draft Bill provides for amendment of section 90(1)(v) of the National Health Act, deleting the final phrase *"but which are not mandatory"*.<sup>21</sup>

Initial reaction to the draft Bill has been vociferous, particularly from the private hospital industry and the medical profession. The Hospital Association of South Africa (HASA) submission on an earlier draft (published as Government Notice No. 475 in Government Gazette No. 30985 of 18 April 2008, requesting comment by 16 May 2008) claimed that *"[t]he Bill is replete with difficulties and does not pass constitutional muster"*.<sup>22</sup> Specifically, it claimed that *"the regulation of hospital and service provider pricing amounts to an unjustifiable infringement of the constitutional rights to property and freedom of trade, occupation and profession"*.<sup>22</sup> To bolster their arguments, HASA published the 'Private Hospital Review 2008'.<sup>23</sup> The South African Medical Association (SAMA) stated that *"the attempt to make the NHRPL an ethical and / or maximum tariff ... is an unethical and diabolical step for all concerned in healthcare"*.<sup>24</sup>

The debate that was created by the publication of the draft Bill, which was expected to be tabled in its revised form in Parliament without delay, was also significant in that it coincided with the release of a major policy statement on 'health' by the Official Opposition.<sup>25</sup> While not specifically addressing the Bill, the Democratic Alliance's (DA) preferred policy options included greater use of PPPs. It noted that *"[t]he private sector, although able to offer a substantially*

*better service, is not immune to problems and, in particular, it is not immune to the brain drain"*.<sup>25</sup> Echoing similar calls for an 'internal market' in health care, the DA noted that *"[p]atients in both the public and the private sectors need to be empowered to compare benefits and costs of the service they need"*.<sup>25</sup> They also called for the urgent establishment of the Office of Standards Compliance, but *"as an autonomous institution, governed by regulation and funded partly by the state and partly by private hospitals themselves"*.<sup>25</sup>

In short, while much of the National Health Act has remained in abeyance since 2003, much-needed attention has been paid to the issue of affordability of health care, a necessary element in any attempt to introduce compulsory health insurance. However, in the absence of a clear policy document, stakeholders were asked to comment on a draft Bill for which no explanatory memorandum was available. After the very truncated comment period had passed, a revised Bill and memorandum were published, and the Bill was tabled for consideration in the shortened 2008 parliamentary term.

## The Medicines and Related Substances Amendment Bill, 2008

Although draft Regulations to the Medicines Act were published for comment in 2004, these were never finalised.<sup>26</sup> Included in the draft Regulations was a new definition: *"'health fraud' means the promotion, advertisement, distribution, or sale of medicines or articles, intended for human or animal use, that is represented as being effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), or to provide a beneficial effect on health, but which has not been proven safe and effective for such purposes and such practice is intended to defraud or mislead the public"*.<sup>26</sup>

In essence, all legislative activity in this regard went into abeyance, pending the completion of an inquiry headed by the Minister of Health's special advisor, Prof Green-Thompson. This process was finally completed and the task team's report made available on the Department of Health (DoH) website on 22 May 2008.<sup>27</sup> By this time, however, the comment period on the draft Medicines and Related Substances Amendment Bill, 2008 had already passed.

The Bill was subsequently tabled in Parliament on 17 June 2008.<sup>28</sup> However, there were major differences between the Bill and at least some of the elements proposed by the task team. The task team proposed that: *"The new South African Health Products Regulatory Authority (SAHRA) will be solely responsible for the regulation of all therapeutic*



products seeking market authorization in South Africa. As such, it will integrate the functions of a number of entities or government organisations presently engaged in the fractionated responsibilities for this function. These therapeutic products will include all human prescription medicines, including pharmaceuticals, products of biotechnology, and radiopharmaceuticals; all non-prescription medicines for use in humans, including non-prescription pharmaceuticals, African Traditional Medicines, herbal, homeopathic, and other products referred to as complementary medicines; medical devices; medicines for farm, companion, and wild animals, both prescription and non-prescription; cosmetics with medicinal content or claims; and, certain foods with medicinal content or claims. It will also be responsible for the authorization, audits, and investigations of all clinical trials, including veterinary animal trials leading to veterinary medicines; surveillance of marketed products; as well as inspections and investigations of manufacturing standards within South Africa. Through international agreements, it will ensure the manufacturing quality of all therapeutic products marketed in South Africa".<sup>27</sup>

Instead, the Bill provided for a two-stage process of medicines regulatory approval. First, the new authority (SAHRA) would 'certify' products (i.e. medicines, medical devices, or any cosmetic or foodstuff in respect of which a medical claim is made) on the basis of evidence of efficacy, safety and quality. The Authority would consist of a full-time Chief Executive Officer (CEO) and such staff as would be appointed. The CEO would be able, "subject to the approval of the Minister, appoint committees ... to investigate and report ... on any matter within the purview of the Authority", but no details were included on the possible composition of such advisory structures, how their advice would be given or the access interested parties would have to their deliberations or reports.<sup>28</sup>

Then, the Minister of Health would 'register' products, taking into account the following factors:

- i) "Public health interests including national epidemiological trends;
- ii) economic interests in relation to health policies;
- iii) whether the product is supportive of national health policy and goals in the long term;
- iv) whether the product is likely to significantly improve access to health care for vulnerable groups within society;
- v) the experience of other countries concerning the marketing, distribution and use of the product; and
- vi) generally, whether the public would be best served by such registration".<sup>28</sup>

While no advisory structure for this activity was specified, a senior official in the DoH explained in a media interview that the Pricing Committee would play this role: "The pricing committee would rule on the value for money of the drug in question. "These committees have to report to someone to make the final say and it has to be the minister", said Pillay. He denied that the process would be slowed down significantly stating that many of the applications could run in parallel. According to Pillay, international evidence showed that government would also have more bargaining power in terms of pricing if the drug was not registered until an agreement was reached on the price".<sup>29</sup>

The Bill provides that "Veterinary medicines shall be registered by the Minister after consultation with the Minister of Agriculture".<sup>28</sup> However, contrary to the recommendations of the task team, the Bill has not addressed the overlap between the Medicines and Related Substances Act (Act 101 of 1965) and the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of 1947). New draft Regulations have in fact been published for comment in terms of the latter Act.<sup>30,31</sup>

The Minister of Health's power is also seen as being increased by an amendment to section 36 of the Act. Instead of the Minister only being allowed to exclude a medicine from any of all of the provisions of the Act on the unanimous recommendation of the Council (in other words, on the recommendation of all members present at a meeting of the Council, without exception), such a decision would be possible on the recommendation of the Authority.

Reaction to this Bill has also been vociferous. In a joint submission on the draft Bill, the Treatment Action Campaign (TAC) and AIDS Law Project expressed the opinion that, "if the draft Bill were ever to become law ... its enactment would signal the final death knell of the scientific governance of medicines and clinical trials in South Africa".<sup>32</sup> They also submitted that provisions to limit the powers of the High Court in reviewing the decisions of appeals committees were "arguably in violation of sections 34 and 38 of the Constitution".<sup>32</sup> At the first of three days of public hearings, Jonathan Berger of the AIDS Law Project predicted that "If passed in its current form ... it will go to litigation".<sup>33</sup> That an improvement in the efficiency of the Regulatory Authority is needed cannot be gainsaid, the evidence provided by the Ministerial Task Team is clear. Whether a full-time structure that would cost as much as R100 million extra from the fiscus per year, supplemented by a similar amount in user fees, would be feasible in a relatively small developing country where specialist skills in medicines regulatory issues are in short supply, remains to be seen.

## The Medical Schemes Amendment Bill, 2008

Also published in the same Gazette as the National Health Amendment Bill was the Medical Schemes Amendment Bill (Bill 58 of 2008). The intended outcomes, as outlined in the memorandum were to provide for:

- the establishment of the Risk Equalisation Fund (REF);
- the greater cross-subsidisation between members of medical schemes (by altering benefit structures);
- improved governance of medical schemes; and
- the emergence of risk-pooled medical scheme products for low income beneficiaries.<sup>34</sup>

A new Chapter 3A is envisaged, which provides for the creation of the REF, the information needed for the process of risk equalisation and the methodology to be followed. Section 19P states that *"The Council may recommend to the Minister a schedule for the progressive implementation of financial transfers taking into account the potential impact of the financial transfers on the financial soundness and viability of medical schemes in general"*.<sup>34</sup> In addition, promulgation of this Act, once passed, will not automatically result in the implementation of the REF, as this would (in terms of section 27 of the Bill) require the written approval of the Minister of Health, in concurrence with the Minister of Finance, certifying to the adequacy of the systems in place to allow the Council for Medical Schemes (CMS) to effectively manage risk equalisation transfers.

The Bill also tightens the provisions for admission of beneficiaries, the definition of 'basic' and 'supplementary' benefits, and how these are to be costed, using community rating as the basis. The use of preferred providers is also made more explicit by the inclusion of this wording (section 32H): *"A medical scheme may provide in its rules for a discount to apply off the contribution payable by a member in respect of the basic benefits or a supplementary benefit option because the member agrees to the choice of a particular provider or provider network for the provision of specified services to that member and his or her dependants, provided that -*

- a) *such choice promotes greater efficiency in the delivery of benefits and does not give rise to unfair discrimination against beneficiaries of the medical scheme; and*
- b) *the discount shall be disclosed in the rules of the medical scheme as a uniform percentage of the relevant contributions and is approved by the Registrar in terms of section 33"*.<sup>34</sup>

Reaction to the draft Bill has been muted, perhaps reflecting the longer policy development process undertaken by the CMS. However, the degree to which the Bill, as drafted, will truly enable the launch of a Low-Income Medical Scheme (LIMS) is open to debate. That policy trajectory has, however, been threatened by the outcome of the Guardrisk case, which is dealt with in more detail below. The final Bill, as tabled, amended the definition of 'business of a medical scheme', to insert the word 'or' after *"to make provision for the obtaining of any relevant health service"*, and replace the word 'and' with 'or' after *"to grant assistance in defraying expenditure incurred in connection with the rendering of any relevant health service"*.<sup>35</sup> The intent of these changes is to prevent the expected increase in risk-rated health insurance products aimed at the young and healthy, following the Guardrisk case, which has the potential to undermine the cross-subsidisation that lies at the very core of the private funding model. That risk will remain if the Bill fails to be passed in the current term or if its subsequent promulgation is delayed.

The extent to which other legislation had the potential to undermine community rating was also demonstrated by the wording of the Insurance Laws Amendment Bill (Bill 26 of 2008).<sup>36</sup> This Bill would have amended the definition of a 'health policy' (in essence, to be *"a contract in terms of which a person, in return for a premium, undertakes to provide policy benefits upon a health event"*, but excluding *"any contract ... that provides for the conducting of the business of a medical scheme referred to in section 1(1) of the Medical Schemes Act, 1998 (Act No. 131 of 1998)"*, but providing that this would be done *"after consultation with the Minister of Health"*.<sup>36</sup> It was subsequently agreed between all the parties concerned (National Treasury, CMS and DoH) that such determinations would be done jointly, taking into account the objectives of the Medical Schemes Act.

## The Criminal Law (Sexual Offences and Related Matters) Amendment Act, 2007

Although not a law under the direct control of the DoH, the Criminal Law (Sexual Offences and Related Matters) Amendment Act (Act 32 of 2007), passed in late 2007, has direct relevance for health practitioners.<sup>37</sup> Chapter 5 of the Act was brought into effect on 21 March 2008 and Chapter 6 on 16 June 2008. The Act deals extensively with the commercial sexual exploitation of children, changes the legal definition of rape and sexual assault, sets down what services ought to be available for victims of alleged sexual offences and deals with compulsory HIV testing of alleged sex offenders.

The Act replaces the common law definition of rape, specifically including forced anal or oral sex, irrespective of the gender of either the victim or the perpetrator. These previously carried a lesser charge of sexual assault. The Act therefore recognises male rape, which was previously classified as indecent assault, and also widens the definition of rape to include sexual penetration with an inanimate object or animal genitalia.<sup>38</sup> The Act describes the crime of rape as one person unlawfully and intentionally committing an act of sexual penetration with another person without that person's consent. The act of sexual penetration has been defined as any act that causes the penetration to any extent by genital organs, any other body part, or any object resembling genital organs or the genital organs of an animal into the genital organs, mouth or anus of another person.

Consent has been defined as "*voluntary and uncoerced agreement*".<sup>37</sup> The Act has eliminated the differentiation drawn between the age of consent for different consensual acts and provides special provision relating to prosecution and adjudication of consensual sexual acts between children older than 12 but younger than 16 years. Consent is, however, lacking in certain circumstances. In this Act a 'child' means a person under the age of 18 and with references to sections 15 and 16, a person 12 years or older but under the age of 16 years. Section 15 aims to criminalise acts of sexual penetration by adults with children between the ages of 12 and 16 years, despite their consent. Here it is important to remember that the Children's Amendment Act (Act 41 of 2007) allows for a child of any age to access contraception.<sup>39</sup>

The ethical and legal dilemma facing health care workers is whether or not to supply a child under the age of 16 with contraception and then report the case as one of statutory rape. The Act does give some guidance on the legal aspect of this dilemma. Section 16 is intended to criminalise acts of consensual sexual violation committed by adults with children between the ages of 12 and 16 years. The Act provides, among others, that children who engage in certain acts with each other, such as kissing, cannot be prosecuted for doing so if both agreed to such acts and the age difference between the two children is not more than two years. The Act even goes further to ensure that children who innocently engage in certain acts with each other are not prosecuted, by affording the Directors of Public Prosecutions the discretion to decide whether prosecutions should be instituted or not in those cases where there are two children involved.<sup>40</sup>

The Act acknowledges the high incidence of sexual offences committed in South Africa. According to statistics released by the South African Police Service (SAPS) on rape for the

period 2004/05, 55 114 cases of rape were reported. Since it is estimated that only one out of nine rapes is reported, the total number of rapes is potentially far larger. These figures do not include incidents of indecent assault (10 123 over the same period). In future, in terms of the new definitions contained in the Act, many cases previously defined as indecent assault should now be treated as rape.<sup>41</sup>

Chapter 5 of the Act allows for a victim / survivor of a sexual offence at risk of exposure to HIV to receive post exposure prophylaxis. However, this service will only be available after he or she has laid a charge with the SAPS or reports an incident in the prescribed manner at a designated health establishment, within 72 hours after the alleged sexual offence. The Act also allows the victim / survivor to have the offender tested for HIV. This right is, however, limited, in that testing must be done within 90 days of the alleged incident, the victim / survivor must apply to the magistrate for the test to be done, and the offence must have been reported and a charge must have been laid.<sup>42</sup> The Act also allows for the investigating officer to apply to the magistrate for an order that the alleged offender be tested for HIV (in accordance with the prevailing norms and protocols). The result of the HIV test will be disclosed to the victim / survivor, the investigating officer, the prosecutor and to the alleged offender. The South African Law Reform Commission (SALRC) had recommended that the Act include a provision recommending the State provide psychosocial support and healthcare to victims / survivors of sexual offences.<sup>43</sup> In spite of strong support for this in public submissions, the Department of Justice and Constitutional Development did not accept this recommendation and the provision was not included in the Bill introduced to Parliament in 2003. The recommendation remained excluded from the 2006 draft of the Bill. Removal of this clause failed to take into account the seriousness of the physical and psychosocial trauma resulting from sexual offences and ignored the currently differential availability of, and access to, services for wealthy and poor South Africans.

Perhaps most importantly, the Act does not benefit victims who, for whatever reason, do not report the alleged offence. These include those who are in abusive domestic relationships, victims / survivors who have been subjected to gang rape and those whose assailants are not in custody.

## **The Foodstuffs, Cosmetics and Disinfectants Amendment Act, 2007**

The Foodstuffs, Cosmetics and Disinfectants Amendment Act (Act 39 of 2007) was assented to by the President in February 2008.<sup>44</sup> Some of the changes brought about by this amendment are of little consequence (e.g. updating



reference to the Drugs Control Act of 1965 to read the Medicines and Related Substances Act). In general, the amendments served to bring the Act in line with more recent legislation (such as the National Health Act), and retained the definitions that distinguish a foodstuff and a cosmetic from a medicine. These definitions are important when deciding on the registrability of borderline products, the so-called nutraceuticals and cosmeceuticals.

### **The South African Red Cross Society and Legal Protection of Certain Emblems Act, 2007**

South African Red Cross Society and Legal Protection of Certain Emblems Act (Act 10 of 2007) was assented to in August 2007.<sup>45</sup> In terms of the Act, the South African Red Cross Society was recognised as the national Red Cross Society for the Republic and their symbols (red cross and a red crescent moon) protected.

### **The Choice on Termination of Pregnancy Amendment Act, 2008**

The Constitution of the Republic of South Africa Act (Act 108 of 1996) provides that everyone has the right to equal protection of the law, to have their inherent dignity respected, to life, to be free from private and public violence, to make decisions regarding their reproduction, to privacy and to access health services, including reproductive health care.<sup>46</sup> South Africa has also ratified the 1981 Convention on Elimination of Discrimination against Women (CEDAW), which is often described as an International Bill of Rights for women. Consequently laws should be changed in order to be in line with the rules of the CEDAW. By accepting the Convention, states commit themselves to the following measures:

- to incorporate the principle of equality of men and women in their legal system, abolish all discriminatory laws and adopt appropriate ones prohibiting discrimination against women;
- to establish tribunals and other public institutions to ensure the effective protection of women against discrimination; and
- to ensure elimination of all acts of discrimination against women by persons, organisations or enterprises.<sup>47</sup>

The South African Constitution is one of the few in the world that guarantees gender equality and establishes a Commission on Gender Equality (CGE). The Choice on Termination of Pregnancy Act (Act 92 of 1996) recognised

the Constitutional values of human dignity, equality and enhanced the human right status of women.<sup>48</sup> This Act also recognised that the decision to have children is fundamental to a woman's physical, psychological and social health. The Act also states that a woman does not need consent from her husband or partner before she has a termination. While this entrenches her autonomy, it has been construed as being contrary to customary traditions. Research undertaken by the South African Medical Research Council (MRC) to evaluate the 1996 Act has demonstrated that the proportion of women presenting to hospitals with severe complications of incomplete abortions has significantly reduced.<sup>49</sup> However, half of South African women still do not know of the legislative change and many of those who do, have insufficient knowledge to be able to access a legal termination of pregnancy (TOP). Inequities and barriers still remain which render it very difficult for women to access TOP services. One of these barriers is that of conscientious objection to performance of the TOP by health care workers based on their own ethical belief system. Whilst it is recognised that all health care workers have fundamental rights to freedom of conscience, religion, thought and belief, these may impact negatively on women's health and limit their ability to make informed decisions and cause them to seek unsafe alternatives. In some circumstances the effect of a conscientious objection may be to take away the right of individual women to obtain such services, thereby precluding their right to exercise their right to conscience.<sup>50</sup> That said, as part of the process of informed consent, patients should always be informed of the risks, benefits and alternatives to the procedure offered. Any health care professional who does not comply with these requirements may be in breach of her / his respective professional ethics.

The Objects of the Amendment Act, the Choice on Termination of Pregnancy Amendment Act (Act 1 of 2008), were to:

- allow registered nurses and midwives, who have undergone training, to perform terminations of pregnancy;
- allow the Member of the Executive Council (MEC) responsible for health in a province to designate TOP facilities;
- allow all private and state facilities that have a 24 hour maternity service to terminate pregnancies of up to and including 12 weeks, without seeking approval from the MEC concerned;
- empower the MEC to prescribe, by Regulations, the requirements and conditions applicable to facilities where terminations may take place;

- report annually on the number of facilities approved; and
- make it an offence for any person to terminate a pregnancy unlawfully or allow a termination to take place at a facility which has not been approved.<sup>51</sup>

The Amendment Act, aimed to delegate the monitoring, implementation and functioning of termination of pregnancies from national to provincial levels. This allowed for MECs in each province to identify gaps in services within their respective provinces, and to address them.

No discussion of the TOP field is complete without mention of the growing jurisprudence in this regard. In 1998 the Christian Lawyers Association (CLA) sought to have the Choice on Termination of Pregnancy Act declared unconstitutional, based on the right to life of the foetus.<sup>52</sup> This claim was dismissed by the High Court. The CLA then launched another action in 2001, the primary argument being that abortion would have long-term detrimental physical, spiritual and emotional effects on a child and that it was thus in the best interests of the child (a constitutionally protected right) that the Act require parental consent for a minor to access an abortion.<sup>53</sup> The court again dismissed this claim. The right to free TOP services has also been entrenched in terms of section 4(3)(c) of the National Health Act (Act 61 of 2003).<sup>9</sup> The most recent legal action has involved the matter between a nursing sister, Wilhelmiën Charles, and her employer, the Gauteng DoH, as to whether her unfair discrimination complaint against her employer should be prosecuted in the Equality Court or the Labour Court.<sup>54</sup> The dispute began when Charles voiced her conscientious objection to prepare patients for evacuations following terminations of pregnancy. Charles claims that her subsequent transfer from the theatre ward constituted unfair discrimination against her on the basis of religion, conscience and belief. In seeking to have her matter heard under the Promotion of Equality and Prevention of Unfair Discrimination Act (Act 4 of 2000), Charles contended that the remedies she sought were not available under the Employment Equity Act (Act 55 of 1998). In June 2003, this case was heard by the Labour Appeal Court, which referred the case to the Commission for Conciliation, Mediation and Arbitration (CCMA).<sup>55</sup>

## The Traditional Health Practitioners Act, 2007

On 30 April 2008, certain sections of the Traditional Health Practitioners Act (Act 22 of 2007) were signed into operation by the President.<sup>56</sup> In 2006, the Constitutional Court had declared the Traditional Health Practitioners Act invalid due

to the failure of Parliament to facilitate the required level of public involvement. The order of invalidity was, however, suspended for a period of 18 months to enable Parliament to re-enact the statute.

The sections of the Act that were brought into operation (Chapter 2, sections 7, 10, 11 (3), 12 to 15 and Chapter 5, sections 47, 48 and 50) deal with the structure and functioning of the Traditional Health Practitioners Council. This Council is to be comprised of 22 members appointed by the Minister of Health, including registered traditional health practitioners from each province. The Council will also include a representative of the DoH, a pharmacist, a medical practitioner and a person with knowledge of the law. Three members representing the community and a member from each category of traditional health practitioners defined in the Act complete the Council.

In September 2007, the Minister of Health established the Professional Board for Ayurveda, Chinese Medicine and Acupuncture and Unani Tibb. The process of bringing the many thousands of traditional health practitioners within the envisaged regulatory framework still faces considerable challenges.

## The Health Professions Amendment Act, 2007

The Health Professions Amendment Act (Act 29 of 2007) was passed in 2007 and assented to in January 2008.<sup>57</sup> Added to the objects and functions of the Health Professions Council were the following obligations: to submit to the Minister of Health, a *"five-year strategic plan within six months of the council coming into office which includes details as to how the council plans to fulfil its objectives under this Act; every six months a report on the status of health professions and on matters of public importance that have come to the attention of the council in the course of the performance of its functions under this Act; and an annual report within six months of the end of the financial year"*.<sup>57</sup> The Council was also required to *"ensure that an annual budget for the council and the professional boards is drawn up and that the council and the professional boards operate within the parameters of such budget"*.<sup>57</sup> Ministerial supremacy was also underlined by an amendment requiring that the Council's rules be *"consistent with national health policy determined by the Minister"*.<sup>57</sup>

Membership of the Council was also denied to anyone who, at the time of appointment or in the preceding 12 months was *"a member of a municipal council, a provincial legislature or Parliament or a provincial or national office bearer or employee of any party, organisation or body"*

of a political nature”.<sup>57</sup> Reasons for removing a Council member from office were also expanded, with the addition of the following circumstances: “*deliberately [acting] in a manner that will prejudice the interests of the council, the health professions or the public or violates the Charter of the council*”, if the Minister dissolved the council, or being an “*office bearer of an organisation that has a conflict of interest with the council, unless such member elects to immediately vacate his or her office in that organisation*”.<sup>57</sup> These sections were criticised as being vague as to the identity of such organisations, or the circumstances which would necessitate such intervention.

Apart from sections tightening the financial controls of the Council, the Amendment Act also addressed issues related to disciplinary action and the control of education and training.

Consequent amendments to the applicable Ethical Rules have been published for comment.<sup>58</sup> This is to bring the guidelines in line with recent legislation, for example, the dropping of the age of consent for medical and surgical treatment to 12. The amendments of the ethical rule also address the issues of employment of locums, financial interests in hospitals and other health care institutions and main responsibilities of Health Practitioners. These focus on obtaining an informed consent, continuing professional development, record keeping and sharing information with the patient. The document is dated 8 April 2008.

## The Nursing Act, 2005

Although much attention has been paid to the contested replacement of the Nursing Council and Registrar, the promulgation of the new Nursing Act (Act 33 of 2005) has gone almost unnoticed.<sup>59</sup> Three promulgation notices were issued:

- Government Notice R4, Government Gazette No. 29634, 16 February 2007 - which brought into effect sections 1 to 4, 8, 11, 13, 17 to 29, 30, 31, 37, 40, 58, 59, 61 and 62;
- Government Notice R18, Government Gazette No. 30159, 8 August 2007 - which brought into effect sections 5, 6, 7, 9, 10, 12, 14, 15, 16 and 60; and
- Government Notice R6, Government Gazette No. 3086, 13 March 2008 - which brought into effect sections 32 to 36, 38 and 39, 41 to 57, thus completing the process.

Issues that have already been settled in the form of Regulations or other instruments include:

- draft and final Regulations covering the nomination and appointment of the Nursing Council;<sup>60,61</sup>

- particulars to be furnished for the keeping of the Registers, and the initial categories of practitioners;<sup>62,63</sup> and
- the performance of community service by newly registering nurses.<sup>64,65</sup>

The nomination and appointment of the Nursing Council has not been without controversy. While the Act stipulated the composition of the Council (14 professional nurses or midwives with expertise in nursing education, nursing, community health, primary health care, occupational health and mental health; one officer of the national department; a person with special knowledge of the law; a person with special knowledge of financial matters; a person with special knowledge of pharmacy; a person with special knowledge of education; a person with knowledge of consumer affairs; three people representing communities; a registered staff nurse and a registered auxiliary nurse), the Regulations that were issued went beyond these categories, restricting some in ways not envisaged by the Act. Regulation 3 stated that the Minister of Health “*must request nomination of one person each from*” the Director-General: Health, from the Law Society, the Financial Services Board, the South African Pharmacy Council, the Council on Higher Education, the Consumer Council and from the MEC responsible for health in each province (from which the three community representatives would be chosen).<sup>61</sup> The draft version had restricted the nominating bodies even further, for example, called for nomination from the Law Society of the Northern Provinces only.<sup>60</sup> The AIDS Law Project objected to this restriction, as well as to the restriction on nominations of persons ‘representing communities’, stating: “*Instead of communities nominating their own representatives, as the Act permits, the draft regulations allocate that power to the nine MECs for health. Not only is this not authorised by the Act, but it also reflects a particularly disturbing and patronising view of communities, who are deemed not to be able to determine for themselves whom to nominate*”.<sup>66</sup>

However, in terms of coordination with other pieces of legislation, a key element that remains in limbo is the designation of special categories of nurses who will have proven competence to “*assess, diagnose, prescribe treatment, keep and supply medication for prescribed illnesses and health related conditions*” (as provided for in section 56).<sup>59</sup> This is the basis for the designation of certain nurses as ‘authorised prescribers’ in terms of the Medicines and Related Substances Act, and for the listing of the medicines each category would be competent to prescribe in the Schedules. Although the transitional arrangements provided for in section 61 allow all nurses who have been issued with section 38A permits to continue as if they hold

the permit contemplated in section 56(6), no new Regulations have been issued to cover new permits. In addition, the need for psychiatric nurses to prescribe Schedule 5 medicines and for palliative care nurses to prescribe Schedule 6 medicines has been enabled in law, but remains difficult to put into practice.

## **The Tobacco Products Control Amendment Bill, 2008**

The latest amendments to tobacco legislation were dealt with in two parts. The Tobacco Products Control Amendment Act (Act 23 of 2007) was passed in 2007, assented to in February 2008, and was followed by the Tobacco Products Control Amendment Bill (Bill 7 of 2008), the latter being a section 76 Bill.<sup>67,68</sup>

In keeping with the 2008 World Health Organization (WHO) Report on the Global Tobacco Epidemic (the MPOWER package), the WHO Framework Convention on Tobacco Control and available local data, particular attention was paid to the ways in which adolescents' access to tobacco products could be regulated.<sup>69,70</sup> Sales to persons under the age of 18 years are to be prohibited. These prohibitions will include not only the sale of tobacco products to anyone under the age of 18 years, whether for her / his personal use or not, but also no person under the age of 18 years in the employ of an owner of a business can sell or offer to sell any tobacco products. No person may sell or supply any confectionary or toy that resembles or is intended to represent any tobacco product and tobacco products may not be sold in any health establishment, including any pharmacy or any place of education or training. Additional restrictions on the placement of vending machines are also provided for in the Bill. A section which would have banned the sale of loose cigarettes was removed by the Portfolio Committee on Health, as it felt this provision was not enforceable.

The Bill also empowers the Minister of Health to prescribe the information to be displayed on a package containing tobacco products and any notices or signs displaying tobacco products. These may be in the form of graphic images of diseased lungs and gums as is done in other countries. Fines for contravention of the Act are also increased to a maximum of R1 million. However, the Portfolio Committee did respond positively to some of the requests from the tobacco industry, for example, replacing the section reading *"A manufacturer or importer of a tobacco product shall not make a charitable financial contribution or sponsorship unless such contribution or sponsorship is made anonymously"*, with a far less-restrictive provision, *"A manufacturer or importer of a tobacco product may make a charitable*

*commercial contribution or sponsorship, provided that such contribution or sponsorship is not for the purpose of advertisement"*.<sup>68</sup>

Final deliberations in the Portfolio Committee took place in early June 2008, and the Official Opposition indicated that it would seek a debate on the Bill in the National Assembly, given its importance. One last change was inserted. Where the Bill prohibited Internet sales of tobacco products (*"No person shall sell, offer to sell, supply, distribute or buy any tobacco product through the postal services, the internet or any other electronic media"*), this was limited by the addition of a sub-section making it clear that this prohibition did not apply to *"commercial communication between a tobacco manufacturer and its trade partners, business partners, employees and share holders"*.<sup>68</sup> With this last series of amendments, the Bill was adopted by the Portfolio Committee. Hearings in the provinces are planned, before the Bill returns to Parliament for further processing.

## **The Draft Intellectual Property Rights from Publicly Financed Research Bill, 2007**

A draft Bill, entitled the Intellectual Property Rights from Publicly Financed Research Bill, was gazetted for comment in June 2007.<sup>71</sup> The Bill would create a new agency, the National Intellectual Property Monitoring Office, and the establishment of government 'walk-in' rights for intellectual property secured with public financing. While welcomed as an attempt to improve access to the fruits of publicly funded research, the Bill was criticised by the AIDS Law Project as needing some 'fine tuning'.<sup>72</sup> The final version of the Bill (Bill 46 of 2008) was gazetted by the Minister of Science and Technology on 13 July 2008.<sup>73</sup>

## **The Prevention of and Treatment for Substance Abuse Bill, 2008**

Introduced by the Minister of Social Development, and not by the Minister of Health, the Prevention of and Treatment for Substance Abuse Bill (Bill 12 of 2008) also has relevance.<sup>74</sup> This Bill would replace the Prevention and Treatment of Drug Dependency Act (Act 59 of 1992), and has the following objectives:

- to provide for a coordinated effort to combat substance abuse;
- to provide for the conditions for registration of all programmes, including those in treatment centres and halfway houses;
- to provide for the conditions and procedures for the admission of persons to treatment centres and the release of persons from treatment centres;

- to provide for early intervention, treatment and reintegration programmes for vulnerable persons; and
- to establish a Central Drug Authority, whose powers and duties are to monitor and oversee the implementation of the National Drug Master Plan.

## Jurisprudence

The judgment that perhaps had the most important impact on the legislative programme in 2007/08 was probably that delivered by the Constitutional Court in the case of *Doctors for Life International v Speaker of the National Assembly and Others* (CCT12/05).<sup>75</sup> The court held (with two dissenting voices) that the National Council of Provinces had failed to hold public hearings in relation to the Traditional Health Practitioners Act and the Choice on Termination of Pregnancy Amendment Act, and that this was unreasonable. Both Acts were thus found to be invalid, but Parliament was given a period of 18 months to enact these statutes afresh, in accordance with the provisions of the Constitution. Both Acts were thus returned to Parliament, and taken through the full process, including fresh public hearings. As a consequence, Parliament also became demonstrably responsive to accusations that sufficient opportunity for input had not been provided, delaying the consideration of the Tobacco Products Control Amendment Bill in order to provide for more hearings in May 2008.

Three other court cases are dealt with in more detail below. One is of relevance to medicines policy, the other of direct import for the move towards National Health Insurance. Mention is also made of the continued and potential litigation around the question of medicine prices.

### Treatment Action Campaign / South African Medical Association v Rath and others

The central role of medicines legislation was again emphasised by the court action launched by the TAC and SAMA in November 2005. The TAC and SAMA sought an interdict from the Cape High Court preventing Dr Matthias Rath and his colleagues, structures and supporters (the Dr Rath Health Foundation Africa, Professor Sam Mhlomo, Dr David Rasnick, Dr Alexandra Niewiecki, Advocate Anthony Brink, and the Treatment Information Group) from distributing unregistered medicines being provided via the South African National Civics Organisation and clinics in Cape Town and from conducting unapproved clinical trials in these settings. They also sought to ensure that the government (initially represented by the Director-General, DoH, the Chairperson of the Medicines Control Council

(MCC), the Registrar of Medicines and the MEC for Health, Western Cape) took the necessary steps to apply the Medicines and Related Substances Act in this respect.<sup>76</sup>

The case was finally decided on 14 June 2008 (one respondent being deceased and two others settling out of court), with Judge Zondi ruling that:

- the studies being conducted by the Rath respondents were unlawful and should cease;
- the respondents also cease making claims about the efficacy and safety of the sole product they still distributed in relation to its use in AIDS, “*pending the submission by the aforementioned respondents of the VitaCell to the MCC to review its medicinal claims*”; and
- the government respondents (now the Minister of Health and Director-General) take reasonable measures to stop the actions above and also to investigate the past actions of the Rath respondents and take such action as was required (in terms of the Medicines Act).<sup>77</sup>

In his judgment, Judge Zondi also criticised the wording of a contested ‘call-up’ notice for complementary medicines, issued by the MCC in 2002, referring to it as ‘inelegantly worded’ and appearing to be ‘self contradictory in terms’. However, he saw it fit to rule on the basis that the call-up was in effect, and that it applied to the product ‘sold’ by the Rath organisation. By 2006, the DoH had announced that 20 000 applications in terms of this notice had been received, and 14 000 of these had been ‘assessed’.<sup>78</sup> There remains considerable confusion in this space. On the one hand, claiming ‘complementary’ status would seem to offer the shelter provided by the ‘call-up notice’ (Government Notice No. 204, 22 February 2002), yet on the other, a ‘tonic’ containing multivitamins, minerals, amino acids and ginseng had been ruled in 2005 by the High Court to be subject to full registration by the MCC.<sup>79</sup> While the duties of the government were confirmed, the status of ‘complementary’ medicines remained unclear and the public remained potentially vulnerable.

### Guardrisk Insurance v Registrar of Medical Schemes and another

On 28 March 2008, the Supreme Court of Appeal ruled in the matter between Guardrisk Insurance Company and the Registrar of Medical Schemes and the CMS.<sup>80</sup> At issue was whether this short-term insurer, in offering the AdmedGap and Admed Pulse policies, was breaching the Medical Schemes Act, in that it was conducting the business of a medical scheme while not being registered to do so. This had initially been held to be the case by the Johannesburg High Court.



The Supreme Court of Appeal held that the three paragraphs of the Medical Schemes Act that defined the 'business of a medical scheme' should be read conjunctively, instead of disjunctively. At present, the definition reads as follows: *"'business of a medical scheme' means the business of undertaking liability in return for a premium or contribution:*

- a) to make provision for the obtaining of any relevant health service;*
- b) to grant assistance in defraying expenditure incurred in connection with the rendering of any relevant health service; and*
- c) where applicable, to render a relevant health service, either by the medical scheme itself, or by any supplier or group of suppliers of a relevant health service or by any person, in association with or in terms of an agreement with a medical scheme".<sup>80</sup>*

Read conjunctively, all three must be satisfied, and not any one. In other words, (a) and (b) and (c) must be offered, not (a) or (b) or (c). The disjunctive reading had, until this finding, always been applied in deciding whether a particular product (such as an insurance policy) met the definition.

The consequences of this far narrower reading of the Act were immediately apparent. Risk-rated insurance products, deemed not to offend the Medical Schemes Act, would be launched, to appeal to a younger and healthier demographic. This had the potential to seriously undermine the protection for community-rated medical schemes intended by the legislation. When application to appeal to the Constitutional Court was denied, it was apparent that legislative change would be needed. It must be noted, however, that the Supreme Court of Appeal was not convinced of the arguments regarding the potential consequences: *"Although the provisions of the Medical Schemes Act fundamentally changed the operation of medical schemes in that membership of a medical scheme and, through that, access to core health and medical services were made accessible to a broader spectrum of people, as discriminatory considerations based on age, sex and health status are no longer permissible and differentiation between members may only occur on the basis of income and number of dependants, there is no factual indication before us that the policies of the appellant are undermining or would undermine the Medical Schemes Act, or would in any way affect the viability of medical schemes in general"* (para 21).<sup>80</sup> Instead, they held that *"Practical reality has shown that there exists a need for this type of insurance and there seems to be no reason why it should not be permitted"* (para 22).<sup>80</sup>

The Senior Specialist: Strategy of the CMS has published an extensive overview of the legislative history of the definition on the Council's web site.<sup>81</sup> He concludes that: *"The historical context of the legislation suggests that:*

- paragraph (a) was originally intended to refer to entities of the nature of the old 'medical benefit schemes';*
- paragraph (b) was originally intended to refer to entities of the nature of the old 'medical aid schemes' – which are essentially the same as medical schemes in existence today; and*
- paragraph (c) while originally intended (through the 1993 amendment) to refer to HMO-type entities, since 1998 was intended to also refer to a broader range of managed care-type arrangements which by today have been entered into in one form or another by the majority of medical schemes".<sup>81</sup>*

He conceded that *"the drafting of this definition in the 1998 Act was imperfect".<sup>81</sup>* The Medical Schemes Amendment Bill (Bill 58 of 2008) is intended to correct this imperfection.

## Medicine pricing regulations

Previous chapters in the South African Health Review have dealt with the court actions over the medicines pricing regulations.<sup>82-84</sup> Despite apparent progress being made towards an out-of-court settlement between the NDoH and the Pharmaceutical Society of South Africa, a court date was set. Negotiations have continued, and indications are that agreement has been reached and that this could be made the subject of a court order. The possibility of renewed litigation was raised by dispensing practitioners, who remain bound by the initial dispensing fee (in their case, 16% capped at a maximum of R16 per item).<sup>85</sup> Although annual increases in the single exit price have been gazetted in 2007 and 2008, other aspects of this intervention remain inoperative, including the international benchmarking and the dispensing fee.

## Policy

Public participation in health policy processes remains limited to the legislative components. Although no overarching policy documents have been issued by the Ministry or the DoH in recent years (in essence, since the 1997 White Paper of the Transformation of the Health System in South Africa), some far-reaching technical policy documents have been issued in 2007/08, including:

- Policy and Guidelines for the Implementation of the PMTCT Programme, 2008.<sup>a</sup>

a Available at: <http://www.doh.gov.za/docs/policy/pmtct.pdf>

- Infant and Young Child Feeding Policy, 2008.<sup>b</sup>
- A Policy on Quality in Health Care for South Africa, 2007.<sup>c</sup>
- HIV & AIDS and STI Strategic Plan for South Africa, 2007-2011.<sup>d</sup>
- Draft Tuberculosis Strategic Plan for South Africa, 2007-2011.<sup>e</sup>
- The National Infection Prevention and Control Policy & Strategy, 2007.<sup>f</sup>
- The National Infection Prevention and Control Policy for TB, MDRTB and XDRTB, 2007.<sup>g</sup>

Recent guidelines issued by the NDoH have included:

- Guidelines for the Management, Prevention and Control of Meningococcal Disease in South Africa, 2008.<sup>h</sup>
- Regular Treatment of School-Going Children for Soil-Transmitted Helminth Infections and Bilharzia, 2008.<sup>i</sup>
- Guideline for Leprosy Control in South Africa, 2008.<sup>j</sup>
- Guidelines for the Treatment of Malaria in South Africa, 2007.<sup>k</sup>

## Conclusion and Recommendations

The 2008 legislative programme in the field of health has proven to be no less controversial than in previous years. To some extent, this reflects the strong vested interests that exist within the health arena. Large corporates have the ability to access legal advice and to use the courts where they feel that their interests are affected by legislative interventions. Equally, civil society actors have continued to show their ability to use court action to intervene in a variety of settings. However, the strong sense that much legislation is hastily drafted, and hence subject to technical criticism and attack, cannot be avoided. The absence of detailed policy documents, perhaps even a revamped White Paper on Health, make critical assessment of the new legislative instruments difficult. Even when passed by Parliament,

and assented to by the President, some enabling provisions (like the Certificate of Need) remain unimplemented for a considerable time. Others (like the medicine pricing provisions) remain captive to court actions for years. Ensuring meaningful public participation in all forms of legislative and policy processes remains a challenge.

The following recommendations can therefore be offered.

- That a fundamental revision of the White Paper on Health be considered, not least in view of the policy prescriptions outlined at Polokwane, and in particular with reference to the way forward in regard to National Health Insurance.
- That this process be as inclusive as possible, using the Green Paper route, and involve extensive opportunities for public comment on early drafts and for meaningful public engagement via Parliamentary structures.
- That the timelines and processes for the development of draft legislation and its subsequent handling by Parliament be reconsidered, so that meaningful public participation can occur and the quality of subsequent legislation (and its probability of successful and smooth implementation) be improved.

The General Election, combined with the constitutionally-mandated change of President, promise to make 2009 a milestone year in the history of South Africa. The opportunity exists to outline in far greater detail, how the health system will evolve into the future, and in particular how health care will be funded and provided in order to give impetus to the progressive realisation of the rights provided for in section 27 of the Constitution.<sup>86</sup>

b Available at: <http://www.doh.gov.za/docs/policy/infantfeed.pdf>

c Available at: <http://www.doh.gov.za/docs/policy/ipc/qhc-policy.pdf>

d Available at: <http://www.info.gov.za/otherdocs/2007/aidsplan2007/index.html>

e Available at: <http://www.doh.gov.za/tb/docs/stratplan/2007-2011/tb/index.html>

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h Available at: <http://www.doh.gov.za/docs/factsheets/guidelines/meningococcal.pdf>

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