Chapter 7

Traditional and alternative health care

CONTENTS

7.1 Introduction

The main focus of the chapter is on traditional health care, discussing how this system – which was marginalised in the past – is in the process of being recognised and regulated by South African policy and law. It also explains why traditional medicines need to be registered and why government has a duty to ensure that all medicines – regardless of their source – are safe and effective.

The chapter begins, however, by providing universally accepted definitions of traditional health care and alternative health care. This is necessary because of the disapproving fashion in which discussion about traditional and alternative health care has often taken place. It also examines the tensions between traditional and alternative health systems on the one hand and biomedicine on the other, with a particular focus on ethical and legal issues.

Definitions

A variety of imprecise terms are often used in discussions about traditional and modern health care systems, including "alternative" versus "conventional" and "traditional" versus "western". Using these terms reflects the awkwardness of the discussion and the fact that it is politically loaded. These terms are often unhelpful in describing the many diverse principles, philosophies and practices they represent.

The World Health Organisation (WHO) acknowledges this difficulty, but also notes that working definitions are essential. It therefore proposes this definition for *traditional medicines*:

> *"Diverse health practices, approaches, knowledge and beliefs incorporating plant, animal and/or mineral based medicines, spiritual therapies, manual techniques and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness."*

The WHO gives this definition for African traditional medicine:

> *"The sum total of all knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental, or societal imbalance, and relying exclusively on practical experience and observation handed down from generation to generation, whether verbally or in writing."*

According to the WHO, *alternative health care* relates to practices such as acupuncture, homeopathy and chiropractic systems that are a "broad set of health care practices that are not part of a country's own tradition, or not integrated into its dominant health care systems".

Other authors have defined alternative and complementary health care more specifically as those "interventions for improving, maintaining, and promoting health and well-being, preventing disease, or treating illnesses that are not part of standard North-American biomedical regimen of health care or disease prevention".

In this chapter:

- we use the terms *alternative*, *complementary* and *allied* health systems and practitioners interchangeably to mean the same thing; and
- we do not include the practice of traditional health practitioners as part of alternative health care because we deal with traditional health care as a separate category.

7.2 Traditional and alternative health care in South Africa

The main focus of health law and policy in South Africa is on biomedicine, its practitioners and its regulation. *Biomedicine*, which is also known as *evidence-based medicine*, is based on the application of the principles of the natural sciences, especially biology and biochemistry.

Biomedicine is central to the practice of allopathic health care. By this we mean, the treatment of disease through biomedical medicines and surgery, and a special concern for preventive and public health measures. But in addition to biomedicine, South African has its own indigenous medical tradition, a tradition that predated modern biomedicine and which continues up to today.

African traditional healers are loosely divided into two categories:

- *diviner-diagnosticians* (also called diviner-mediums), who give a diagnosis through spiritual means; and
- *healers or herbalists*, who choose and supply remedies on the basis of a diagnosis.

In South Africa, however, most people associate traditional health care with the herbs, remedies (or *muti*) and advice given by African traditional healers known as *sangomas* or *izinyangas*.

The WHO estimates that up to 80% of people in Africa make use of traditional medicine. In sub-Saharan Africa, the ratio of traditional healers to the population is approximately 1:500, while medical doctors have a 1:40 000 ratio to the rest of the population. This means that there are 80 times more traditional healers than biomedical doctors. South Africa's Department of Health (DoH) estimates that there are 200 000 traditional healers active in this country alone.

Simply put, millions of people – in South Africa and across the continent – make use of traditional forms of health care instead of (or in addition to) biomedicine. Sometimes they do this because of choice, but more often because they do not have access to appropriate health care services – because they are too poor or because these services are not available in peri-urban and rural areas.

Nevertheless, both traditional and alternative health care have the potential to make a valuable contribution towards improving the health of all people in South Africa. However, the historic lack of official recognition, research and focused development has created a gap in standards between these systems and biomedicine.

The impact of colonialism

Human knowledge of medicine has developed over many centuries and comes from many different parts of the world, including Africa. In the history of medicine, Indian, Egyptian, Chinese, Islamic and European scholars and traditions have all added to our knowledge of disease and how to treat it.

In Africa, however, a century of colonialism, cultural imperialism and *apartheid* in South Africa have held back the development of African traditional health care in general and medicines in particular. During several centuries of conquest and invasion, European systems of medicine were introduced by colonisers. Pre-existing African systems were stigmatised and marginalised. Indigenous knowledge systems were denied the chance to systematise and develop.

Exclusion of traditional and alternative health care

- In 1953, the then Medical Association of South Africa declared alternative therapies illegal and unscientific, and included provisions in the medical code that prohibited co-operation between allopathic and alternative practitioners.
- The Witchcraft Suppression Act of 1957 and the Witchcraft Suppression Amendment Act of 1970 prohibited diviner traditional healers from practising their trade.

Today, the issue of traditional versus allopathic health care is often politicised and confused. There is no doubt that African traditional health care is a legitimate branch of medicine that has been historically suppressed. However, this history does not mean that traditional and alternative health systems should *not* be measured by the same standards as allopathic health care today.

Standards that guarantee the safety and efficacy of medicines, for example, are important, regardless of the medicines' origin. Indeed, these standards are vital if traditional and alternative health care systems are to gain recognition and if people's rights are to be protected.

The gap between biomedicine and traditional medicine

Biomedical literature refers to the use of traditional medicines as phytotherapy, which means "medicine using plants". However, many other branches of medicine also have their origins in the use of herbs and plants. Similarly, although colonial powers and structures criticised traditional health care because of its strong spiritual component, they overlooked the fact that for many centuries European and other health care systems also had strong spiritual and religious components. Nowadays, however, one of the main distinctions between the two is that much of traditional medicine is based on observation, contrasted with the scientifically verified cause-and-effect of biomedicine.

One of the consequences of many years of discrimination and unregulated traditional health care practice has been the widening of the gap between traditional healers and the practitioners of biomedicine. This gap becomes clear within the public health system when users of biomedicine and traditional medicine come to expect the same standard of care. This is, of course, not possible when traditional healers and their products are unregulated.

The large number of traditional healers in South Africa, coupled with their historical role in traditional communities, demands that their potential contribution to the public health system be supported. But for this potential to be fully realised, traditional healers and their medicines will need to be regulated and held to the same standards as biomedicine.

Central to the need for such regulation are the rights of users of traditional health care services, including:

- the right to traditional health care services being administered in a safe and health-promoting manner; and
- the right to know what information is available about traditional medicines, including the right to know what is not yet known about them.

As traditional health care becomes more regulated, access to such information should become increasingly available to people who use – or are considering using – traditional health care services.

Current research into traditional medicines

Very few traditional medicines have been properly researched. It is therefore generally not possible to know which ones have health-promoting potential, or what interactions – whether positive or negative – they may have with other medicines. Because of this, government is collaborating with the Medical Research Council (MRC) and the Council for Scientific and Industrial Research (CSIR) to evaluate traditional medicines.

Traditional Medicines Research Unit

In 1997, the MRC established a Traditional Medicines Research Unit that collaborates with various departments at the University of Cape Town (UCT). The unit's areas of activity include:

- research into various medicinal plants, with a particular focus on anti-TB and anti-malarial research;
- the registration of provisional patents; and
- training of postgraduate students in research.

One of the MRC/UCT joint ventures was the creation in 2000 of a traditional medicines database called TRAMED III that aims to gather all relevant research on traditional medicines in one user-friendly source.

Over the past few years, the MRC's Traditional Medicines Unit has studied over 50 plants. Of these, five have shown potential anti-malarial activity. Interestingly, despite the increasing use of traditional medicines (TM) to combat HIV, the MRC has yet to produce any research on traditional medicines that would either verify or negate their efficacy in fighting HIV.

Key Point: Resources For researching traditional medicines

The only way to establish scientifically whether traditional medicines have the potential to cure or improve the quality of life of people living with HIV or other diseases is to invest significantly more resources into traditional medicines research, to be conducted according to acceptable standards of ethics. Unfortunately, the political rhetoric about the value of traditional medicines is not being matched by state investment. For example, the 2004 budget of the entire MRC was R350 million, far short of the WHO recommendation of 2% of the national health budget towards research.

Institute For African Traditional Medicines

In 2003, the Institute for African Traditional Medicines was set up as a reference centre at the CSIR. One of its aims is to screen most of South Africa's 24 000 indigenous plants for biologically active constituents. As part of an agreement signed with traditional healers in 1999, some 500 plants provided by these healers are being investigated for scientifically validated uses.

The mandate of the Institute for African Traditional Medicines is to:

- develop an appropriate regulatory framework for the registration, regulation and control of African traditional medicines; and
- streamline efforts to protect intellectual property related to traditional medicines and the communities that own this indigenous knowledge.

For more about the role of intellectual property in blocking access to affordable medicines, see Chapter 14 on access to medicines.

The CSIR also collaborates with traditional healers in order to design experimental protocols to determine the efficacy and toxicity of traditional medicines, based on the healer's preparation and administration of these medicines.

There is no doubt that through the research that has been initiated in South Africa and elsewhere, some traditional medicines will be confirmed as safe and effective remedies for certain ailments. Already, for example:

- some plants used by Zulu traditional healers have been effective in treating diarrhoea;
- a traditional medicine used in Uganda to treat *herpes zoster* has shown better results than the biomedicine currently prescribed;
- artemisia, a plant whose active ingredient is now widely used as a new drug for malaria, has been grown and used as a herbal medicine in China and Vietnam for thousands of years; and
- 30% of the world pharmacopoeia (collection of drugs) comes from plants.

But it is also likely that some substances will be demonstrated to be harmful to the user. A 2001 published study into traditional medicine poisoning and mortality amongst patients admitted at George Mukhari (formerly Ga-Rankuwa) Hospital reinforces concerns about the safety of some traditional medicines. It notes as follows:

> *"Some medicinal plants used by traditional healers in South Africa have shown significant degree of toxicity, which obviously outweighs their benefits. Similar studies in various laboratories have also analysed herbal medications with the identification of therapeutically active ingredients as well as harmful and toxic agents."*

For this reason, the DoH has established centres for pharmacovigilance and phytovigilance. These centres monitor the side effects of all registered medicines, regardless of their origins.

For more on pharmacovigilance and phytovigilance, see section 7.6 on page 220.

7.3 Relevant law and policy on traditional health care

Recognising and protecting indigenous knowledge

In the past, particularly under the apartheid government in South Africa, traditional knowledge held by African communities was ignored and marginalised. However, in the era of the New Partnership for Africa's Development (NEPAD), official recognition and support has been given to reviving and strengthening indigenous knowledge systems.

As early as 1996 in South Africa, for example, the National Drug Policy promised that traditional medicines would be "investigated for efficacy, safety and quality with a view to incorporating their use in the health system". It also stated that "marketed traditional medicines will be registered and controlled". This has not happened. Instead, much focus has been placed on the importance of protecting indigenous knowledge, including that dealing with traditional medicine. Thus, in November 2004, a national indigenous knowledge system policy was adopted as an overall framework to guide and coordinate the work of different government departments in relation to indigenous knowledge. Among its objectives are developing a system for recording indigenous knowledge, encouraging small business in indigenous knowledge and making South Africa's intellectual property law protective of indigenous knowledge.

These developments are important. But while a number of measures have been taken to recognise and modernise traditional and alternative health systems, they do not go far enough. Correctly, a focus has been placed on regulating and formally recognising traditional and alternative health practitioners and their practice.

Yet the slow pace of movement regarding the regulation of traditional and alternative medicines undermines the state's attempts to discharge its constitutional duties regarding the right of access to health care services. Those obligations require the government to take all reasonable steps to ensure that *all* health systems are held to the same high standards.

The constitutional framework

The Constitution of the Republic of South Africa, 1996, says that people have the right to choose their own cultures and beliefs, and to be protected against unfair discrimination on the basis of these beliefs. Yet it also requires of us all, regardless of our different religions, customs, cultures and beliefs, to respect fundamental human rights. Importantly, the state has a duty always to act rationally and reasonably and to promote and maintain a high standard of professional ethics, particularly in the realm of health care, where quality of care is integral to improving health status.

The Constitution, in speaking about a right to have access to health care services, does not distinguish between different systems of health care services. Read in its broader context, which includes the right in section 15 "to freedom of

conscience, religion, thought, belief and opinion", everyone has a right to make choices about the type of health care systems or services that he or she accesses.

However, the right to have access to health care services imposes a duty on the state to ensure that a person's life is not put at risk because of inadequate standards and regulations. The Ministry of Health, therefore, should not hide behind the false rhetoric of choice and promote traditional medicines or health systems unless and until they satisfy internationally agreed norms regarding safety, quality and efficacy.

Example: The State's role in health promotion

An example of this principle in action is the investigation conducted by the Public Protector into a complaint made in 2004 that the Cabinet had acted illegally by approving the use of antiretroviral medicines as part of its *Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment*. While being aware that there may be differences of opinion on the role of ARV medicines, the Public Protector nevertheless identified a specific role for the state. In particular, he concluded that the Constitution requires the development of public health policy that follows "the collective opinions of the international community based on research and the best available information" (paragraph 11.4).

This report is also discussed in Chapter 2 in considering the role of the office of the Public Protector in regulating the general exercise of public power.

Traditional health care within a constitutional culture

Whilst the Constitution recognises – in section 31(1) – that "[p]ersons belonging to a cultural … community may not be denied the right, with other members of that community … to enjoy their culture", it expressly states in section 31(2) that the right "may not be exercised in a manner inconsistent with any provision of the Bill of Rights."

In the health context, this means that traditional health care cannot be practiced in a manner that violates constitutional guarantees such as the right that everyone has to "to security in and control of their body" (section 12(2)(b)) or the right of "access to … any information that is held by another person and that is required for the exercise or protection of any rights" (section 32(1)(b)).

Our courts have yet to consider any constitutional challenges to traditional health care. But they have looked at the broad relationship between African customary law and the Constitution. In the 2004 case of *Bhe v Magistrate, Khayelitsha* 2004 (2) SA 580 (CC), the Constitutional Court declared the customary law of male primogeniture unconstitutional and invalid because it unfairly discriminated against women and illegitimate children. In its judgment the court said:

> *"Quite clearly the Constitution itself envisages a place for customary law in our legal system. Certain provisions of the Constitution put it beyond doubt that our basic law specifically requires that customary law should be accommodated, not merely tolerated, as part of South African law, provided the particular rules or provisions are not in conflict with the Constitution."*
> (Paragraph 41, emphasis added)

The same statement applies with equal force to traditional health care and medicines. While there is a responsibility on government to "accommodate" traditional health care, there is also a duty on practitioners and advocates of traditional medicine to face up to the challenge of adapting a historically underdeveloped and unregulated culture-based system to fit in with the values of our new Constitution.

The Traditional Health Practitioners Act

In the post-colonial period, a number of African countries took formal steps to recognise traditional healers and to set up traditional healer organisations. More recently in South Africa, the Traditional Health Practitioners Act 35 of 2004 ("the THPA") was enacted (but not brought into force), albeit after a fundamentally flawed process.

In *Doctors for Life International v The Speaker of the Nationat Assembly* CCT 12/05 (17 August 2006), the Constitutional Court held that Parliament's failure "to comply with its constitutional obligation to facilitate public involvement before passing the … Traditional Health Practitioners Act 35 of 2004 as required by section 72(1)(a) of the Constitution" means that the statute is invalid. Parliament has been given 18 months "to re-enact … [the THPA] in a manner that is consistent with the Constitution". (paragraph 225)

Further, the declaration of invalidity was suspended for this 18-month period, meaning that those provisions of the law that were already in force at this time remain in force. On 11 February 2005, before the proceedings challenging the law had been launched, the THPA had been promulgated.

In terms of the relevant government notice, some (but not all) of its sections came into force on 13 January 2006.

Importantly, the decision in *Doctors for Life International* does not address the substance of the law, other than to recognise its importance:

> *"This was a Bill that was intended to regulate traditional medicine and traditional healing, areas that had been the subject of discrimination in the past. People who practice this branch of medicine were previously marginalised and received no recognition; they were referred to as 'witchdoctors'."* (paragraph 174, footnote omitted)

Understanding the Act

The THPA recognises and regulates traditional healing in South Africa by:

- establishing an Interim Traditional Health Practitioners Council of South Africa;
- setting up a regulatory framework to ensure the efficacy, safety and quality of traditional health care services; and
- providing for the management and control over the registration, training and conduct of practitioners, students and specified categories in the traditional health practitioners' profession.

It defines *traditional health practice* as:

> *"the performance of a function, activity, process or service based on a traditional philosophy that includes the utilisation of traditional medicines or traditional practice and which has as its object –*
>
> *a) the maintenance or restoration of physical or mental health or function; or*
>
> *b) the diagnosis, treatment or prevention of a physical or mental illness; or*
>
> *c) the rehabilitation of a person to enable that person to resume normal functioning within the family or community; or*
>
> *d) the physical or mental preparation of an individual for puberty, adulthood, pregnancy, childhood and death".*

It further identifies four categories of traditional health practitioners:

- traditional surgeons, known as *iingcibi*
- traditional birth attendants, known as *ababelekisi*
- herbalists, known as *iinyanga* or *izinyanga*
- diviners, known as *izangoma (sangomas)*.

Importantly, it expressly excludes allopathic and alternative health professionals. Their practice is regulated by other statutes.

Interim Traditional Health Practitioners Council

The THPA sets up a new statutory body for the regulation of traditional healers, known as the Interim Traditional Health Practitioners Council of South Africa. It is to be comprised of up to 22 members including registered traditional health practitioners from each province, a DoH representative, a person with knowledge of the law and a medical practitioner who is a member of the Health Professions Council of South Africa.

It also sets out the objects and functions of the Council, including:

- registering traditional health practitioners;
- establishing registers for various traditional health practitioners;
- determining codes of professional conduct and ethics, disciplinary procedures and the scope of traditional health practice;
- issuing guidelines on traditional health practice; and
- controlling and regulating traditional health practice.

Registration and practice guidelines

While a number of sections in the THPA set out the procedures for the registration of traditional health practitioners, it does not provide details on minimum training or practice requirements to become a traditional health practitioner. This is left to the Minister of Health to be dealt with in regulations, after having received recommendations from the Council.

Importantly, the THPA Act states that:

- no person may practise as a traditional health practitioner within South Africa unless he or she is registered;
- the practice of traditional healing without registration is an offence punishable with a fine or imprisonment;
- the Council may institute an inquiry into any complaint, allegation or charge of unprofessional conduct against any registered traditional healer; and
- if the Council finds a traditional healer guilty after an inquiry, it may impose a range of penalties.

One problematic part of the THPA is section 49(g), which states that it is an offence for unregistered practitioner – and not registered practitioners – to diagnose, treat, offer to treat, prescribe for cancer, HIV and AIDS, and any other prescribed terminal disease. Effectively, this appears to empower registered practitioners to make unfounded claims regarding the treatment of illnesses such HIV infection. To date, there is no evidence that any African traditional health service or medicine is effective in treating HIV infection. At best, traditional medicines are useful in treating certain HIV-related opportunistic infections.

Regulating traditional health practices that may be harmful

In African tradition and culture, including the practice of traditional health care, there are a number of practices that may be harmful or which violate fundamental human rights to dignity and bodily autonomy. These include practices such as initiation and virginity testing. The THPA regulates some of these practices (such as initiation and circumcision) by including a particularly broad definition of traditional health practice: the "physical or mental preparation of an individual for puberty, adulthood, pregnancy, childbirth and death".

As one of the functions of the Council is "to control and regulate traditional health practice", it is likely that in future regulations governing initiation will be passed. Already, there is a range of other laws that deal with practices such as circumcision and virginity testing:

- the Limpopo Circumcision Schools Act 6 of 1996, which regulates circumcision schools in Limpopo province;
- the Children's Act 38 of 2005, which provides that every male child has the right to refuse circumcision and prohibits the practice of virginity testing amongst children; and
- the National Health Act 61 of 2003, which empowers the Minister – in the interests of the health and well-being of persons attending initiation schools – to prescribe the conditions under which the circumcision of a person as part of an initiation ceremony may be carried out. That Act defines the term "initiation school" to mean any place at which one or more persons are circumcised as part of an initiation ceremony.

For more on provincial powers to make laws, see Chapter 2.

For more on children and health, see Chapter 9.

For more on the National Health Act, see Chapter 4.

Regulating alternative health care

Alternative medicine, like traditional medicine, has not been subject to modern scientific evaluation. But unlike traditional health practitioners, practitioners of alternative health care have been regulated for over 20 years by the Allied Health Professions Act 63 of 1982, which regulates the practice of these ten professions of alternative health care:

- Ayurveda;
- Chinese medicine and acupuncture;
- chiropractics – a system of treating bodily disorders by manipulating the spine;

- homeopathy;
- naturopathy
- osteopathy;
- phytotherapy or herbalism;
- therapeutic aromatherapy;
- therapeutic massage therapy; and
- therapeutic reflexology.

For definitions of these terms, see http://www.ahpcsa.co.za.

These professions are governed by a statutory body called the Allied Health Professions Council, tasked with assisting "in the promotion and protection of the health of the population". This Council has the power to "govern, administer and set policy for the professions registered with the council", and also to control the registration of alternative health practitioners. By 2003, the Council had registered more than 5000 alternative health care practitioners in South Africa.

While alternative health care has been regulated longer than traditional medicine, there has not been any substantial research into alternative or complementary medicines. Alternative practices have not shown significant benefits in treating HIV/AIDS, but some have provided complementary support.

Patient rights

Users of traditional and alternative health care systems have the same rights as users of evidence-based health care services. Similarly, traditional and alternative health practitioners have the same duties and responsibilities as biomedical practitioners. This means, for example, that all traditional and alternative heath care – including treatment, operations and procedures – may be provided only after patients have given full and informed consent. This can only happen if they have access to all relevant information about the care to be provided. Importantly, all information relating to a person's health should be treated with confidentiality.

Key Points: Making complaints

Complaints against traditional and alternative health care practitioners can be made as follows:

- complaints against traditional healers should be reported to the Traditional Health Practitioners Council; and
- alternative health users can lodge complaints with the Allied Health Professions Council of South Africa.
  If the complaints are upheld, the Council can institute diciplinary pocedures.

7.4 Registering and regulating traditional and alternative medicines

All medicines for human use are subject to the Medicines and Related Substances Control Act 101 of 1965. In terms of this Act, the Medicines Control Council (MCC) protects the public by ensuring that all medicines that are sold, distributed and used in South Africa are safe, effective and manufactured according to acceptable standards of quality. Historically, however, traditional and alternative medicines have largely fallen outside of this framework.

For more detail on developing, registering and using medicines, see Chapter 13.

Steps towards registration and regulation

As a consequence of the legal recognition of traditional and alternative health care systems, traditional and alternative medicines must now also be brought under regulatory control. If these medicines are to be prescribed and marketed as part of health care systems that the law recognises, they must meet the same strict standards of efficacy, safety and quality as other scientifically validated medicines. This much is recognised by the National Drug Policy of 1996.

Recent developments in this regard include the following:

- In 2000, an expert committee on African Traditional Medicines was established by the MCC
- In October 2006, a Presidential task team on African Traditional Medicine was constituted. Disturbingly, this task team is headed by Mr Herbert Vilikazi, who is also known for promoting the use of “ubheyane” (an untested traditional herbal mixture) to treat HIV/AIDS.
- The CSIR, MRC and Department of Health have worked together to collate all existing scientific knowledge of phytotherapy in an easily accessible database.

- Applications in respect of 11 800 complementary medicines have been submitted for evaluation to the MCC's Complementary Medicines Committee.
- In 2004, draft regulations governing the registration of traditional and complementary medicines were published for comment (*Government Notice* R844, 16 July 2004). Unfortunately, these regulations were later withdrawn and have yet to be reintroduced, in any form.

Resistance to registration and regulation

As with many other areas of health reform, the process of regulating traditional and alternative medicines has proved complex and controversial. Concerns have been raised that the scientific methods that are used to evaluate biomedicine are not appropriate for traditional and alternative medicines, which are based on different belief systems and understandings about illness and health. Groups such as the Complementary and Traditional Medicines Stakeholders Committee in South Africa have argued that the state should follow the example of Canada in creating a special Office of Natural Health Products, responsible for registering and regulating complementary and alternative medicines.

There has also been resistance from people and organisations in both traditional and alternative medicine who have monetary and other interests in maintaining a situation where their products do not have to be independently validated for safety, efficacy and quality. Part of the reason for this type of resistance is that registration processes may be costly.

But of more concern is the tragic reality that some of these people and parts of this industry depend on the desperation of people who are ill, combined with their ignorance of medicine, to advertise and sell products that claim to have medicinal properties but are of no value and may often be harmful. If these medicines had to be registered, many of them would be forced off the shelves. But without this kind of regulatory approval, an often desperate population remains vulnerable to exploitation.

Example: Untested products

Partly as a result of the HIV epidemic and partly because of a growing public awareness of "healthy living", the last few years – both in South Africa and beyond – have seen a growing number of advertisements regarding HIV-related therapeutic claims for products such as "immune boosters", micronutrients,

vitamins and alternative medicines. In this country, none of these products has been registered by the MCC, nor have the therapeutic claims been verified by any independent scientific body. Yet the industry remains a very lucrative one – thought to be valued at over R2bn annually.

See Chapters 12 and 13 for more information about health research, ethics and the registration of medicines

RATH AND THE WAR ON SCIENCE

In addition to resistance to regulation, South Africa has recently experienced a hostile campaign against evidence-based medicine in general and antiretroviral (ARV) medicines – used to treat HIV infection – in particular. The campaign has attempted to suggest that all allopathic medicine, including ARVs, is part of a global conspiracy by multinational pharmaceutical companies to profit from ill health. This campaign, led by the Dr Rath Health Foundation, has rejected modern medicine and claimed that illnesses, including HIV, can be cured by a combination of micronutrients and unspecified traditional medicines.

In its own right, the campaign is dangerous, particularly when it convinces vulnerable people to abandon proven treatments for HIV. But of more concern than Rath himself is the support he has been provided by senior government officials, who have not only come to his defence but have largely failed to take action against him for numerous breaches of the Medicines Act. This has resulted in legal proceedings being initiated by the Treatment Action Campaign and the South African Medical Association against Rath, the Minister of Health and others.

For more on the Rath case, see http://www.tac.org.za.

7.5 Other laws that impact on traditional and alternative health care

The legal recognition of alternative and traditional health care has implications in a number of other areas of law and policy. In this section, we discuss examples of these: the Medical Schemes Act, 131 of 1998, the Basic Conditions of Employment Act, 75 of 1997, the National Health Act, 61 of 2003, the National Environmental Management: Biodiversity Act, 10 of 2004 and the Patents Amendment Act, 58 of 2005.

The Medical Schemes Act

The role of medical schemes is fully set out in chapter 6 dealing with private health care. According to the Medical Schemes Act, all medical schemes must provide a minimum package of medical benefits, known as the Prescribed Minimum Benefits (PMBs). The Minister of Health determines the PMBs – which are periodically updated – on the advice of the Council for Medical Schemes.

At the moment, the PMBs only make reference to evidence-based medicine – they do not require medical schemes to cover the costs of traditional or alternative medicines or consultations. This may change if traditional and alternative medicines are registered by the MCC. However, there is nothing in law preventing medical schemes from including traditional and alternative health care in their benefit options. Indeed, a number of schemes already offer benefits for alternative therapies. If they choose this option, they may apply to the Council for Medical Schemes to approve and register these benefits.

The Basic Conditions of Employment Act

The Basic Conditions of Employment Act regulates employment relationships and basic working conditions. It provides that a medical practitioner or any other person who is registered with a professional council established by an Act of Parliament may issue a medical certificate (a sick note).

This means that once the Interim Health Practitioners Council issues regulations and registers traditional health practitioners, registered traditional healers may provide sick notes to their patients to present to employers to justify sick leave. Employers will have to accept these certificates in the same way that they do with other registered health professionals.

The National Health Act

The National Health Act regulates the health system as a whole. This Act is discussed in detail in Chapter 4. It defines a "private health establishment" as a health establishment that is not owned or controlled by an organ of state. Once traditional healers are registered, this will include the practices of traditional health practitioners. This means that providers and users of the traditional health system will have the same rights as users of other private health care services, such as patients in private hospitals.

For more on private health care rights, see Chapter 6.

The National Environmental Management: Biodiversity Act and the Patents Amendment Act

Traditional medicines are sometimes based on indigenous knowledge of plants – community-owned knowledge that is passed down from generation to generation. However, sometimes communal owners of indigenous knowledge are located across national borders. This makes the protection of this knowledge from commercial theft and exploitation (known as "bio-piracy") more difficult. Although this is recognised as a problem, there is no standard international or regional framework currently in place to deal with bio-piracy in respect of traditional medicines.

A recent example of an appetite-suppressant used by the San reveals both the potential dangers and potential rewards that may face owners of indigenous knowledge from the scientific validation of their traditional medicine.

The San have used *Hoodia gordonii*, a cactus-like plant, to stave off hunger for thousands of years during times of drought or food scarcity. In 1997, the CSIR patented a chemically synthesised version of the active ingredient in the plant. The patent was licensed to a company known as Phytopharm. It then sub-licensed the rights in the patent to pharmaceutical giant Pfizer. Ironically, Pfizer's interest in the patented molecule is to use it to develop a diet pill for people in developed countries who eat too much food.

In response, the San had a long legal battle with the CSIR, demanding compensation. The outcome has been a benefit-sharing agreement in which the CSIR has agreed to pay the San:

- 8% of "milestone payments" at various stages during the clinical trial phase of the drug; and
- 6% of all royalties over the lifetime of the patent, if and when the drug makes it onto the market.

For more information, see http://www.irinnews.org/report.asp?ReportID=33086.

The potential benefit to the San of several hundred million rand emphasises the importance of devising policies that protect the historic owners of indigenous knowledge. In 2004 and 2005, Parliament adopted new laws to protect indigenous knowledge:

- The National Environmental Management: Biodiversity Act, whose purpose includes "the fair and equitable sharing of benefits arising from bio-prospecting involving indigenous biological resources" establishes a new statutory body known as the South African National Biodiversity

Institute. It also deals extensively with 'bio-prospecting', with the aim of ensuring that indigenous knowledge is protected and that the material and scientific benefits that may come from indigenous knowledge are shared with communities.

- Similarly, the Patents Amendment Act seeks to protect communities from bio-piracy. It amends the Patents Act by requiring "an applicant for a patent to furnish information relating to any role played by an indigenous biological or genetic resource or traditional knowledge or use in an invention". In appropriate circumstances, it prohibits the granting of patents where benefit-sharing agreements have not been concluded.

Currently, both the CSIR and the MRC have benefit-sharing policies to compensate traditional healers and their communities for commercialising medicinal plant products.

For more information on patents and access to essential medicines, see Chapter 14.

7.6 Traditional health practitioners and HIV/AIDS

Co-operating with traditional healers on HIV/AIDS

In many countries traditional healers were already active in working with health care services on primary health care strategies before the era of HIV/AIDS. With rapidly escalating HIV prevalence rates in sub-Saharan Africa, people's expectations of traditional healers and their workload are likely to increase greatly.

However, while many traditional healers work hand in hand with clinics and hospitals, some traditional healers still view HIV/AIDS as an old disease that can be treated by traditional healers alone.

Conditions such as *ilumbo*, *umeqo* and *ncunsula* exhibit the same type of symptoms as AIDS-related illnesses. They are said to result from bewitchment and infidelity, and can be "cured" by cleansing the body. Once the symptoms are gone, the traditional healer considers the patient cured. But there is no evidence to date that cleansing the systems of people living with HIV/AIDS will be beneficial to their health. In fact, it may actually be harmful.

Key Points: Benefits of co-operation on HIV/AIDS

- Traditional healers need the support, education and co-operation that formal health care systems can offer.
- Formal health systems can benefit by expanding the reach and efficacy of their HIV prevention and treatment programmes by working with traditional healers.
- The high numbers of people living with HIV who use traditional healers will be best served if healers are properly educated on HIV prevention, treatment, care and support.

CASE STUDY: RESPONSE TO HIV/AIDS

Zeidan Hammad is an internal medicine specialist at the CHU-Tokoin hospital, the main hospital in Lome, Togo. The hospital does not treat patients with AIDS.

"There is nothing we can do for them here", he says. "If they're rich, they go off to Europe. If they're poor, we send them home to die." It's not entirely true that the hospital can do nothing. Hammad can treat the opportunistic infections that attack … patients in the early stages of HIV infection, and if their immune systems have not deteriorated too badly, he can prolong their lives.

And this is where Hammad's frustration with traditional healers manifests itself. "I have people come to me with problems that suggest they may be HIV positive, and I tell them, go get tested and then come back," he says. "And they disappear for six months. I go to the test lab and ask, what happened to this person? And they say, yes, we tested him.

"Then suddenly six months later the person shows up in my office again, practically on the point of death. And he says, 'Oh, I tested HIV positive, so I went to a traditional healer, but it didn't work. So I went to another healer, but that didn't work either.'" So now they're back, and now I can't do anything for them. It's too late."

(Steinglass in Lingua Franca, 2001)

The government's Operational Plan

The *Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa* recognises the role that traditional healers and traditional and complementary medicines may play in dealing with the HIV/AIDS epidemic. Although traditional healers will not be trained to use antiretroviral therapy, the Operational Plan envisages the training of traditional healers on a range of other interventions, including:

- HIV prevention and care;
- adherence to medicines;
- general counselling;
- toxicity monitoring; and
- patient education.

The plan emphasises the importance of patient choice in electing health care:

> *"South Africans living with HIV and AIDS will be encouraged to make their own informed choices about the types of treatment they wish to seek. A wide range of interventions and options will be provided through this comprehensive package of care. These may include advice on general health maintenance strategies, positive living, exercise, nutrition, traditional and complementary medicines, and anti-retroviral therapy. All potential clients will be informed about these care and treatment options and encouraged to make their individual informed choices."* (Emphasis added.)

Although the statement above seems quite neutral, it carries the danger of suggesting that patients have equal choices to choose between traditional medicines or nutrition or ARV therapy. Regrettably, the Minister of Health has repeatedly and intentionally made confusing statements that suggest this is indeed the case.

Key Point: Empowering people to make informed decisions

In order to enable people to make an informed choice, health workers should inform patients that, unlike ARV medicines that have been tested scientifically, nutrition and traditional medicines are not proven treatments for HIV infection or AIDS-related illnesses.

Safety and efficacy of traditional and complementary medicines

The Operational Plan notes the importance of research into the safety and efficacy of traditional medicines. This confirms that, for people living with HIV/AIDS to be empowered to make informed choices, they must be provided with access to accurate, evidence-based information.

People need to know which medicines – whether traditional, alternative or allopathic – have been proven to treat HIV infection and AIDS-related opportunistic infections. To be able to provide clients with this information, various government-backed research bodies are currently studying traditional medicines.

The Operational Plan also makes provision for:

- Incorporating traditional and complementary medicines into the pharmacovigilance process. Pharmacovigilance is the science of detecting, assessing, understanding and preventing adverse effects of medicines or any other drug-related problems.
- Developing a national database on phytovigilance – the monitoring and prevention of adverse reactions to traditional medicines. It also focuses on interactions between ARV medicines *and* traditional and complementary medicines.

In September 2004, a pharmacovigilance centre was opened at the University of Limpopo. The centre aims to detect, assess and prevent adverse reactions to ARV medicines, and traditional and complementary medicines, when used by people living with HIV/AIDS.

Key Points: Interaction between traditional and ARV medicines

- Recent research shows that potential life-threatening interactions can occur between traditional medicines and ARV medicines.
- A study published in January 2005 shows that two popular traditional medicines (the African potato and the *Sutherlandia* plant) decrease the efficacy of ARV medicines significantly, leading to possible treatment failure, viral resistance or drug toxicity. (Mills and others, 2005)

7.7 Conclusion

As providers of health care, traditional and alternative health practitioners can play an important role in building South Africa's health system, as well as strengthening and supporting the national response to HIV/AIDS and TB.

But they cannot fully play this important role unless human rights principles are strictly applied to all aspects of traditional and alternative health care. For this to happen, registering traditional medicines and implementing the registration of traditional healers are urgent.

More importantly, there is a need for strong leadership from the Minister of Health and her department. They should not only encourage co-operation and mutual support, but also ensure that their strong advocacy in support of traditional medicines is supported by scientific evidence. Public interest demands this.