

ABSTRACT

In accordance with the State's duty to realise the right of access to health care services, it has adopted a wide range of legislative and other measures. Though the pace at which these measures have been adopted has been challenged and criticised by some, there is no doubt that the range of legislative measures presently in place, if properly implemented, are likely to go a long way in ensuring access to health care services, in developing a rights framework in respect thereof and ultimately in holding institutions and individuals accountable for the delivery of efficient and quality health care services for all South Africans.

This chapter discusses some of the key legislative developments over the past year, provides an overview of current pending legislation and discusses some of the key court challenges and legal debates relating to health legislation and policy in the South African context.

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INTRODUCTION

The National Department of Health's Strategic Plan 2006/7 to 2008/9¹ lists the legislation that is considered to be specifically within the Minister of Health's portfolio. The Acts mentioned are shown in Table 1. Those that are still to be repealed as the National Health Act is brought into effect are listed. Acts that deal with specific areas of policy or practice or which create statutory and other bodies are listed in date order. Only the principal Acts are listed. Many of these Acts have been the subject of Amendment Acts over the years. In some cases, the names of Acts have been changed by such amendments.

TABLE 1:
Acts within the Minister of Health's portfolio

Fundamental Act(s)	Specific policy areas	Statutory bodies
National Health Act (Act 61 of 2003)	Medicines and Related Substances Act (Act 101 of 1965)	Pharmacy Act (Act 53 of 1974)
Acts to be repealed by the National Health Act ♦ National Policy for Health Act (Act 116 of 1990) ♦ Health Act (Act 63 of 1977) ♦ Academic Health Centres Act (Act 86 of 1993) ♦ Human Tissue Act (Act 65 of 1983)	Foodstuffs, Cosmetics and Disinfectants Act (Act 54 of 1972)	Health Professions Act (Act 56 of 1974)
	Hazardous Substances Act (Act 15 of 1973)	Nursing Act (Act 50 of 1978)
	Occupational Diseases in Mines and Works Act (Act 78 of 1973)	Dental Technicians Act (Act 19 of 1979)
	International Health Regulations Act (Act 28 of 1974)	Allied Health Professions Act (Act 63 of 1982)
	Tobacco Products Control Act (Act 83 of 1993)	South African Medical Research Council Act (Act 58 of 1991)
	Choice on Termination of Pregnancy Act (Act 92 of 1996)	Medical Schemes Act (Act 131 of 1998) Council for Medical Schemes Levy Act (Act 58 of 2000)
	Sterilisation Act (Act 44 of 1998)	National Health Laboratory Service Act (Act 37 of 2000)
	Mental Health Care Act (Act 17 of 2002)	Traditional Health Practitioners Act (Act 25 of 2004)

Source: DoH, 2006.^{1,a}

In addition, as with all aspects of government, the Constitution² provides the guiding framework. More than a decade has now elapsed since the constitutional recognition of the right of access to health care services. The last few years have witnessed the adoption of key pieces of post-apartheid legislation aimed at giving effect to this important constitutional right. This chapter covers the developing legislative framework at national level aimed at giving effect to the right as well as the challenges to its implementation, as have

a Acts passed since 1994 are accessible from <http://www.info.gov.za/documents/acts/index.htm>



been borne out by recent jurisprudence on the subject. A large number of Regulations and rules relating to health have been issued in the last year. These are beyond the scope of this chapter, but remain crucial elements of a transforming body of law. However, certain Regulations have been delayed for considerable periods of time. Notably, draft Regulations published in terms of the Medicines Act in mid-2004 have yet to be finalised.³

THE CONSTITUTIONAL FRAMEWORK

Section 27 of the Constitution reads as follows:

“Health care, food, water and social security

- (1) Everyone has the right to have access to
 - (a) health care services, including reproductive health care;
 - (b) sufficient food and water; and
 - (c) social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.
- (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
- (3) No one may be refused emergency medical treatment.”

The framework within which the right is protected has been discussed in detail in the South African Health Review (SAHR) 2003/2004⁴ and will accordingly not be repeated in this chapter. We do, however, examine the standard of ‘reasonableness’ against which legislation, policy, budgets and programmes within the health sector fall to be assessed, and the related concept of the ‘progressive realisation’ of rights.

The Constitutional Court, in *Government of the Republic of South Africa and Others v Grootboom and Others*,⁵ established certain guidelines in respect of the State’s constitutional duty to take “reasonable legislative and other measures” to realise a range of socio-economic rights. In the first instance, the Court observed that a duty to take reasonable legislative and other measures imposes positive obligations on the State and requires the State to devise a comprehensive and workable plan to meet its obligations under the subsection.

The Court noted that in assessing whether the State has complied with its positive obligations, the ultimate question will be whether the measures taken by the State are “reasonable”. It formulated the test for establishing reasonableness as follows:

“A court considering reasonableness will not enquire whether other more desirable or favourable measures could have been adopted, or whether public money could have been better spent. The question would be whether the measures that have been adopted are reasonable. It is necessary to recognize that a wide range of possible measures could be adopted by the State to meet its obligations. Many of these would meet the requirement of reasonableness. Once it is shown that measures do so, this requirement is met.”
(para 41)

The Court further observed that mere legislation is not enough for the State to satisfy its obligations. Legislation, according to the Court, has to be supported by well-directed policies and programmes, which must be reasonable both in their conception and implementation, in order to ensure compliance with State obligations (para 42). The Court’s reference to “reasonable implementation” is a particularly positive aspect of the judgment as is its specific reference to the requirements for effective implementation. The Court observed that effective implementation requires at least adequate budgetary support by national government and that it requires that it “plan, budget and monitor the fulfilment of immediate needs and the management of crises”. The Court interpreted the result of a programme that is “effectively implemented” to be that a “significant number” of desperate people in need are afforded relief, “though not all of them need receive it immediately” (para 68).

Although the Court acknowledged that the capacity of institutions responsible for implementing a given programme is relevant to the consideration of reasonableness, it significantly recognised that a reasonable programme must clearly allocate responsibilities and tasks to the different spheres of Government and ensure that the appropriate financial and human resources are available (para 39). The Court nevertheless observed that the availability of resources is an important factor in determining what is reasonable

(para 46). It did, however, state that a reasonable part of the national budget must be devoted to realising the right in question, and the precise allocation is for national government to decide in the first instance (para 66).

Significantly, the Court also analysed the substantive aspects of the reasonableness test in *Grootboom*.⁵ In particular, it acknowledged that reasonable measures required special regard for certain vulnerable groups. It pointed out that if the measures, though statistically successful, fail to respond to the needs of those most desperate, they may not pass the test (para 44). It went on to state that a programme that excludes a significant segment of society cannot be said to be reasonable (para 43).

The Court also recognised the importance of the realisation of socio-economic rights to the advancement of race and gender equality and the evolution of a society in which men and women are equally able to achieve their full potential (para 23).

The landmark case that tested these concepts in relation to health care services in particular was *Minister of Health and Others v Treatment Action Campaign and Others (No 2)*, in which the Court evaluated the constitutionality of government's policy decision not to make antiretrovirals for the prevention of mother-to-child transmission generally available to all women attending public health establishments.⁶

The following key points can be distilled from the above:

- ◆ The ultimate test against which legislative and other measures are to be assessed is that of reasonableness.
- ◆ Legislation, policies and programmes must be reasonable both in their conception and implementation.
- ◆ Reasonable measures require special regard for certain vulnerable groups.
- ◆ A failure to respond to the needs of those most desperate may not pass the test.
- ◆ The needs of women and children fall within the purview of vulnerable groups.

Developments in the last year are assessed with this framework in mind.

NATIONAL LEGISLATION

In her briefing to the National Assembly Portfolio Committee in March 2005, the Minister laid out an extensive legislative programme for the 2005 sessions. While some of those Bills have yet to be tabled, progress has been made with others. Each proposed Bill and the progress made to date are listed in Table 2. Those that have been passed or tabled are then dealt with in more detail. First, progress with the implementation of legislation already passed is tracked.

TABLE 2:
Minister's briefing to the Portfolio Committee, 8 March 2005 – progress to date^b

Identity of Bill / Act	Status as at September 2006
Nursing Bill	Bill 26D of 2005 passed by Parliament (dealt with as a section 76 Bill); assented to by the President in May 2006 and designated as Act 33 of 2005; not yet promulgated
Health Professions Amendment Bill	Tabled April 2006 (Bill 10 of 2006) as a section 75 Bill; hearings held by the National Assembly Portfolio Committee on Health and amended Bill accepted
Tobacco Products Control Amendment Bill	Tabled September 2006 (Bill 24 of 2006) as a section 75 Bill
Medical Research Council Amendment Bill	Not yet tabled or published in draft form
Medicines and Related Substances Amendment Bill	Not yet tabled or published in draft form
Pharmacy Amendment Bill	Not yet tabled or published in draft form
Allied Health Professions Amendment Bill	Not yet tabled or published in draft form
Foodstuffs, Cosmetics and Disinfectants Amendment Bill	Tabled in October 2005 (Bill 35 of 2005) as a section 76 Bill; currently before the National Council of Provinces
South African Red Cross Society and Legal Protection of Certain Emblems Bill	Tabled September 2006 (Bill 25 of 2006) as a section 75 Bill
Risk Equalisation Fund Bill	Not yet tabled or published in draft form

Other legislation of relevance to health has included the 2010 FIFA World Cup South Africa Special Measures Bill (Bill 13 of 2006).

^b Details of the legislative process can be accessed at <http://www.pmg.org.za/parlinfo/sectionb3.htm>



THE NATIONAL HEALTH ACT (ACT 61 OF 2003)⁷

The SAHR 2005 reported in depth, on the content of the National Health Act, noting that some sections, but not all, had been brought into effect: “While this move is significant, the impression has been created that some real challenges still lie ahead and that much still needs to be clarified. Draft Regulations, covering the necessary detail that would allow those sections as yet not promulgated to come into effect, were reported to be almost ready to be published for public comment”.⁸

The direct link with the constitutional requirements described above can be seen in section 3 of the Act, which requires that “the national department, every provincial department and every municipality” must establish such health services as are required in terms of the Act, and that “all health establishments and health care providers in the public sector” must equitably provide health services within the limits of available resources. It has been noted that a fairly controversial provision in Chapter 6 of the Act is that provided for by section 36, which provides for certificates of need. In terms thereof, a person may not establish or operate a health establishment or health agency or provide prescribed health services without being in possession of a certificate of need. The objective of this provision is clearly to ensure the equitable and fair distribution of and access to health care services within the country. In terms of section 39, the Minister is obliged (after consultation with the National Health Council) to make Regulations in respect of a number of key aspects pertaining to certificates of need, including the requirements for issue or renewal thereof. It is thus unfortunate that more than a year since the adoption of the National Health Act has now elapsed and the provisions of Chapter 6, which are vital to the development of an equitable health system, have still not come into operation.

Where subordinate legislation is required (such as Regulations), the implementation of the National Health Act has been slow. No Regulations have been adopted as yet under the National Health Act, nor have any been published either in draft form or for public comment. This is an area that falls to be carefully monitored by individuals and groups working in the sector, as such Regulations must, in terms of the National Health

Act, be published for comment at least three months before their contemplated date of commencement. Accordingly, the adoption of Regulations presents an important opportunity for public participation aimed at informing the content of such Regulations.

Where Regulations appear to be contemplated but are not in place, the authorities have, however, indicated a willingness to use such sections as are already in effect. This was apparent during the debate surrounding the management of a patient with extremely drug resistant tuberculosis (XDR-TB), who had discharged herself from a Gauteng hospital. The provincial health authorities indicated that section 7 of the National Health Act would have been invoked, if necessary. Sections 7 to 9 of the National Health Act, which are already in effect, provide for such treatment without consent. The wording of section 9(1) would seem to signal the intention to develop Regulations regarding the details of information to be provided. Such Regulations are not in place, nor have these provisions been tested in law.

Inaugural meetings of some structures contemplated in the Act (such as the National Consultative Health Forum^c) have been held, but other important structural elements remain slow to come to fruition (such as the Office of Standards Compliance and the requisite Inspectorates). As can be seen, this is also a feature of other legislation, notably the Mental Health Care Act.

MENTAL HEALTH CARE ACT (ACT 17 OF 2002)⁹

The Mental Health Care Act was assented to on 28 October 2002 and came into operation on 15 December 2004. Regulations were first published (under GN R1467 in GG 27117) on 15 December 2004 and subsequently corrected by Regulations published on 11 February 2005 (GN R98 in GG 27236). Chapter 4 provides for the establishment of Mental Health Review Boards. The Member of the Executive Council (MEC) responsible for health services in a province must, after consultation with the head of the provincial department concerned, establish a Review Board in respect of every health establishment providing mental health care, treatment and rehabilitation services in

^c Details of this meeting are accessible at <http://www.doh.gov.za/docs/misc/nhcf.html>

that province. A degree of flexibility is provided for as the Review Board may be established for a single, a cluster or all health establishments providing mental health care services in that province. The powers and functions of the Review Board include, amongst a wide range, considering appeals against decisions of the head of a health establishment; making decisions with regard to assisted or involuntary mental health care; treatment and rehabilitation services and considering reviews and making decisions on assisted or involuntary mental health care users. It is therefore of concern to note that the Strategic Plan of the Department of Health 2006/7 to 2008/9 reported that the implementation of Mental Health Review Boards had been particularly slow, as some provinces had been unable to muster the resources required.¹

THE NURSING ACT (ACT 33 OF 2005)¹⁰

The Nursing Act, unlike other Acts dealing with statutory health councils, does not amend the Nursing Act (Act 50 of 1978), but will, once brought into effect, replace that Act in its entirety. The Act was assented to by the President in May 2006, but has as yet not been promulgated. No draft Regulations have yet been published for comment.

Two aspects of the Act generated much debate during the process of parliamentary hearings. The first related to the manner in which the Nursing Council was to be appointed. In the past, members of the Nursing Council, like those of other statutory health councils, have been either elected by nurses or appointed by the Minister of Health. Citing the costs involved, the low voter turnout in the previous elections, and the challenge of transforming a council when the membership of the profession was as yet not reflective of the demographics of the country, the drafters of the Nursing Act replaced this with a nomination and appointment system:

“COMPOSITION AND DISSOLUTION OF COUNCIL

5. (1) (a) The Council consists of not more than 25 members, of whom 14 must be registered in terms of section 31(l)(a) and (b), appointed by the Minister taking into account their expertise in nursing education, nursing, community health, primary health care, occupational health and mental health.

- (b) Of the 25 members –
 - (i) one person must be an officer of the national department;
 - (ii) one person must have special knowledge of the law;
 - (iii) one person must have special knowledge of financial matters;
 - (iv) one person must have special knowledge of pharmacy;
 - (v) one person must have special knowledge of education;
 - (vi) one person must have knowledge of consumer affairs;
 - (vii) three persons must represent communities;
 - (viii) one person must be registered in terms of section 31(l)(c); and
 - (ix) one person must be registered in terms of section 31(l)(d).

(2) (a) The members must be appointed by the Minister on the basis of nominations made by interested parties, after publication of a notice in the Gazette inviting nominations for new members.

(b) If the Minister receives no nomination or an insufficient number of nominations within the period specified in the invitation, the Minister may appoint the required number of persons who qualify to be appointed in terms of subsection (1).”

While it easy to see how the interests of various categories of nurses, such as professional nurse (registered in terms of section 31(1)(a)), midwives (section 31(1)(b)), staff nurses (section 31(1)(c)) and auxiliary nurses (section 31(1)(d)), were to be balanced, the exact process whereby “interested parties” could make nominations is not obvious. Considerable power was vested in the Minister, not only to make a choice between nominated members, but also to dissolve the Council and to exercise the powers of the Council. Section 5(7)(b) holds that “All the functions of the Council are vested in the Minister until a new Council is appointed”.



Chapter 2 of the Act regulates education, training, research and practice within the nursing profession. Chapter 3 regulates the powers of the Council with regard to unprofessional conduct. The Council is given the power to conduct an inquiry into charges of unprofessional conduct and may institute an inquiry into any complaint, charge or allegation of unprofessional conduct. Significantly, in the absence of a complaint, charge or allegation, the Council may institute an inquiry into any alleged unprofessional conduct that comes to its notice – in other words the Council may undertake an inquiry in the absence of a formal complaint or charge. If the Council doubts whether an inquiry should be held in connection with a complaint, charge or allegation, it may consult with or seek information from any person, including the person against whom the complaint, charge or allegation has been lodged, to determine whether an inquiry should be held. The Act also regulates the procedure to be adopted by the Council in respect of the inquiry.

The second section of the Act that elicited considerable input related to the prescribing and dispensing privileges afforded to professional nurses, midwives and staff nurses. Instead of replacing section 38A of the existing Act with a reference to the provisions outlined in the Medicines and Related Substances Act (Act 101 of 1965), the drafters chose to retain both provisions:

“SPECIAL PROVISIONS RELATING TO CERTAIN NURSES

56. (1) Despite the provisions of this Act or any other law, the Council may register a person who is registered in terms of section 31(l)(a), (b) or (c) to assess, diagnose, prescribe treatment, keep and supply medication for prescribed illnesses and health-related conditions, if such person –
- (a) provides proof of completion of prescribed qualification and training;
 - (b) pays the prescribed registration fee; and
 - (c) complies with subsection 6.
- (2) The Council must issue a registration certificate to a person who complies with the requirements referred to in subsection (1).
- (3) The registration certificate referred to in subsection (2) is valid for a period of three years.
 - (4) The Council may renew a registration certificate referred to in subsection (2) subject to such conditions as the Council may determine.
 - (5) A person registered in terms of subsection (1) may
 - (a) acquire, use, possess or supply medicine subject to the provisions of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965); and
 - (b) dispense medicines subject to the provisions of the Medicines and Related Substances Act, 1965.
 - (6) Despite the provisions of this Act, the said Medicines and Related Substances Act, 1965, the Pharmacy Act, 1974 (Act No. 53 of 1974), and the Health Professions Act, 1974 (Act No. 56 of 1974), a nurse who is in the service of –
 - (a) the national department;
 - (b) a provincial department of health;
 - (c) a municipality; or
 - (d) an organisation performing any health service designated by the Director-General after consultation with the South African Pharmacy Council referred to in section 2 of the Pharmacy Act, 1974, and who has been authorised by the Director-General, the head of such provincial department of health, the medical officer of health of such municipality or the medical practitioner in charge of such organisation, as the case may be, may in the course of such service perform with reference to –
 - (i) the physical examination of any person;
 - (ii) the diagnosing of any physical defect, illness or deficiency in any person; or
 - (iii) the keeping of prescribed medicines and their supply, administering or prescribing on the prescribed conditions; any act which the said

Director-General, head of provincial department of health, medical officer of health or medical practitioner, as the case may be, may, after consultation with the Council, determine in general or in a particular case or in cases of a particular nature, if the services of a medical practitioner or pharmacist, as the circumstances may require, are not available.

- (7) A person contemplated in subsection (1) is not entitled to keep an open shop or pharmacy
- (8) For the purpose of subsection (7) “open shop” means a situation where the supply of medicines and scheduled substances to the public is not done by prescription by a person authorised within the scope of practice concerned to prescribe medicine.”

Quite how the apparent conflict between the sentiments of section 56(5) and 56(6) will be resolved is not clear. Confusing signals have also been sent to provincial departments of health, which have variously been told to ensure that all nurses who dispense complete the supplementary training contemplated in the Medicines Act and apply for a dispensing licence, or to continue to use section 38A of the existing Nursing Act until the new Act comes into effect.

HEALTH PROFESSIONS AMENDMENT BILL (BILL 10 OF 2006)¹¹

Although the principal Acts of other statutory health councils had been identified for amendment, the first of these to be tabled was the Health Professions Amendment Bill, in April 2006.

As with the Nursing Act, the major debate in relation to this Bill during the public participation process revolved around the abolition of direct election by those registered in terms of the Act of members of the professional boards. The Bill proposed to replace election of the majority of the members of each board with appointment, after a process of nomination to the Minister:

“13. Section 15 of the principal Act is hereby amended:

- (c) by the substitution in subsection (5) for paragraph (a) of the following paragraph:

“(a) the [**majority**] appointment of the members of a professional board [**to be elected**] by the Minister on the basis of nominations made by the members of the health profession or professions involved;”

The words in bold in square brackets would be deleted, to be replaced by the underlined text.

Another controversial change involved replacing the word “in” with the word “after” in relation to the consultation process required before the Minister makes Regulations relating to unprofessional conduct:

“52. Section 61 of the principal Act is hereby amended –

- (a) by the substitution in subsection (1) for the words preceding paragraph (a) of the following words:

“The Minister may, [**in**] after consultation with the council, make Regulations relating to –”

The original wording had been the subject of considerable debate in 1997, when the last substantive amendments to the Acts creating the various statutory health councils were passed. At the time it was felt that the Minister should not be held hostage by a council, for example by a wording to the effect that Regulations could only be made “on the recommendation” of the council. Equally, it was held that “after consultation” implied that the council had little role to play, whereas “in consultation” denoted a cooperative process. The amendment proposed to this Act would mirror that accepted in the new Nursing Act (Act 33 of 2005). Despite opposition, it survived the first hurdle posed by the Portfolio Committee and its hearings. It is thus anticipated that similar provisions will be enacted in relation to the elections and regulation-making processes provided for in the Pharmacy Act, the Allied Health Professions Act, and the Dental Technicians Act. It remains to be seen whether similar attempts in relation to the legal profession will survive challenges that these constitute an unacceptable diminution of the independence of the profession, and thus, potentially, of the judiciary. Also controversial was the inclusion in the grounds for disqualification from membership



of the Council of anyone who was or who became “a provincial or national office bearer or employee of any party, organization or body of a political nature”. Other grounds for dismissal added were acting “in a manner that will prejudice the interests of the council” and being “an office bearer of an organisation that has a conflict of interest with the council”.

As with in the Nursing Act, this Amendment Bill empowers the Minister to dissolve the Council under certain circumstances. It also clearly establishes a hierarchy of policy, as explained in the Memorandum:

“The Bill aims to –

- (a) make clear and more comprehensive the objects and functions of the council in order to ensure that the objectives are achieved and are in line with the national health policy determined by the Minister”.

The Bill also addresses a number of technical issues that have arisen, such as the need to exempt certain persons from community service. At least one issue identified in the Memorandum seems to have been omitted from the Act – the promised provision that would “accentuate the provisions of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) in so far as this Act regulates the compounding and dispensing of medicines and the prohibition of keeping an open shop or pharmacy”.

FOODSTUFFS, COSMETICS AND DISINFECTANTS AMENDMENT BILL (BILL 35 OF 2005)¹²

The Foodstuffs, Cosmetics and Disinfectants Amendment Bill was tabled in late 2005 and is currently before the National Council of Provinces. As explained in the Memorandum to the Bill, it aims to authorize medical practitioners, environmental health practitioners and veterinarians to administer certain provisions of the Act, as opposed to only health inspectors employed by local authorities. While many of the provisions of the Bill are of a purely technical nature, two definitions have been corrected that have wider relevance. These are now to read as follows:

- ◆ ‘cosmetic’ means any article, preparation or substance (except a medicine as defined in the Medicines and Related Substances Act, 1965 (Act

No. 101 of 1965) intended to be rubbed, poured, sprinkled or sprayed on or otherwise applied to the human body, including the epidermis, hair, teeth, mucous membranes of the oral cavity, lips and external genital organs, for purposes of cleansing, perfuming, correcting body odours, conditioning, beautifying, protecting, promoting attractiveness or improving or altering the appearance, and includes any part or ingredient of any such article or substance.

- ◆ ‘foodstuff’ means any article or substance (except a medicine as defined in the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) ordinarily eaten or drunk by a person or purporting to be suitable, or manufactured or sold, for human consumption, and includes any part or ingredient of any such article or substance, or any substance used or intended or destined to be used as a part or ingredient of any such article or substance

The import of these definitions is that any substance that fits the definition of a medicine, as stated in the Medicines Act, cannot be claimed to be either a cosmetic or a foodstuff. Products that exist at the boundaries of these definitions, such as ‘cosmeceuticals’ and ‘nutriceuticals’ should thus be regulated as medicines, if they fit the definition of a medicine. In terms of the Medicines Act, a ‘medicine’ means “any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in:

- ◆ the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or
- ◆ restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine”.¹³

TOBACCO PRODUCTS CONTROL AMENDMENT BILL (BILL 24 OF 2006)¹⁴

The latest in a series of Tobacco Bills was tabled in September 2006, and has elicited strong reactions from a wide range of stakeholders. The stated intent of the Bill is to “amend the Tobacco Products Control Act, 1993 (Act No. 83 of 1993) ... to bring it in line with the World Health Organization(WHO) Framework Conventions on Tobacco Control, to which South

Africa is a signatory”. The Memorandum also states that the Bill “intends to close loopholes that exist in the current legislation. These loopholes are exploited by the tobacco industry and make prosecutions for contraventions of the Act very difficult”.

The most fundamental change is probably in the definition of a ‘tobacco product’, which will now read as follows: “‘tobacco product’ means a product containing tobacco that is intended for human consumption, and includes, but is not limited to, any device, pipe, water pipe, papers, tubes, filters, portion pouches or similar objects manufactured for use in the consumption of tobacco”. The previous definition included only products “manufactured from tobacco and intended for use by smoking, inhalation, chewing, sniffing or sucking”. Other definitions altered are those for ‘organised activity’, ‘public place’ and ‘workplace’. New definitions are introduced for ‘brand element’, ‘composition’, ‘emission’, ‘ingredient’, ‘manufacturer’ and ‘public conveyance’.

The prohibition on smoking in a public place has been widened to include “any area within a prescribed distance from a window of, ventilation inlet of, doorway to or entrance into a public place”. In addition, smoking may be prohibited by the Minister in “any prescribed outdoor public place, or such portion of an outdoor public place ... where persons are likely to congregate within close proximity of one another or where smoking may pose a fire or other hazard”.

Much media attention has focused on the considerable increases in the maximum fines that may be levied for contraventions of the Act. Fines of up to R1 million are to be provided for by the Amendment Bill. Failure to comply with requirements to display the prescribed signs in a public space may attract a fine not exceeding R50 000, where before this was limited to R200.

SOUTH AFRICAN RED CROSS SOCIETY AND LEGAL PROTECTION OF CERTAIN EMBLEMS BILL (BILL 25 OF 2006)¹⁵

Also tabled in early September 2006, this Bill provides for statutory recognition of the South African Red Cross Society and its emblems (the red cross and the red crescent, but not, as yet, the red crystal). The Bill generally prohibits the use of these symbols by anyone

“not connected with the International Red Cross and Red Crescent Movement or any body forming part of that movement”, but allows for certain exceptions. For example, the Minister of Defence may allow use of such an emblem by the National Defence Force. The Minister’s briefing in March 2005 indicated that the Bill would “ensure there is no duplication of services around rescue and disaster management”. Two provisions in the Bill would seem to address this issue. The Bill provides that “if so requested, the Society may place its medical personnel and resources at the disposal of the State”. Regulations are contemplated which will prescribe how civilian persons are authorised to employ an emblem during a time of armed conflict or during times of peace. Such Regulations may not be in conflict with the Act or International Conventions (Geneva Convention for the Amelioration of the Condition of the Wounded and Sick in Armed Forces in the Field; Geneva Convention for the Amelioration of the Condition of Wounded, Sick and Shipwrecked Members of Armed Forces at Sea; Geneva Convention relative to the Treatment of Prisoners of War; Geneva Convention relative to the Protection of Civilian Persons in Time of War).

JURISPRUDENCE

Two challenges highlighted in the SAHR 2005 have been brought to some degree of finality in the past year. These are the challenges to the medicine pricing Regulations issued in terms of the Medicines and Related Substances Act and to the Choice on Termination of Pregnancy Act. A third issue, with direct relevance to the reasonableness of actions taken by a government department, has unfolded in relation to prisoners’ access to antiretroviral treatment.

MINISTER OF HEALTH AND ANOTHER V NEW CLICKS SOUTH AFRICA (PTY) LTD AND OTHERS¹⁶

The Medicines and Related Substances Act (“the Medicines Act”) was first enacted in 1965. It has been amended on no less than 15 different occasions since then. From 1965 until 1997 the main focus of the Medicines Act was ensuring the efficacy, safety and quality of medicines. In 1997 measures were introduced



into the legislation directed towards making medicines more affordable, in accordance with the State's constitutional obligation to provide everyone with access to health care services. The newly introduced measures made provision for controls to be introduced in respect of the production, importation, distribution and sales of medicines, the relaxation of certain patent restrictions, the promotion where possible of generic substitution of medicines, and the establishment of a Pricing Committee to make recommendations for the introduction of a pricing system for all medicines sold in the Republic.

The SAHR 2005 outlined the early stages of the court challenges to the pricing Regulations.⁸ Initially, two legal challenges to these Regulations were launched, and were heard simultaneously by a full bench of the Cape High Court in June 2004. In August 2004 the applications were dismissed, with one of the three judges dissenting. An appeal was then heard by the Supreme Court of Appeal on 30 November 2004. The Supreme Court of Appeal ruled in favour of the applicants, and declared the pricing Regulations invalid and of no force and effect on 20 December 2004. The Minister then appealed to the Constitutional Court. The judgment of the Constitutional Court was delivered on 30 September 2005. This judgment is extensive (running into some 250 pages) and will accordingly not be discussed at any great length. Two aspects are highlighted:

- ◆ The lawfulness of the pricing system provided for in the Regulations; and
- ◆ The “appropriateness” of the dispensing fee for pharmacists.

The lawfulness of the pricing system provided for in the Regulations

The Regulations provided for a pricing system for medicines and scheduled substances with the aim of making medicines more affordable. The system envisaged a “single exit price” (SEP) for the sale of each medicine that was sold by a manufacturer or importer. The SEP thus established became a fixed price at which the manufacturer or importer had to sell the product. However, the wholesalers and distributors were entitled to a logistics fee for their services (to be paid by the manufacturer or importer) and the pharmacists were entitled to an “appropriate” dispensing fee for their

services. The result was that medicines would become available to all consumers, other than the State, wherever they were, and whoever they might be, and from whatever source they were supplied, at the SEP and a transparent and easily understood dispensing fee. The pharmacies contended (amongst other contentions) that the Regulations introduced a system of price control that was not authorised by section 22G or any other provision of the Medicines Act and was therefore unlawful.

The Court unanimously held that section 22G of the Medicines Act not only permitted, but in fact required, price control measures to be made that affected all parties in the distribution chain, based on the wording of the relevant provisions of the Act and accordingly held that there was no substance in the submission that section 22G does not contemplate price control measures.

An ‘appropriate dispensing fee’ for pharmacists

Section 22G(2)(b) of the Medicines Act authorised the Minister, on the recommendation of the Pricing Committee, to make Regulations ‘on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C(1)(a) of the Medicines Act’. It was contended by the pharmacies that the dispensing fees thus prescribed were not “appropriate” and that these Regulations were accordingly invalid. The applicants (the Minister and the chairperson of the Pricing Committee) contended that Courts were ill-equipped to deal with economic matters and ought not to sit in judgment on what were essentially political decisions taken by the Executive in making Regulations.

The majority of the Court (six judges) held that a Court should not refrain from examining the lawfulness of the dispensing fee simply because the decision as to what it should be involved economic and political considerations. The Court further held that the purpose of section 22G of the Medicines Act, read in the context of the Medicines Act as a whole, was to enhance the accessibility and affordability of medicines. This was an obligation of the State, which, in terms of section 27 of the Constitution, was obliged to take reasonable measures to enhance access to health care. The Court further held that section 22G required the

measures taken to achieve this end to be ‘appropriate’. According to the Court, the cost of medicine was relevant to accessibility, but it was not the only factor. The medicine had to be available to those who required it. Pharmacies were an essential component of the distribution chain. If pharmacies went out of business, the Court noted, accessibility to medicines would be impaired. According to the Court, an appropriate fee was thus one which at least struck a balance between these requirements of cost and availability.

The Court reaffirmed that accountability, responsiveness and openness on the part of government were foundational values of the Constitution. An allegation had been made by professional organisations representing pharmacists that the dispensing fee would destroy the viability of pharmacies, and impair access to health care. That allegation was supported by a sufficient body of evidence to show that this was a real possibility. In the circumstances, the Court held that the applicants were under an obligation to explain how they had satisfied themselves that this would not be the result of the dispensing fee prescribed in the Regulations. The Court observed that despite being the only persons who could provide this information, they failed to do so. Absent such explanation, the Court concluded that there was sufficient evidence on record to show that the dispensing fee was not appropriate (para 404).

The aspects of the judgment highlighted above demonstrate three important issues in respect of the State’s attempt to ensure access to affordable medication:

- ◆ the Medicines Act requires the adoption of price control measures;
- ◆ notwithstanding the fact that such price control measures involved economic and policy issues, they are still subject to review by a Court in terms of whether they constitute “reasonable measures” in terms of the Constitution; and
- ◆ the State bears the obligation of demonstrating the appropriateness of a dispensing fee, and that notwithstanding, in this matter, it had failed to proffer any explanation in this regard. Accordingly, the Court concluded that the evidence on record was sufficient to show that the dispensing fee was not appropriate.

The consequence of this judgment has been that new Regulations have been published, making such changes as were mandated by the Court. In addition, opportunities for input on what would constitute a ‘reasonable’ dispensing fee were created and draft fees published for comment. The Minister is expected to publish the final Regulations outlining the dispensing fee in late September 2006. This process is, however, not yet complete, as the Minister has indicated a desire to cap the logistics fee. In addition, a process of international bench-marking of medicine prices is expected to be followed by the introduction of a reference pricing system. The SEPs have not been adjusted since 2004, when they were based on 2003 prices. A maximum allowable increase in the SEP is also expected to be announced, as will be done annually thereafter.

The entire medicine pricing system also rests on a prohibition on certain marketing practices. Section 18A of the Medicines and Related Substances Act¹³ states that “no person shall supply any medicine according to a bonus system, rebate system or any other incentive scheme”. Once the pricing system is in place, strict enforcement of this provision can be expected.

DOCTORS FOR LIFE INTERNATIONAL V SPEAKER OF THE NATIONAL ASSEMBLY AND OTHERS¹⁷

The SAHR 2005 covered the challenge mounted by the Christian Lawyers Association to the Choice on Termination of Pregnancy Act.⁸ In what could be seen as another attempt to secure the same outcome, Doctors for Life International (DFL) applied directly to the Constitutional Court in order to challenge the constitutional validity of a number of health-related Bills. The Bills involved were the Sterilisation Amendment Bill, the Traditional Health Practitioners Bill, the Choice on Termination of Pregnancy Amendment Bill and the Dental Technicians Amendment Bill. In its application, DFL argued that the required public participation process had not been followed in respect of these four Bills, and in particular that the National Council of Provinces (NCOP) had failed to allow for public hearings in the provinces. The Court unanimously found that it was the only court that could hear such an application. On the grounds



that such a challenge could only be entertained in respect of a Bill that had been passed and assented to by the President, the court dismissed the challenge relating to the Sterilisation Amendment Act (which was in Bill form when the challenge was mounted). As the other three Acts had been passed and signed into law when the challenge was mounted, the Court held that it was competent to grant relief and to declare these laws invalid. In a judgment in which the majority of the Court concurred, Ngcobo J confirmed that the NCOP had an important role to play in the national law-making process, and that there was an obligation on Parliament to facilitate reasonable public involvement in that process. Given the degree of public interest expressed in the Traditional Health Practitioners Act and the Choice on Termination of Pregnancy Amendment Act, he held that the NCOP's failure to hold public hearings, as was contemplated in section 72(1)(a) of the Constitution, was unreasonable. In contrast, as the degree of public interest in the Dental Technicians Amendment Act was of a far lower magnitude, the NCOP was not held to have acted unreasonably in not inviting written representations or holding public hearings. Accordingly, the Traditional Health Practitioners Act and the Choice on Termination of Pregnancy Amendment Act were declared to be invalid, but the order of invalidity was suspended for a period of 18 months. This would allow Parliament to follow the processes contemplated by the Constitution in respect of their adoption. It bears mention that the judgment only bore relevance to the Choice on Termination of Pregnancy Amendment Act. The principal Act, which affords the right to choice in respect of termination of pregnancy, is still intact and not affected by this judgment.

While dissenting judgments pointed out that compliance with every step of the legislative process, including processes for public participation, were desirable but could not be considered to be constitutional requirements, the majority judgment has provided a nuanced interpretation of such a requirement. In cases where public interest in a piece of legislation is intense, it would be unreasonable for the legislatures not to provide opportunities for debate and deliberation. This may well have considerable time implications, especially where Bills are certified as section 76 Bills (ordinary Bills that affect the provinces) but is nonetheless a product of a democratic legislative process.

THE WESTVILLE PRISON ANTIRETROVIRAL ACCESS CASE^{18,d}

In May 2006, the Aids Law Project lodged an urgent application in the Durban High Court seeking the removal of all restrictions that were preventing 15 inmates at the Westville Prison in KwaZulu-Natal from accessing the necessary antiretroviral treatment. In July 2006, an interim execution order was issued by Judge Pillay, compelling the prison to provide such treatment. The Department of Correctional Services (DCS) and the Westville Prison authorities were also ordered to indicate, both to the prisoners and to the court, how treatment access was to be effected. The DCS then applied for leave to appeal against the judge's order. In his response to that application, Judge Pillay made reference to the Grootboom case, citing Yacoob J: "The formulation of a programme is only the first stage in meeting the State's obligation. The programme must also be reasonably implemented. An otherwise reasonable programme that is not implemented reasonably will not constitute compliance with the State's obligations". The application for leave to appeal was rejected by Judge Nicholson in August 2006. In addition to ordering the authorities to immediately provide antiretroviral treatment to those prisoners in need at Westville Prison, the judge made a very strong statement about what he considered to be contempt of court on the part of the government (referring to the decision not to comply with the requirement to submit a plan of action): "If the Government of the Republic of South Africa has given such an instruction then we face a grave constitutional crisis involving a serious threat to the doctrine of the separation of powers. Should that continue the members of the judiciary will have to consider whether their oath of office requires them to continue on the bench" (para 33). A new date was set for the submission of the required plan of action and this was subsequently met. An opportunity was, however, created for the initial applicants to provide comment on the plan, which they did. A number of defects were identified.

^d Extensive material relating to this case can be accessed at <http://www.alp.org.za> (accessed 18 September 2006).

NATIONAL POLICIES AND PLANS

Two policy areas have dominated debate in the past year – the Human Resource Plan¹⁹ and the Health Charter.

Chapter 7 of the National Health Act gives the Minister of Health a mandate to take concrete steps to develop and manage the national health system. Despite the progress made by the Department of Health (DoH), there is an overall shortage of health personnel as well as inequitable distribution between urban and rural areas and between the public and private sectors. The national human resources plan for health seeks to address these challenges.

The Plan is based on 11 core guiding principles which include the following:

- ◆ Stewardship for health care lies with the national DoH.
- ◆ South Africans must enjoy a reliable supply of skilled and competent health professionals for self-sufficiency.
- ◆ Planning and development of human resources linked to the needs and demands of the health system must be strengthened.
- ◆ The optimal balance, equitable distribution and use of skilled health professionals to promote access to health services must be developed.
- ◆ Health workers must have the capacity and appropriate skills to render accessible, appropriate and high quality care at all levels.
- ◆ Work environments must be conducive to good management practice in order to maximise the potential for the health workforce to deliver good quality health services.
- ◆ South Africa's role in international health issues contributing to leadership, scientific advances and global health professions is critical.
- ◆ SA contribution, in the short to medium term, to the global health market must be managed in such a way that it contributes to the skills development of health professionals.
- ◆ Mobilisation of funding to ensure successful implementation of the Plan.

- ◆ The DoH must ensure that it has the technical expertise necessary to lead health workforce planning.
- ◆ There must be reasonable remuneration of health professionals and attractive working conditions to enable them to regard the public health sector as employer of choice.

Translating the Human Resource Plan from paper to action will require considerable effort.

Another of the challenges facing the sector is the need to advance transformation and to better coordinate the efforts of the public and private health sectors. A process of negotiating a Health Charter is underway at present. The parties to the Health Charter desire to facilitate and effect transformation of the health sector in the following key areas: access to health services; equity in health services; quality of health services, and black economic empowerment. Considerable progress has been made in moving from the initial draft Charter document to a version more acceptable to the various parties involved.^{20,21} The Revised Draft Health Charter states that the parties agree to “create for South Africa a health system that is coherent, patient-centred, efficient, cost-effective and quality driven and which optimises the utilisation of public and private sector resources within the health system for the benefit of the entire population”. A Charter Council is envisaged, perhaps related in some way to the National Consultative Health Forum.

CONCLUSION

In accordance with the State's duty to realise the right of access to health care services, it has adopted a wide range of legislative and other measures. Though the pace at which these measures have been adopted has been challenged and criticised by some, there is no doubt that the range of legislative measures presently in place, if properly implemented, are likely to go a long way in ensuring access to health care services, in developing a rights framework in respect thereof and ultimately in holding institutions and individuals accountable for the delivery of efficient and quality health care services for all South Africans.



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