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GENERAL NOTICE

Government Gazette No. 31265 is hereby withdrawn and substituted by the following:

NOTICE 906 OF 2008

DEPARTMENT OF HEALTH

NOTICE: DRAFT POLICY ON AFRICAN TRADITIONAL MEDICINE FOR SOUTH AFRICA

Members of the public are invited to submit any substantiated comments on the draft policy on African Traditional Medicine for South Africa to the Director-General of Health, Private Bag X828, Pretoria, 0001, (for the attention of the Director: Traditional Medicine) within three months from the date of the publication of this notice.

Foreword by the Minister of Health

It is with great pleasure that I present this draft Policy for the institutionalization of African Traditional Medicine in the healthcare system of the country.

This draft policy is in furtherance of the right to healthcare services as enshrined in the Bill of Rights, chapter 2, section 27 of the Constitution of the Republic of South Africa, 1996 to provide of health range of disciplines for the citizen.

The draft policy marks an important epoch in the history of African Traditional Medicine in our country. It symbolises the respect and recognition of the African Traditional Medicine by Government for sustaining health care in the urban and rural areas for a number of years, in spite of its oppression and marginalisation during the era of colonialism and apartheid.

The draft policy on African Traditional Medicine comes at a time when the public health care system is in a dire need to reflect the diverse health disciplines which the citizen utilize for their healthcare needs in South Africa.

This draft policy will within the context of the Alma Ata Declaration on Primary Health Care strengthen the capacity of healthcare personnel, health services and communities to ensure

It provides a transformational process for formal recognition of the African Traditional Medicine system to acknowledgement our heritage as a country and to address issues of (a) capacitating and protecting Traditional Health Practitioners and the users of African Traditional Medicine, (b) protecting African Traditional Medicine Knowledge, and (c) strengthening the National Health System.

Government is committed to institutionalizing African Traditional Medicine in the healthcare system.

I am confident that this draft policy, when implemented, will contribute to the improvement and accessibility of healthcare delivery.

DR ME TSHABALALA-MSIMANG, MP
MINISTER OF HEALTH

Date: 10-7-2008

EXECUTIVE SUMMARY

The Draft National Policy on African Traditional Medicine in South Africa is designed to provide a framework for the institutionalisation of African Traditional Medicine in the South African healthcare system. The World Health Organisation (WHO), The African Union (AU) as well as Southern African Development Community (SADC) have all passed resolutions, which urge member states to implement national policies and regulations on Traditional Medicine. At the Lusaka Summit of Heads of State, the African Union adopted a Plan of Action on the decade for African Traditional Medicine (2001 – 2010). The primary objective of the Plan of Action is the institutionalisation of African Traditional Medicine in the public health systems of member states by 2010.

The South African government has taken steps towards the official recognition and institutionalisation of African Traditional Medicine, including establishing a Directorate of Traditional Medicine in 2006 to co-ordinate and manage initiatives regarding African Traditional Medicine within the Department of Health as well as enacting the Traditional Health Practitioners Act (No. 22 of 2007) which established the Traditional Health Practitioners Counsel. The Government has also provided funding for research and the development of African Traditional Medicine (ATM) to manage and control diseases.

The Presidential Task Team on African Traditional Medicine was appointed in 2006 to make recommendations with regard to a national policy and an appropriate regulatory and legal framework for the institutionalisation of African Traditional Medicine in South Africa. The Task Team after consultation with some stakeholders drafted the Draft National Policy on African Traditional Medicine in South Africa.

The draft policy defines African Traditional Medicine as a body of knowledge that has been developed over thousands of years which is associated with the examination, diagnosis, therapy, treatment, prevention of, or promotion and rehabilitation of the physical, mental, spiritual or social wellbeing of humans and animals.

A survey of comparative international practices and policies with regard to the institutionalisation of Traditional Medicine shows that certain common trends can be identified. These include:

- official support for acceptance and recognition of traditional medicine in the formal healthcare sector often through a national focal point such as an institute.

- establishment of a system to regulate, register and license Traditional Health Practitioners and the provision of formal training of such practitioners;

- the establishment of a system to develop, regulate and register Traditional Medicine to ensure safety, quality and efficacy, including scientific research;

- the development of a national Pharmacopoeia or the updating of existing ones as part of the regulatory system;

- collaboration with other countries and the World Heath Organisation in order to exchange information and promote policies and regulation according to international standards.

RECOMMENDATIONS

To institutionalise African Traditional Medicine the following steps are recommended:

Regulation of African Traditional Medicine

It is recommended that legislation on African Traditional Medicine be enacted to provide an enabling environment for African Traditional Medicine in its entirety and scope, covering but not limited to:

- the regulation of African Traditional Medicine in South Africa;

- registration and regulation of African Traditional Medicines and Medicinal Products in South Africa;

- protection of African Traditional Medicine knowledge and Intellectual Property rights; and

- the protection of the rights of persons involved in the discipline of African Traditional Medicine in South Africa.

Education, Training, Research and Development

It is recommended that a National Institute of African Traditional Medicine should be established. Such an Institute should devise strategies, coordinate, undertake and provide leadership in the research of African Traditional Medicine and collaborate with other institutions on a needs basis. The Institute should be funded by Government but may obtain additional independent funding.

Research priority areas should be identified and developed and addressed through well developed, scientifically rigorous and ethical research protocols. Different research methodologies and registration processes will need to be developed as current research methodologies for allopathic medicine are not in all instances appropriate.

A National Ethics Committee for African Traditional Medicine research should be formed, consisting of both orthodox phytochemists and clinical trialists with experience in African Traditional Medicine research, as well as traditional health practitioners.

Cultivation and Conservation of South African Medicinal Plants

It is recommended that Traditional Medicine be classified into two categories i.e. indigenous plants, animals or other biological materials for domestic use and indigenous plants used for the commercial production of medicine. The development of commercial medicinal plants should be limited to cultivated raw materials with wild harvesting only allowed under exceptional circumstances.

Pharmacopoeia

It is recommended that a national pharmacopoeia of African Traditional Medicine in South Africa be developed.

General Recommendations

It is recommended that an Interministerial Committee on African Traditional Medicine be established in order to ensure coordination between government departments in developing and institutionalising ATM. The Ministry of Health should chair such a committee.

It is recommended that information and communication tools should be put in place to promote African Traditional Medicine in South Africa and facilitate its acceptance and inclusion in the National Healthcare System.

It is recommended that a national implementation plan be developed by the National Department of Health.

It is recommended that a resource mobilisation plan be devised to facilitate and ensure the implementation of all aspects of the African Traditional Medicine Policy.

CHAPTER ONE

1.1 Concept and Philosophy of African Traditional Medicine

African Traditional Medicine is a body of knowledge that has been developed and accumulated by Africans over tens of thousands of years, which is associated with the examination, diagnosis, therapy, treatment, prevention of, or promotion and rehabilitation of the physical, mental, spiritual or social wellbeing of humans and animals.

African Traditional Medicine is holistic in approach; that is, processes of the physical body, mind, emotions and spirit, work together in determining good health or ill health. The equation of good or ill health also includes the interaction and relationship between nature, the cosmos, and human beings. Practitioners of African Traditional Medicine must have in-depth knowledge of all the parts of this equation.

The philosophical underpinning of African Traditional Medicine is UBUNTU: '*Umuntu ngumuntu ngabantu/motho ke motho ka batho/a human being is a human being through other human beings*'. One of the important causal factors considered in African Traditional Medicine is the type of relations existing between the particular individual and other human beings, both the living, and those who have passed away. Thus, philosophy/religion, psychiatry, physiology and biology, are all part and parcel of the conception of African Traditional Medicine.

African Traditional Medicine bases itself upon the understanding of Nature but does not regard Nature as a `thing', as an `instrument' to be manipulated by Human Beings.

In African Philosophy, the Human Being should not be a reckless `Sovereign Ruler' over Nature, doing as he/she pleases with Nature. Nature is regarded as a living force, with Personality, Protocol, and Will of her own.

The respect for nature and for animals in African Traditional Medicine and in African Philosophy, in general, has a scientific basis. In addition, African Philosophy made the regard and respect for Nature, for Ecology, a top priority matter. This is in line with the campaign of ecologists and humanists for a more humane relationship and understanding between Human Beings and Nature.

1.2 Introduction

The official recognition, empowerment, and institutionalization of African Traditional Medicine, and its incorporation and its utilisation within the National Health System, would be an important step towards delivery of cost effective and accessible clients based healthcare.

The World Health Organization defines Traditional Medicine as follows:

> *"Traditional Medicine includes 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." (1)*

The resolution of the Executive Board of the World Health Organization, urges member states, where appropriate, to draft and implement national policies and regulations on traditional medicine in support of the proper use of traditional medicine, and its integration into national health care systems, depending on the circumstances in their countries.

At the Lusaka Summit of Heads of State and Government in June 2006, the African Union adopted a Plan of Action on the Decade for African Traditional Medicine (2001-2010), (AHG/Dec 164 XXXVIII). The main objective of the Plan of Action is the recognition; acceptance, development and institutionalisation of African Traditional Medicine by all Member States into the public health care system in the region by 2010.

This policy document is aimed at the institutionalization of African Traditional Medicine and not its integration with allopathic medicine; the intention is for the two systems to function side by side within the health care system.

Studies on the use of Traditional Medicine in the African Continent demonstrate that Traditional Health Practitioners (THPs):

Provide for healthcare needs of more than 80% of people in the Sub-Saharan Africa,

Are very knowledgeable about health related cultural norms, and
Are highly respected members of their communities.

These findings prompted the following interventions:

The World Health Organization

Recommended that there was a need for recognition of the role of Traditional Health Practitioners in providing health care according to the Alma Ata Declaration of 1978.(2).

The World Health Organization (African Regional Office) has developed a strategy that provides a framework for action to promote the use of Traditional Medicine in reducing mortality and morbidity

The African Union -

has acknowledged the critical role of African Traditional Medicine in health care provision in the African Continent;

has developed a Plan of Action and declared the period between 2001 and 2010 as the Decade of African Traditional Medicine;

has developed the Africa Health Strategy: 2007 – 2015: Strengthening of Health Systems for Equity and Development in Africa

African Health Ministers -

Took a decision in 2001 to celebrate African Traditional Medicine Day on the 31st of August of each year;
during the 49th World Health Organization African regional Office meeting in Ouagadougou.

Plan of Action on the AU's Decade of African Traditional Medicine in Gaborone.

The SADC Inter-Ministerial Subcommittee on Traditional Medicine at its meeting of 16 September 2005 recommended that member states should provide the legal framework for the recognition of African Traditional Medicine. The Minister's also recommended that resources should be mobilised for technical and financial support for capacity building in order to ensure implementation of African Traditional Health policies.

African Traditional Medicine as a discipline has been suppressed and disempowered. It is therefore not sufficient to recognise African Traditional Medicine but structures and a system should be provided for its effective institutionalisation. The intention is to allow for the development and enrichment of African Traditional Medicine in South Africa as a distinct system within the formal health care sector in South Africa, equal in status to allopathic medicine as is the case countries such as China and India.

Fortunately, as a result of a world-wide revival in the popularity of traditional medicine and its formal recognition over the last few decades, a new attitude towards African Traditional Medicine has emerged and is gaining ground. There is a willingness to regard African Traditional Medicine as a discipline and paradigm on its own, with its own methodology, which should be promoted and given space, within government structures, to exist and function just like modern allopathic medicine, Ayurvedic medicine, Traditional Chinese Medicine and other great healing systems of the world.

1.3 Motivation for a Policy on African Traditional Medicine in South Africa

The South African government is a member of the World Health Organization and accepts its recommendations with regard to the need for policies and strategies that institutionalise African Traditional Medicine; as well as its guidelines in the

formulation of such policies. Furthermore South Africa is a member of the African Union and SADC, which adopted the plan of action on the decade for African Traditional Medicine 2001 to 2010.

Most importantly in recognition of the reality that the majority of South African people still use and continue to rely on African Traditional Medicine for their primary healthcare needs, there is a need for a policy to institutionalise and regulate African Traditional Medicine. Such institutionalisation is required in terms of South Africa's international and continental obligations. (See Introduction)

Such institutionalisation should take place through among others the following actions:

- Policy finalization and adoption.
- Development of legislation on the discipline of African Traditional Medicine in South Africa (ATMSA).
- Strengthening the national health system as a contribution towards improving the health and quality of life of all South Africans.
- Recognition and practise of ATMSA.
- The development of new systems of service delivery.
- Regulating the initiation, circumcision and virginity testing practices for the purpose of benchmarking (traditional surgeons and circumcision schools).
- The establishment of a National Institute of ATMSA.
- Creation of an enabling environment, including the establishment of institutions of healthcare based on the theory and practice of ATMSA.
- Capacitating traditional health practitioners and the users of ATMSA.
- Protecting traditional health practitioners and the users of ATMSA against unqualified or incompetent individuals selling medicine and/or acting as traditional health practitioners.
- Protection of African traditional medicine knowledge and intellectual property rights.
- Training and development of practitioners and researchers.
- Improved coordination of current research and planning of new research at research institutions.
- Conservation of medicinal plants and animals and counteracting unsustainable harvesting practices.

- Development of acceptable standards of safety and quality for African Traditional Medicines and raw materials.
- Formal documentation and systematisation of ATMSA in order to preserve codify and protect the cultural heritage, including the development of a pharmacopoeia of ATMSA.
- Establishment of an African Traditional Medicine pharmaceutical industry for the production and processing of ATMSA (including research and development) to ensure a sustainable supply of high quality, affordable products and to maximise economic benefits to the country.
- Education of street vendors regarding sanitation, conservation and harvesting of medicinal plants.
- Creation of linkages between ATMSA and other paradigms of theory and practice of medicine and to strengthen cooperation in the area of ATM and TM, both regionally and internationally.

The WHO estimates that in the 2000, 25 countries reported having a national Traditional Medicine Policy (1). It argues that where such a policy exists a sound basis for institutionalisation of Traditional Medicine in national healthcare delivery is provided; and this ensures that the necessary regulatory and legal mechanisms are in place to ensure access, safety and efficacy of therapy. It further states that:

> *A national policy is urgently needed in those developing countries where the population depends largely on Traditional Medicine for healthcare, but without it having been well evaluated or integrated into the national health system. Many developed countries are now also finding that Traditional Medicine issues concerning, for example, safety and quality, licensing and providers and standards of training, and priorities for the research, can best be tackled within the framework of a National Traditional Medicine Policy* (1).

The WHO recommends that three areas be provided for in a national policy:

Safety, efficacy and quality

- Establish registration and licensing of providers.
- Establish national regulation and registration of herbal medicines.

- Establish safety monitoring of herbal medicines and other Traditional Medicine therapies.
- Provide support for clinical research into use of Traditional Medicine for treating country's common health problems.
- Develop national standards, and technical guidelines and methodology, for evaluating safety, efficacy and quality of Traditional Medicine.
- Develop national pharmacopoeia and monographs of medicinal plants.

Access

- Identify safe and effective Traditional Medicine therapies and products.
- Support research into safe and effective treatment for those diseases which represent the greatest burden.
- Recognise role of Traditional Medicine providers in providing health care.
- Optimize and upgrade the skills of Traditional Medicine providers.
- Protect Traditional Medicine knowledge through recording and preservation.
- Cultivate and conserve medicinal plants to ensure their sustainable use.

Rational use

- Develop training guidelines for country's most commonly used Traditional Medicine therapies.
- Strengthen cooperation between Traditional Medicine providers and other health care providers.
- Make reliable information on proper use of Traditional Medicine therapies and products available for consumers.
- Improve communication between health care providers and their patients concerning use of Traditional Medicine.

South African policy on African Traditional Medicine would differ slightly to these WHO recommendations in that support for clinical research in ATMSA would not be 'selective'; and this research would encompass all the diseases that afflict mankind – and not just those diseases of 'mass burden' that afflict 'poorer populations'.

The importance of Traditional Medicine is supported by estimates of its economic impact. The reported annual contributions of Traditional Medicine to the economies of some countries are:

Australia - A$1000 million (A$621 million);

China - 17.57 billion Chinese Yuan (US$2.3 billion) in 1995, an increase of 212.6% compared with 1990;

Japan - US$1.5 billion per year (herbal medicines products), 3.5% of the total market for pharmaceutical products (3).

Southern Africa has rich plant diversity and has 10% of the world's plants on less than 2% of the worlds land surface (4). Very few plants have been commercialized and despite the significant botanical and cultural diversity few research-based products are available. The potential economic benefits of the commercialization of research-based products in South Africa can be judged from the following estimates: The annual trade in raw medicinal plants is valued at R520m, Traditional Health Practitioners (THPs) prescribe Traditional Medicine worth R2.6bn per year, while the annual sales of herbal medicines is worth R588m, making the total contribution of Traditional Medicine to be more than R3bn. In addition, the health care services rendered by approximately 200,000 THPs makes it the biggest health service industry in the country. (5)

1.4 Current Interventions by South African Government

In South Africa, the Government, through the National Department of Health, made interventions towards the official recognition, institutionalisation and empowerment of African Traditional Medicine through the following:

- The *National Drug Policy* (1996) that recognises, the potential role and benefits of available remedies of African Traditional Medicine in the

national health system and the potential role of traditional healers in the formal health care sector.

- The *Directorate: Traditional Medicine*, a new directorate that was established to manage the work related to Traditional Medicine within the Department of Health.

- The *Ministerial Task Team on the New Regulatory Authority* has made proposals for the registration and regulation of African traditional medicines.

- The Traditional Health Practitioners Act, 2007 (Act No. 22 of 2007), the purpose of which is to establish the *Traditional Health Practitioners Council*.

- Funding for research and development of African Traditional Medicines to manage and control diseases.

- Initiated an *African Traditional Medicine Day* and a *Traditional Medicine Week*, in line with the *Plan of Action on the AU Decade of Traditional Medicine* (2001-2010).

The draft policy is premised on the following:

- The Constitution of the Republic of South Africa, 1996.
- Implementation of the recommendations, resolutions and pronouncements on Traditional Medicine of the World Health Organization to Member States (Resolution of the Executive Board of the World Health Organization, Ninth Meeting, 24 January 2003, WHO document EB111/SR/9); the OAU/African Union and SADC Health Sector call to Member States; resolutions of SADC Ministerial Subcommittee on Traditional Medicine pronouncements of the President of the Republic of South Africa and the National Minister of Health, on the need to officially recognize, institutionalise, and empower African Traditional Medicine, and to incorporate it within the National Health Care System.
- Implementation of the Plan of Action on the Decade for African Traditional Medicine (2001-2010) adopted by the OAU/African Union at the Lusaka Summit of Heads of State and Government (AHG/Dec

164 XXXVIII). The main objective of the Plan of Action is the recognition, acceptance, development and integration of African Traditional Medicine by all Member States into the public health care system in the region by 2010.

- The reality that African Traditional Medicine in South Africa (ATMSA) has been at the centre of the livelihood of South African people long before colonialism and western civilisation touched the shores of the African continent, bringing with it western medicine and western ways of treating diseases, and
- Acknowledgement that the majority of South African people still continue to use, and rely on, African Traditional Medicine (ATM) for their healthcare needs.

A comparative study of 123 countries showed that national recognition and regulation of traditional medicine vary greatly (7). However, the process of integrating traditional medicine into the national health care system follows a predictable progression of steps (1) :

1. The adoption of a national policy on traditional medicine.

2. Establishment of a national focal point (typically a National Institute of Traditional Medicine).

3. Establishment of a National Federation or Council of Traditional Health Practitioners and/or a national register and licensing system.

4. A national strategy or action plan to direct the process through which traditional medicine will be institutionalized and regulated over a period of several years.

5. The development of a pharmacopoeia or other regulatory mechanisms to register and control traditional medicines, with emphasis on safety and quality.

6. Collaboration with other countries and the World Heath Organization in order to exchange information and to harmonize policies and regulations according to international standards.

The following Chapters provide details of the draft policy.

CHAPTER TWO

SUMMARY OF COMPARATIVE INTERNATIONAL PRACTISES WITH REGARD TO THE UTILISATION AND INSTITUTIONALISATION OF TRADITIONAL MEDICINE

2.1 Introduction

National recognition and regulation of Traditional Medicine vary greatly amongst 123 countries surveyed by the World Health Organisation in 2001 (7).

In general, there is a widespread and increasing appreciation of the role of Traditional Medicine, primarily because it is used by a large part of the world's population, who considers it more affordable and more in line with the patient's ideology. Traditional Medicine has proven efficacy in a number of important treatment areas, including mental health, prevention of disease, treatment of non-communicable diseases and improved quality of life in elderly people and in persons suffering from chronic diseases.

With regard to the legal status of Traditional Medicine, key countries can be divided into the following categories:

In Argentina, Cuba, Italy, Japan, Germany and Spain Traditional Medicine has become popular but allowed to be used or practiced by allopathic doctors.

In Austria, France, Malaysia, Nigeria, Switzerland and the United States of America TM is illegal but tolerated by law (although some aspects, such as herbal remedies, may be promoted through laws, regulations or interim measures).

In Chile, Mexico, Peru, Philippines, South Africa and Zimbabwe TM is being actively promoted with the aim of making it part of the national health care system

In China, Germany, Ghana, India, Indonesia, Pakistan, Mali, Myanmar (Burma), Republic of Korea, Thailand, United Kingdom of Great Britain and Viet Nam, Traditional Medicine is already an integral part of the national health care system (in some cases reintroduced after periods of political or ideological change). In most of these countries, Traditional Medicine has been systematised and

documented over long periods (several centuries in the case of China, India and Thailand) and the traditional system exists in parallel to the allopathic system. Many of the countries have national institutes, hospitals, and universities entirely or partly devoted to Traditional Medicine.

The following reviews include three countries from Africa (Ghana, Mali and Zimbabwe), one from South America (Peru), two from Europe (Germany and the UK), five from Asia (China, India, Indonesia, the Philippines and Thailand). The traditional healing systems of these countries, despite their diversity, have striking similarities; they are typically holistic (considering the complete mind-body continuum and not only the ailment), underpinned by a sophisticated (albeit sometimes undocumented) theoretical framework, use biological materials (mainly plants but also animals) and various minerals and employ a diversity of spiritual therapies, manipulations and exercises. Often, no clear distinction is made between medicine and food (some foods are eaten for their physiological or health-promoting activity rather than for their nutritional value or taste). In some countries, several traditional systems co-exist simultaneously.

2.2 Country Cases

China

Background information: Chinese Traditional Medicine (TCM) is an ancient system based on a well-documented theoretical framework and philosophy (*yin* and *yang* – opposites that complement each other, and the five elements – metal, wood, water, fire and earth). The system dates from the 8th century BC and is used in many parts of the world.

Legal framework, legislation and infrastructure: Chinese Traditional Medicine has co-existed with allopathic medicine for more than a century. Important National Institutions include the Bureau of Traditional Medicine, as part of the Central Health Administration (established in 1984) and the State Administration of Traditional Chinese Medicine (established in 1986). There is a well-established infrastructure for TCM – each county in China has a traditional hospital (more than 2600 in total). In addition, 95% of general hospitals have separate units for TCM. There are no less than 170 research institutions for TCM, e.g. the Academy of Traditional Medicine in Beijing. TCM products and services provided by state hospitals are inexpensive and very popular.

Registration of THPs: THPs are registered in much the same way as allopathic practitioners. The former apprenticeship method of training that existed before 1960 was gradually replaced by a formal educational system taught by a variety of private school recognized by the government (typically 5 years of study). There are also many secondary schools and at least 28 universities and colleges of Chinese traditional medicine and pharmacology.

Regulation of TMs: Herbal drugs and products are regulated and registered by the State Drug Administration (SDA), using quality criteria from the Pharmacopoeia of China and the Ministerial Drug Standards and Pharmaceutical Standards of SDA.

Pharmacopoeia: Pharmacopoeia of the People's Republic of China (1988); Pharmacopoeia of the People's Republic of China (3 volumes, 2005).

Germany

Background information: Herbal medicine is part of everyday life and has its roots in Galenic medicine (the four elements – earth, air, fire, water and the four humours – blood, phlegm, black bile and yellow bile) and in ancient scripts such as the famous *De Materia Medica* written by the Greek physician Dioscorides in the first century AD. The European and German system of herbalism (and modern derivatives such as homeopathy and anthroposophic medicine) has remained a very popular, sophisticated and rational method of treating ailments, often considered to be supportive rather than curative.

Legal framework, legislation and infrastructure: There is no legal monopoly on the practice of medicine – all licensed medical practitioners, including traditional practitioners or so-called *Heilpraktikers*, may practice medicine and use complementary or alternative medicine. There is a sophisticated legal system that regulates all aspects of allopathic and non-allopathic medicine, the latter functioning as independent systems within the health care system.

Registration of THPs: Licensed non-allopathic physicians (*Heilpraktikers*) are allowed to practice medicine but there is a list of specific restrictions of certain medicinal interventions that falls outside the scope of practice of the *Heilpraktikers* (e.g. surgery and delivering of death certificates). In 1994, there were between 10 000 and 13 000 *Heilpraktikers* in Germany, who are

coordinated by the *German Federal Association of Heilpraktikers*. More than 75% of allopathic doctors regularly use alternative therapies.

Regulation of TMs: Germany has arguably the most practical, comprehensive and detailed system of regulating traditional medicines, which is now harmonized with the regulatory system of the European Union. The German Commision E Monographs (1974-1994) was a practical system to regulate herbal medicine over many years. The large number of medicinal products on the market in Germany prompted the German authorities to pass a law in 1976 requiring all to be reviewed by expert committees. In 1978, a panel of experts was appointed to evaluate the safety and effectiveness of herbal medicines (the so-called German Commission E, responsible for phytotherapy and herbal substances). The law (AMG 1976) allowed a transition period of 12 years, during which evidence of quality, safety and efficacy still required to be validated. The manufacturer of the product had to provide evidence of pharmaceutical quality, while the evidence for safety and efficacy was relegated to the monographs to be published by the Commission E. Bibliographic evidence was allowed in terms of proof of safety and effectiveness. Traditional use (traditional medicines proven useful over many years) was used as a way to support efficacy. Commission E was appointed by the Minister of Health and comprised 24 members, each an experts in his/her particular area. They were proposed by respective associations (physicians, pharmacists, non-medical practitioners [*Heilpraktiker*], pharmacologists, toxicologists and biostatisticians), as well as representatives of the pharmaceutical industry. Half the commission comprised members from clinical or therapeutic disciplines. Each category had a member and corresponding deputy. Medical claims (label information) must be limited to minor conditions and preventative statements and must include the words "traditionally used for ...". The products are used as supportive and invigorating remedies but are not intended to cure or treat a disease. For products intended to cure or treat a disease, the normal route of application for pharmaceuticals or non-prescriptive medicines are followed.

Pharmacopoeia: The pharmacopoeia has always been an important mechanism in regulating herbal medicine in Germany. Extensive research has been done in German universities over many years, so that the available information on plants is of a very high standard. Examples of German pharmacopoeia include the following: Arzneibuch der DDR (1987); Deutsches Arzneibuch 10 th ed. (1991); Deutscher Arzneimittel-Codex (1986); German Commision E Monographs

(1974-1994). During the period 1978 to 1994, a total of 380 monographs were published in the German *Federal Gazette*, covering 360 individual plant species and combinations. Each monograph included the name of the herb, its constituents, allowed indications for use, contra-indications, side-effects, interactions with other drugs, dosage, method of dosing and the general properties or therapeutic value of the herb or herb product.

Commission E reviewed scientific information, literature on long-term traditional use, chemical, pharmacological and toxicological data, clinical trials and post-market surveillance data. There are two categories of monographs: (1) Positive Monographs, including accepted uses of a particular herb or plant part; (2) Negative Monographs, herbs judged to be unacceptable because of an unfavourable risk-benefit-ratio or alternatively, herbs considered unsuitable because of lack of evidence.

The Commission E monographs played an important role in establishing a process for the control and regulation of traditional medicine. It included only three African traditional herbs (aloe, devil's claw root and buchu leaf). The complete set of monographs was published in English in 1998 and 2000 [Blumenthal M et al. (eds) 1998. The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines. Integrative Medicine Communication; Blumenthal M (ed.) 2000. Herbal Medicine: Expanded Commission E Monographs. Lippincott Williams & Wilkins].

Ghana

Background information: Traditional Medicine is based on herbs, spirituals beliefs and local wisdom.

Legal framework, legislation and infrastructure: The Medical and Dental Decree of 1972 allowed THPs to practice traditional medicine. The Traditional Medicine Practice Act of 2000 established a council to regulate the practice of Traditional Medicine, to register and license THPs and to regulate the preparation and sale of herbal medicines. The Centre for Scientific Research into Plant Medicine (a research unit and hospital) was established in 1975 to help promote and integrate TM into the health care system. The Traditional Medicine Unit (1991) was upgraded to the status of a directorate in 1999. In collaboration with the THP associations, they are developing programmes to promote Traditional Medicine and to develop formal training courses.

Registration of THPs: The Traditional Medicine Practice Act of 2000 provide for a licensing system for traditional practitioners. Training is by apprenticeship, but the Ministry of Health is working towards a formal education system. Today there are more than 100 000 THPs that form the backbone of the health delivery system. There is 1 THP per 400 people (1 allopathic doctor per 12 000 people).

Regulation of TMs: All labelled herbal medicines (crude or prepared) are regulated by the Traditional Medicine Practice Act of 2000.

Pharmacopoeia: The Ghana Herbal Pharmacopoeia Vol. 1 is a compilation of scientific information on selected medicinal herbs in Ghana. The Science and Technology Policy Research Institute (STEPRI) has published a revised edition.

India

Background information: Ayurvedic medicine is an ancient formalized system and a practical and holistic set of guidelines to maintain balance and harmony, and one to ensure a long and happy live. Ayurveda means "the Science of Life". Ayurveda is similar to Galenic medicine in that it is based on basic element (earth, water, fire, air and sky) and bodily humours (*dosas*), which are classified as either somatic or psychic.

Legal framework, legislation and infrastructure: In India, ayurveda has formally co-existed with other healing systems such as siddha, unani, yoga, naturopathy and homeopathy for centuries and are today all fully integrated into the health care system. During the colonial period, TM was neglected in favour of allopathic medicine. The government of India has started the process of formal recognition of ayurveda and other healing systems with the Central Council of India Medicine Act of 1970. The Central Council have set minimum standards of education in Traditional Medicine, developed a *Register of Indian Medicine* and a registration procedure for THPs (including a code of ethics and standards of professional conduct). Several other councils and state departments are dealing with Traditional Medicine and homeopathy. There are seven national institutes, e.g. the National Institute of Ayurveda (established in 1976). Nearly 3000 hospitals provide traditional Indian health care and there are more than 20 000 dispensaries for traditional medicines.

Registration of THPs: All traditional medical practitioners must be registered to practice.

Regulation of TMs: All traditional medicines are registered and controlled through a Register of Indian medicine.

Pharmacopoeia: Pharmacopoeia of India II (1966), III (1985); The Indian Pharmaceutical Codex (1953); Indian Phamacopoeia (1996), with Addenda in 2000 and 2002).

Indonesia

Background information: Traditional medicine in Indonesia has similarities with ATM and four groups of THPs are distinguished: (1) herbalists; (2) skilled practitioners (e.g. traditional birth attendants, bonesetters, masseuses, traditional dentists); (3) spiritualists and (4) supernaturalists.

Legal framework, legislation and infrastructure: The Health Law Act 23 (1992) promoted Traditional Medicine to becoming and an integral part of health care and to regulate traditional medicines. The Centre for Traditional Medicine Research provides training in Traditional Medicine.

Registration of THPs: There are nearly 300 000 THPs and many of them attend training courses offered by the Ministry of Health. Traditional birth attendants are allowed to practice without registration or a licence.

Regulation of TMs: There are nearly 800 manufacturers and several thousands traditional medicines (called *jamu*) that are regulated by the Ministry of Health. The Health Law Act of 1992 classified traditional medicines into two categories: (1) traditional medicines used by individuals or within families. These medicines are made and used by THPs for use by their own patients and need not be registered; (2) commercial traditional medicines that are produced and packed on a small or large commercial scale. These products have to be registered. Scientific studies, safety studies, microbiological testing and other requirements need to be met, including clinical trials for those products that will be used in formal health services. The Directorate General of Pharmacy and Medical Devices Services (Indonesian acronym: DirJen Yanfar dan Alkes) of the

Indonesian Ministry of Health controls the registration of medical devices and household health supplies in Indonesia.

Pharmacopoeia: Farmakope Indonesia (ed. IV) 1995 (in Indonesian).

Mali

Background information: TM in Mali is a holistic, oral-traditional system based on herbal medicine and ancient wisdom.

Legal framework, legislation and infrastructure: The Department of Traditional Medicine and the National Research Institute of Medicine and Traditional Medicine were both established in 1973. A Scientific and Technical Committee was appointed in 1980. Legislation to regulate private consultation clinics, medicinal herbal stores and improved production units of traditional medicine was effected in 1994.

Registration of THPs: Local officials are allowed to authorize the practice of TM within their administrative subdivisions. Some THPs are involved in primary health care programmes.

Regulation of TMs: There are strict rules (Decree 95/1319/mss-pa/sg of June 1995) for controlling all aspects of the manufacture of traditional medicines. Collection of wild plants is not permitted and only cultivated plants can be used commercially. Production units must be supervised by pharmacists or other suitable qualified professionals. Mali regulates private consultation clinics, medicinal herb stores and improved production units of traditional medicine.

Peru

Background information: TM comprises herbalist, traditional birth attendants and bonesetters.

Legal framework, legislation and infrastructure: Traditional Medicine was officially prohibited in Peru in 1969 (but the prohibition was never enforced). New legislation is underway to regulate Traditional Medicine. The National Institute of Traditional Medicine (with 17 branches throughout the country) is responsible for the regulation and development of Traditional Medicine.

Registration of THPs: The Ministry of Health issues practice permits. THPs learn through apprenticeships and there are some official and informal training programmes and courses in Traditional Medicine.

Regulation of TMs: Medicines are regulated according to Section 4 of the Supreme Decree 010-97-SA of 1997. It outlines definitions, procedures and requirements for the registration of traditional medicines.

Philippines

Background information: The Philippines has a rich system of TM that has been dominated by allopathic medicine. In recent years, the government has taken steps to promote and institutionalise Traditional Medicine.

Legal framework, legislation and infrastructure: The Traditional Medicine Division within the Department of Health was established in 1993, and the Traditional and Alternative Medicine Act was promulgated in 1997. A Philippine Institute of Traditional and Complementary/Alternative Health Care was established in 1997.

Registration of THPs: All medical practitioners must be registered. Traditional birth attendants may only practice in areas where no physicians or registered midwives are available. There is a strong drive to train allopathic practitioners in aspects of Traditional Medicine.

Regulation of Traditional Medicines: Natural medicines are sold over the counter in health stores and pharmacies but the current regulatory situation is unclear. The official Philippine Pharmacopoeia, however, was adopted in April 2004.

Pharmacopoeia: Philippine Pharmacopoeia 1st edition 2004.

Thailand

Background information: Thai Medicine is an ancient and very well-documented system based on Indian and Chinese medicine. It has a holistic philosophy and is based mainly on herbs, steam baths, traditional massage, acupressure and reflexology. TM is an important component of the official health care system.

Legal framework, legislation and infrastructure: The National Institute of Thai Traditional Medicine was created in 1993 to work toward the full integration and

re-integration of Thai Medicine into the public health service. A school for Thai medicine was started in 1957 and since then, several others have been established. Thai Traditional Medicine is now integrated into more than 75% of all health care centres in the country.

Registration of THPs: All the different types of traditional medical practitioners are registered with the Medical Registration of the Ministry of Public Health. Allopathic practitioners wishing to practice Thai Traditional Medicine has to undergo a three-year apprenticeship with a registered THP and pass a formal examination set by the Commission for the Control of the Practice of the Art of Healing.

Regulation of TMs: The Eight Public Health Development Plan 1997-2001 includes amongst others, provisions for increasing the use of herbal medicines in Thailand.

Pharmacopoeia: Thai Herbal Pharmacopoeia Vol. 1 (1995), Vol. 2 (2000).

United Kingdom of Great Britain

Background information: Access to numerous alternative and complementary systems is sanctioned by the government.

Legal framework, legislation and infrastructure: The British Research Council on Complimentary Medicines (established in 1982) is responsible for regulating alternative medicine. The UK is the only European country where there are public hospitals for some forms of traditional medicine.

Registration of THPs: Non-allopathic practitioners must be covered by insurance and must adhere to the Code of Professional Ethics in order to become members of professional organizations. Not all non-allopathic medical practitioners are officially registered but all are tolerated by law.

Regulation of TMs: There is a sophisticated system of regulation and registration of medicinal product that rely to a large extent on proven traditional used and the existence of a monograph in an official pharmacopoeia

Pharmacopoeia: British Herbal Pharmacopoeia (1983, 1990, 1996); British Pharmacopoeia XLI (1988); The Pharmaceutical Codex (1979); British

Pharmaceutical Codex (1934-73); Martindale (1989) The Extra Pharmacopoeia. 29th ed.

Zimbabwe

Background information: TM is a holistic, oral-traditional system.

Legal framework, legislation and infrastructure: The first step in official recognition and promotion of TM was the Zimbabwe National Traditional Healers Association (ZINATHA), created in 1980. The Traditional Medical Practitioners Council Act (1981) is considered to be the most comprehensive piece of legislation of the practice of traditional medicine that has ever been enacted anywhere in the world.

Registration of THPs: Provisions are made for a registrar to establish a register of traditional medicine practitioners, who may then use the title "Registered Traditional Medical Practitioner".

COMMON ELEMENTS

Despite the level of development of TM in most countries of the world, the following are common elements and common trends:

Increasing appreciation and official support for the acceptance and recognition of Traditional Medicine in the formal health care sector (often through a national focal point).

Establishment of a system to regulate, register and license THPs, and to provide formal training and to devise practical ways of assessment to ensure an adequate level of training.

Establishment of a system to develop, regulate and register traditional medicines to ensure safety, quality and efficacy, including scientific research and clinical studies.

Efforts to develop a national pharmacopoeia (or to update existing ones) as part of the regulatory system.

Collaboration with other countries and the World Heath Organization in order to exchange information and to harmonize policies and regulations according to international standards.

It is recommended that the above key elements be an essential part of the policy and practise of African Traditional Medicine in South Africa, the Department of Health being the lead department in ensuring the institutionalisation of African Traditional Medicine in line with the principles adopted by the WHO and the above countries.

This include but not limited to museum, hospitals and provincial structures.

CHAPTER THREE

LEGAL FRAMEWORK AND REGULATION OF AFRICAN TRADITIONAL MEDICINE IN SOUTH AFRICA

3.1 Legislative Framework

The foundation for the institutionalisation of ATM in South Africa is the devising of an appropriate legislative framework. South Africa does not currently have an integrated legislative framework or an appropriate regulatory regime for ATM. Prior to the promulgation of the Traditional Health Practitioners Act, no legislation existed to regulate any aspect of the discipline of ATM.

The Traditional Health Practitioners Act provides for the establishment of the interim Traditional Health Practitioners Council of South Africa and for the training and practice of Traditional Health Practitioners. It also aims to protect the interests of members of the public who are clients of Traditional Health Practitioners. The Act is a valuable start and may need to be reviewed in the context of a more comprehensive and integrated legislative framework arising from the finalisation of this policy and appropriate strategies arising from there from.

There are statutes that do not specifically deal with ATM but impact on the discipline. The Medicines and Related Substances Act defines medicine as any substance or mixture used or suitable for use or manufactured or sold for

use in the diagnosis, treatment or prevention of disease or its symptoms. The current registration requirements are more suitable to allopathic medicine and require amendment.

The National Health Act provides for and would also require amendment to provide for inclusion of a chapter on African Traditional Medicine in order to facilitate planning at all levels.

The National Environmental Management: Biodiversity Act 10 /2004 was promulgated to comply with the Convention on Biological Diversity (CBD) after South Africa signed and ratified the CBD on 2 November 1995. The main objectives of the Act are to manage and conserve the biological diversity in South Africa; to ensure the sustainable use of indigenous biological resources and to provide for the equitable sharing of benefits arising from bio prospecting and indigenous knowledge in South Africa.

Indigenous biological resources are defined sufficiently broadly to cover traditional knowledge and African Traditional Medicine.

The Biodiversity Act is a significant advancement which protects Traditional Health Practitioners and growers of traditional plants from exploitation and for sustainable bio prospecting. As provisions of the Act touches on a number of issues affecting the discipline of ATM there is a need for interdepartmental co-operation and monitoring. The Departments of Health, Science and Technology as well as Land and Agriculture need to be involved.

The Patent Act applies to any new invention which involves an inventive step which can be used or applied in trade or industry or agriculture. The invention should be new and not form part of the state of art which is any product, process or information in the public domain either written or oral or in use. Any person who is an inventor or any other person with the authority of an inventor can apply for a patent.

Currently the Medicines Control Council is responsible for the registration of medicine. Currently there are difficulties with the registration of Traditional Medicine and Complementary Medicines due to delays with drawing up appropriate Regulations. The Ministerial Task Team on the new regulatory authority for South Africa has made certain proposals that will rectify this.

The new Medicines Regulatory Authority will be a single umbrella body to regulate medical and veterinary products. There will be a single full-time Chief Executive Officer to the Minister of Health. The objectives for the regulation of medicines will be to ensure safety, quality and efficacy. The main regulatory pillars will be (1) Pharmaceuticals (=medicines): (1.1) Prescription medicine; (1.2) Non-prescription medicine (=over-the-counter medicine); (1.3) Complementary medicines (Chinese, Ayurvedic and other traditional systems); (1.4) African Traditional Medicine; (2) Medical devices; (3) Vaccines; (4) blood derived products for medicinal purposes (5) Radiopharmaceuticals; (6) Food products with medicinal claims and medicinal content; (7) Cosmetics, with medicinal claims and medicinal content. Each of the categories will have separate guidelines for registration and separate protocols for clinical trials.

The problems with the application of the Patents Amendment Act, 2005(Act No. 20 of 2005) to Traditional Medicine are that more often than not, such knowledge have been passed down within the context of a defined communal system with no identifiable inventor or creator. Even where an individual traditional healer may wish to patent his knowledge, he may have difficulty in proving its novelty. Moreover if it is a plant-based medicine then it is not patentable as natural material or plants are not patentable without being processed or modified.

Even more problematic is that no method of treatment of human or animal body by surgery or therapy is patentable. Often Traditional Medicine does not consist only in plant material but also animal and other material. Lack of written records creates difficulties in terms of international protection as patent offices in other countries are not able to access such information for the purpose of establishing in its novelty and inventiveness. For traditional healers, or communities the costs of compiling a patent registration in South Africa and internationally is expensive and the cost of enforcement and infringement proceedings is even more expensive.

The Patents Amendments Act was amended to incorporate the provisions of the Biodiversity Act. The amendment provides for some form of protection for indigenous genetic material, indigenous biological resources, traditional knowledge (meaning the knowledge that an indigenous community has regarding the use of an indigenous biological resource or a genetic resource)

and the way in which an indigenous community uses an indigenous biological resource or a genetic resource. In terms of the amendment every applicant for a patent must state whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource or traditional knowledge or use. The applicant must produce evidence that he or she has a title or authority to utilise the indigenous biological resource or traditional knowledge.

Further amendments may be required to ensure that there are no conflict between its provisions and that of any sui generis ATM legislation subject to compliance by South Africa with its international obligations .

It is apparent that given the nature, content and practice of African Traditional Medicine, it is unsuitable to be protected by the current legislation. The recommended sui generis legislation should make specific provision for a comprehensive regime of IP rights protection for African Traditional Medicine.

3.2 Recommendations

It is recommended that sui generis legislation on African Traditional Medicine be enacted to provide an enabling environment for African Traditional Medicine in its entirety and scope, covering but not limited to the following:

- Regulation of African Traditional Medicine in South Africa (ATMSA).
- Inclusion of African Traditional Medicine in the National Health System.
- Resource mobilization (financial, human and structural) for ATMSA.
- Harnessing of best practices of ATMSA through the establishment of an Institute for African Traditional Medicine, setting up of Education & Training, Research & Development and other regulatory structures;
- Registration and regulation of African Traditional Medicines and Medicinal Products in South Africa.
- The establishment of a national pharmacopoeia.
- Production and/or conservation and/or cultivation of African Indigenous Medicinal Plants.
- Protection of African Traditional Medicine Knowledge and Intellectual Property Rights.
- Protection of the rights of persons involved in the discipline of ATMSA.

It is further recommended that the Department of Health should co-ordinate a review of existing legislation and amends such legislation that falls under the Department and recommend amendments to other legislation in order to harmonise such legislation with adopted policies on ATMSA and new legislation arising from such policy.

CHAPTER FOUR

EDUCATION, TRAINING, RESEARCH AND DEVELOPMENT

4.1 Introduction

African Traditional Medicines (ATM) are playing an increasing role in the South African health care system and this trend is also evident in health sector reform globally (WHO). South Africa has a rich diversity of plants many of which, through cultural diversity, are used daily either as food or traditional medicines (9). Their use amongst the population is widespread with the majority of South Africans consulting traditional healers and using ATM to alleviate symptoms of illness or to prevent illness (10).

Such a resource plays a vital role, as it is often the first resource of many people. Although health care facilities are present, the services and advice given by indigenous practitioners are valued because they are given in terms that patients can understand and in the context of cultural values and practices that are shared by both patients and healers alike.

South Africa and the continent at large are affected by many communicable and non-communicable diseases (11). Intervention strategies for such communicable and non-communicable diseases justify the need for alternate sources of remedies. It has been well documented that certain plants can cure many of the above diseases offering an alternative route to fight the disease at a fraction of the cost of modern medicine.

With the recognition of Traditional Healers and their role in the South African health sector, there is hence a dire need for a research platform to investigate the claims of traditional medicines together with evidence of quality and safety. However, the paucity of research data on the thousands of traditional medicines in common use for centuries should not preclude their use by South Africans. Clinical trials are not needed to justify the continuing use of such traditional medicines by South African communities; but such research will add to our body of knowledge of the safety and efficacy of such medicines.

The rationale for natural medicines has been described as nature, consisting of a gigantic biotechnology facility with hundreds of thousands of product lines, each developed over the course of hundreds of millions of years of experimentation, in millions of experimental reaction vessels called living organisms (12). These are not simply computer-generated structures; but novel chemical entities that have been tested in nature's bioassays over the course of millennia for useful biological and physiological activity. Those that have been proven useless have been discarded in the drug development pipeline through natural selection. Where else would one go therefore to seek out new cures; or clues that might lead to novel therapies?

This chapter highlights the research needs of ethnopharmacology within South Africa and draws attention to the fragmentation and pitfalls that exist in these activities with a view of consolidation and improvements of current infrastructures so as to deliver high quality research on ATM.

4.2 Why the need for Research?

In South Africa, approximately 3000 plant species are used as medicines (4), of which as many as 700 species are traded in large quantities in informal medicinal plant markets. This contributes to a multi-million rand "hidden economy" in the order of US$ 10 million (13). In South Africa alone it is estimated that there are 27 million indigenous medicine consumers with most households spending between 4 and 8% of their annual income on traditional medicinal services. Due to the marginalisation of ATM there is a dearth of research on the subject, with only 25 of the 3000 South African plants fully biomedically characterised in terms of their medicinal properties. The problem of proper control of the quality and safety of TM is also a vexing and complex issue, not only in South Africa but worldwide (14).

There are many extrinsic factors affecting the quality of medicinal plants. It has been well established that environmental factors do affect phytochemical accumulation in plants, Contamination by microbial and chemical agents (pesticides, herbicides, heavy metals), as well as by insect, animal, animal parts, and animal excreta during any of the stages of source plant material production can lead to lower quality and/or unsafe materials. Botanicals collected in the wild often also include non-targeted species either by accidental substitution or by intentional adulteration. Adulteration of herbal medicines with synthetic drugs also represents another problem in product quality. Despite the knowledge of various plants, reports of adverse reactions continue to appear in the literature (9; 15; 16; 17) with the WHO database listing over 9000 adverse drug reaction reports in which herbal preparations are suspected of being implicated (18). The quality and safety (especially related to chronic use) of these products has thus become an important concern for both health authorities and the public (19). A highly focused research agenda on ensuring the quality, safety and efficacy of ATM will therefore fulfil a social and ethical obligation by responding

appropriately to the needs of South Africans in addressing the use of traditional medicines in infectious diseases, chronic illnesses and preventive care, all of which represent vital national health research priorities.

The potential pitfalls in the area of quality and safety of ATM relate to the following:

- Intentional addition of an active drug responsible for therapeutic/adverse effect.
- Unintentional substitution of the plant with a toxic species.
- Environmental contamination of the plant with a chemical or pathogen.
- Suboptimal or varying amounts of 'active ingredient' within plant matrix.
- Adverse effects.
- Drug-herb interactions (concurrent use of multiple products).
- Confounding factors leading to misinterpretation of effect.

4.3 The Current South African Research Environment on African Traditional Medicine

Much of the research within South Africa has focused on isolation of the chemical constituents of medicinal plants, where structural determination has been an end in itself and the activity of compounds isolated have not been assessed. Many potentially useful molecules must have been missed in this way. As a result, despite our wealth in both plant and cultural diversity, South Africa has been unable to leverage this to create a vibrant biotechnological and pharmaceutical base.

There is a highly motivated and trained core staff from Universities and Science Councils involved in TM research but the research is fragmented and uncoordinated in terms of the needs and relevance of the research questions relating to ATM. As a result of this dispersed endeavour, resources are spread thin; funding is limited and thus does not allow for the research process to follow a rational route. Many plants from the region have been screened for antibacterial, antifungal, antihelmintic, antiamoebic, antischistosomal, antimalarial, anti-inflammatory and antioxidant activity as well as psychotropic and neurotropic activity using *in-vitro* assays. Despite these efforts, there has been very little success in putting a product into clinical use from all the efforts. The main reason may be that most of this work has an academic endpoint rather than being research and development / product – oriented. The other reason is that due to the fragmentation, there is no consolidation of expertise, resources and equipment.

The impact of scientific research into African Traditional Medicine in respect of product development is still disproportionately low. At the same time, African traditional medical knowledge and the medicinal plant resources are vanishing as the continent is being ravaged by disease and poverty. Research into African Traditional Medicine should now enter a paradigm where cognisance needs to be taken of the various disciplines that also play a key role in fulfilling the need for research data on traditional medicines. Despite interest by a number of institutions, there is a dire need for a focused and well co-ordinated group with well-equipped infrastructure geared to undertake such research from a single centre having in-house assays. Studies on medicinal plants require the interaction of researchers with indigenous communities, the study of the chemical composition of extracts and the pharmacological activities of the compounds present. It is, by nature, a multidisciplinary science. Successful research must be action-oriented and involve people from a range of disciplines: ethnobotanists, anthropologists, clinicians, epidemiologists, natural products chemists, pharmacologists, taxonomists, traditional healers and/or user communities.

4.4 Recommendations

4.4.1 National Institute of African Traditional Medicine (NIATM)

It is recommended that a National Institute of African Traditional Medicine (NIATM) should be set up. Such an Institute should strategise, coordinate, undertake and provide leadership in the research of African Traditional Medicine and collaborate with other institutions on a needs basis. The NIATM will provide a critical mass of research expertise under one umbrella to undertake the multidisciplinary research into medicinal plants which integrates the various disciplines cited above including public health. The Institute shall be funded by Government but may develop a strategy to obtain additional or even independent funding.

It is recommended that the *National Institute of African Traditional Medicine* should be established in 2008; in order to meet the 2010 deadline prescribed by the Plan of Action adopted by the African Union; ideally comprising of five components, phased in over a period of several years and/or utilizing existing capacity and infrastructure where possible. The five components are:

- A school or faculty, as it is done in sports, where education and training in aspects of traditional medicine and primary health care is provided to traditional practitioners, students of medicine and pharmacy and also allopathic doctors who wish to use TM in their practices. Bridging knowledge

courses can be offered between the conventional/allopathic profession and the ATM profession. The school or faculty can also facilitate the inclusion of ATM in the curriculum of training institutions of health professionals and Department of Education schools, taught by THPs.

- A research institute for the research and development of high quality, safe and evidence-based traditional medicines. Research components include botany, ethnobotany, pharmacognosy, traditional therapies, pharmacy, preclinical research and clinical research, and others as the research agenda evolves.

- A hospital and other facilities where traditional practitioners (alone or in collaboration with allopathic doctors) provide health care. There should be a separate pharmacy where traditional remedies are dispensed (as is the case in China, for example).

- An experimental garden or botanical garden where medicinal plants are grown on an experimental or semi-commercial scale for research and development, as well as for display and educational purposes. This component can be developed in collaboration with other role players such as the Department of Agriculture and the Department of Science and Technology.

- A museum, library and documentation centre, where collections of historical artefacts, traditional medicines, books, documents and other resources are displayed and maintained under proper curation (as experienced in China).

The National Institute of ATM will have a headquarters from which programmes will be developed, implemented and monitored. It is envisaged that the Institute will coordinate and stimulate a diversity of activities that will be the starting point of a long-term process of enriching, developing and systematising ATMSA.

The *National Institute of African Traditional Medicine* should determine priorities for research and use, where desirable, the existing infrastructure, in collaboration with other research institutions such as the MRC and other institutions where desirable to initiate, fund and coordinate new programmes specifically aimed at (1) more focussed research on African Traditional Medicine, including the formalization and documentation of ATM; adapting research methodologies to develop a more holistic

approach (e.g. by studying synergism); produce high quality publications in international scientific journals to demonstrate the profound depth of knowledge vested in African Traditional Medicine; (2) Attract bright young scholars to a career in research on African Traditional Medicine by developing critical mass in some existing research groups in South Africa (or creating new ones at the IATM) and by the introduction of an attractive scholarship scheme for post-graduate programmes that specifically address the needs of formalising and developing African Traditional Medicine.

4.4.2 Research Plan

The focus of research should primarily be on the quality, safety and efficacy of African Traditional Medicine through an evidence-based public health and epidemiological approach, supported by laboratory-based investigations. The research platform will allow for a high standard of scientific excellence in African Traditional Medicine research and provide Government, consumers, and providers of traditional forms of health care with the highest level of product information, standardized botanical extraction, and clinically substantiated ingredient claims. Through this advanced science and extensive research to be conducted within the NIATM, high-quality evidence-based African Traditional Medicine will be developed to meet the growing needs of the South African public and allow for the practice of traditional medicines with scientific rigour alongside conventional medicine. The research focus will also result in the development of regulatory guidelines for African Traditional Medicine and a national pharmacopoeia and monographs of medicinal plants.

It is of critical importance that African Traditional Medicine knowledge be preserved for the purposes of both treatment and research. It may be necessary for the Department of Health after finalisation of the African Traditional Medicine policy to take interim steps to collect and preserve African Traditional Medicine data from African Traditional Medical Practitioners in circumstances where such knowledge may get lost. An example of this may be where a Traditional Healer has extensive knowledge of medicinal plants and their uses but have not been able to pass this knowledge on to his heirs.

The following research priority areas need to be addressed through well developed, scientifically rigorous and ethically approved research protocols:

- To document and catalogue African Traditional Medicine so as to produce a pharmacopoeia on African Traditional Medicine.
- To establish an African Traditional Medicine Information System (ATMIS) that can document usage patterns of African Traditional Medicine,

adverse events and report on safety issues through a process of phyto-pharmacovigilance.

- To develop scientifically rigorous population-based studies including clinical trials that can test African Traditional Medicine interventions within the context of ethno-medicine in order to reduce the risk of communicable and non-communicable diseases.
- To extract and isolate the active moieties for standardisation of extracts and use as markers in clinical investigations. This process will also lead to the production of fingerprint profiles for African Traditional Medicine for the purposes of authentication and quality control. Such markers can also assist in the validation of the accuracy, sensitivity, and specificity of the effects of plant-based therapeutics on known endpoints and their surrogates associated with specific chronic diseases.
- To elucidate biochemical mechanisms and explore the cellular effects that African Traditional Medicine can have on biological systems. As an adjunct to population-based studies, laboratory-based research will be undertaken to explore biologic variables related to acute and chronic use of ATM, which could provide biological plausibility to the clinical outcomes.
- Plant extracts will also be tested using animal models relevant to the disease under investigation.
- To develop validated analytical quality control methods necessary for the adoption of good manufacturing practices (GMPs).
- To inform and educate scientists, health care providers, and the public about the benefits and risks of African Traditional Medicine.

4.4.3 Basic Science Research

The priority areas outlined above indicate that basic science research is critical to developing quality criteria, reference standards for use in clinical trials, exploring and elucidating biological mechanisms for the therapeutic effects and providing a path for compliance of GMP.

4.4.4 Clinical Research on African Traditional Medicine

With regards to clinical research, the scope and design of such studies should be based on information on traditional use obtained from relevant literature, or by consultation with traditional medical practitioners. The requirements to prove efficacy must take cognizance of the extent of traditional use and the experience with a particular traditional medicine and supportive pharmacological data.

Clinical trials for African Traditional Medicine should form a part of the regulatory framework in order to provide investigators with clear and transparent requirements for conducting such trials. The requirements will

ensure the safety of trial participants while recognizing the differences between African Traditional Medicine and conventional pharmaceutical products. This framework will also allow for new combinations of African Traditional Medicine to be tested that do not have a long history of traditional use. Whilst the requirements will be similar to that of drugs, in that we need to ensure the protocol is sound and that participants are not placed at undue risk, the uniqueness of African Traditional Medicine must be taken into account. For instance, the active ingredient of African Traditional Medicine may not be known, or the action may be due to a complex mixture of substances. The methodologies used (at great expense) by the pharmaceutical industry to develop new chemical entities is therefore not appropriate. Different research methodologies and registration processes will therefore need to be developed and used in the scientific evaluation of traditional medicines. The level of the evidence must also correspond to the nature of the illness to be treated

The study design should be evaluated, taking note of, for example, the number of patients, specific diagnosis, dosage, duration of administration, criteria for evaluation (such as improvement of symptoms), absence of simultaneous therapy, and valid statistical analysis. With respect to safety, reported and documented side-effects of the Traditional Medicine and constituents of the Traditional Medicine should be taken into account. Suggested preclinical data should include immunotoxicity, genotoxicity, carcinogenicity and reproductive toxicity.

It is also important that clinical studies be carried out primarily on patient volunteers within the communities that use the Traditional Medicine under investigation as their standard care. Selecting patient volunteers from the communities for such studies does not carry more than minimal risk but doing so for healthy volunteers may constitute more than minimal risk.

Based on their extensive use in humans, common well established African Traditional Medicine may have sufficient information to support limited pilot clinical study with little pre-clinical testing especially when the African Traditional Medicine are prepared in the same way, used in the original form from the traditional healer and if the trial is to be carried out in the same community that use them. However, new plants or new formulations of the African Traditional Medicine may bear different characteristics and scientific behaviour from the original products. These should therefore undergo full scale pre-clinical and clinical evaluation. The general guidelines for clinical research on ATMs from the WHO can be consulted in this regard (20)

4.4.5 Ethical Issues and Agreements in Research

The key players in the exploitation of African Traditional Medicine include the traditional healers who often hold the traditional medical knowledge in trust on behalf of the community, the research scientists whose obligation it is to do research and advance knowledge in medicine and health care, pharmaceutical industry that will bring forth the medicines and medicinal products of research to the public, and the larger society that will ultimately benefit in health and disease. However, in the clinical development of African Traditional Medicine, the tripartite relationship between the researcher, the healer and the research participant is most paramount. The researcher and healer relationship should therefore be resolved based upon mutually agreed terms in the form of prior informed consent or a memorandum of understanding so as to facilitate smooth research on these resources. This measure would enable the healers to divulge information about their remedies according to the confidentiality rules after signing a prior informed consent form. The community and the healers should be educated during the consent process about the time and resources required to carry out research. In addition, the healers and their community should be involved in the ownership of the project and its outcome including patents.

A National Ethics Committee for African Traditional Medicines Research should be formed, consisting of both orthodox phytochemists and clinical triallists with experience in African Traditional Medicine research, as well as traditional health practitioners. This will obviate the confusion that has often occurred when proposals for African Traditional Medicine research are submitted to Ethics Committees that have little understanding or experience in the field; and whose members are not representative of the communities that use African Traditional Medicine. A National Ethics Committee for TM should be established.

4.4.6 Education and Training

The Institute can in the process of research, educate both the public on African Traditional Medicine and provide research capacity development. In addition, it may also be possible to develop continuing education programs for traditional healers. The multidisciplinary team with the NIATM composed of research scientists, clinical research associates, postdoctoral personnel, traditional medical practitioners and postgraduate students will contribute vastly to scholarly knowledge and human capacity development in the area of African Traditional Medicine. Research findings must be backed by research translation and dissemination of findings so as to promote and integrate safe and effective practices as well as to create a sustainable research infrastructure on African Traditional Medicine that spans a range of health

disorders and disciplines. Such research will also provide a wealth of data sufficient to meet the criteria for regulatory purposes and hence provide a domain for such therapies to be integrated into an overall concept of modern medicine.

In order to educate the broader community in terms of all aspects of African Traditional Medicine, all research activities should be highly visible. This visibility can be achieved through publications in popular and scientific media, direct and continuous networking with important stakeholders such as government traditional healers and communities. The outlined research focus areas will serve as a pre-eminent source of credible scientific information on the quality, safety and efficacy of African Traditional Medicine and will increase the availability of scientifically valid information critical to helping (1) the public make decisions about the use of African Traditional Medicine in health care and (2) increase the information available to health care providers and investigators in other disciplines to improve their understanding of and research on the roles of African Traditional Medicine in health care delivery.

This platform can also facilitate the integration of scientific information on African Traditional Medicine within the standard academic education curriculum of health and allied professions and continued education programs for health care providers and traditional healers. Research translation will also form a core function and information should be updated on the ATMIS to incorporate important new research findings.

Courses on the different components of traditional medicine can be introduced early in teaching curricula for health care providers to make them aware of the importance of traditional medicine in the context of their cultural settings. Elements of modern medicine should also be taught to traditional health practitioners in order to make their work more effective.

4.4.7 Research Funding and job creation

Research funding is essential to provide the expensive equipment necessary to produce high quality research. Trade in medicinal plants is playing an important role in the internal economies and providing employment to many people within the county. Hence Government should be funding the research. Research on African Traditional Medicine would also be an economic driver in the same way that biotech is an important sector in emerging economies such as India, Brazil and South Korea - employing many in downstream and associated industries.

CHAPTER FIVE

5.1 Cultivation and Conservation of South African Medicinal Plants and animals

There is a large number of role players already actively involved in the conservation and cultivation of medicinal plants, as well as in the development of strategies for product development.

Notable examples are the Department of Environmental Affairs and Tourism (promotes conservation of medicinal plants), the Agricultural Research Council (research best conditions for growing and propagation of medicinal plants), the Department of Science and Technology through a) National Indigenous Knowledge Systems office (dealing with codification of African Traditional Medicine Knowledge practices) and b) the Council for Scientific Industrial Research (involves in bio-prospecting and research in medicinal plants), the Medical Research Council and universities (that deals with research in African Traditional Medicine) and the private sector (involved in the production and commercialisation of African Traditional Medicines).

These role players are also involved in other aspects of African Traditional Medicine South Africa and the need for collaboration and coordination also exists in other aspects.

The Biodiversity Act and the regulations on bio-prospecting, access and benefit-sharing[1] have an important impact on all activities relating to the conservation and cultivation of indigenous medicinal plants for commercial purposes and the conservation of other organisms, including animals.

The collection, use, propagation, cultivation or trade of indigenous biological resources for domestic use or subsistence purposes are exempt from Chapter 6 of the act[2]. "Domestic use" is defined as "using indigenous biological resources for direct consumption or other traditional practices and excludes the development of new products for commercial or industrial exploitation either alone or in partnership with third party".

[1] Government Gazette No. 30739 of February 2008
[2] Government Gazette No. 30739, page 68, point 2.5

5.2 Recommendations

It is recommended that the *National Institute of African Traditional Medicine*, play a coordinating role to ensure safety, quality and timely availability of African traditional medicines and raw materials.

It is recommended that traditional medicine be classified into two categories (similar to the policy adopted by Indonesia through their Health Law Act of 1992, where medicines used by individuals or in family recipes are regulated in a different manner than those produced for the general public):

> Category 1. Indigenous plants, animals or other biological materials for domestic use. General regulations and principles of conservation need to be observed. A strategy should be developed to assist traditional healers in the conservation and cultivation of rare or threatened plant species or to research and demonstrate the viability of alternative options.
>
> Category 2. Indigenous plants used for the commercial production of medicines. The regulations on bio-prospecting provide for detailed procedures regarding access and benefit-sharing. As a result, the Department of Environmental Affairs and Tourism will document and regulate the cultivation and production of raw materials and medicinal products. A strategy should be developed to coordinate the activities of the various role players to ensure the safety, quality and timely availability of medical products and raw materials.

In principle, the development of commercial medicinal products should be limited to cultivated raw materials (a policy to exclude wild-harvesting was adopted by Mali in 1995, for example). Wild-harvesting can only be allowed under exceptional circumstances (e.g. when the plant occurs in abundance and when only leaves are harvested). It is envisaged that the viability of product development will be severely limited by the availability and sustainability of raw materials such as bark and bulbs, and that these materials may gradually be replaced (e.g. the commercial use in South Africa of *isibhaha* leaves instead of the bark). There are many arguments for and against the use of wild-harvested materials as apposed to cultivated materials, but practical considerations will ultimately determine the choice and long term sustainability.

The agricultural production of medicinal materials of a consistent quality is a complicated process that should be supported by a sophisticated research and analytical infrastructure. The *National Institute of African Traditional Medicine*, in collaboration with the *Medicines Regulatory Authority*, can play an important role in researching and determining quality standards and in guiding and educating the role players. Consideration will have to be given to the choice of varieties (chemotypes, chemical variants) of medicinal plants and the standardisation of cultivation practices to ensure safety, quality and efficacy.

The establishment of an *Advisory Board on Medicinal Plants* is recommended, to give advice on the conservation, cultivation and harvesting of South African medicinal plants at all levels of Government. It is recommended that support mechanisms must be put in place by government to facilitate the establishment of a manufacturing industry that will include large-scale established manufacturers, small and medium enterprises, co-operatives and individual entrepreneurs, with due consideration for black business economic empowerment.

CHAPTER SIX

6. PHARMACOPOEIA

A comparative study has shown that in most countries of the world, the starting point in the process of regulation of traditional medicine is the official pharmacopoeia. The pharmacopoeia provides a list of medicines that is considered safe to use for narrowly specified indication(s) and also gives data on the correct identity of the substance, its composition and other relevant information relating to dosage, safety and efficacy. The purpose of the pharmacopoeia is to regulate over-the-counter medicine and to give marketing authorization for such medicines. Since there is no intervention from a health care practitioner, potentially toxic substances should be excluded. Animal products, although an important component of Traditional Medicine, are usually also excluded because they are rarely suitable for large-scale commercialization and are best used by HPs within the safeguards of traditional practise.

The *African Pharmacopoeia* (published in French in 1985) included mainly non-African plants and was never official in any African country. It is therefore considered inappropriate as a model for South Africa. Two other African initiatives are currently underway: (1) The *Association for African Medicinal Plant Standards (AAMPS)* project, where profiles of the most commercially important African traditional

medicinal plant species are being written up as monographs by a panel of experts from all parts of Africa; (2) The monograph project of the University of the Western Cape. The AAMPS and UWC monographs are scientifically useful documents but are not suitable for use as an official pharmacopoeia.

Unlike other countries in Europe, herbal medicines have a special status in Germany. It is therefore recommended that the German legal and regulatory system be closely studied and used as a guideline. The Chinese model should also be reviewed and used as a guideline for the development of a *National Pharmacopoeia of African Traditional Medicine in South Africa*.

Published information on a large number of indigenous medicinal plants is already available. Furthermore, the necessary local expertise is available to produce a national herbal pharmacopoeia, and it is proposed that a similar procedure is adopted as was done for the German Commission E. The pharmacopoeia should be generally and widely accepted (and sanctioned by the state). A transparent process should therefore be followed and monographs should be produced and reviewed by panels of experts. It is recommended that only plants already in the public domain and already commercialized to some extent be considered for inclusion in the first volume. This will limit the initial task to approximately 25 plants for which at least some data on safety is available. The choice could include dietary supplements and functional foods (e.g. rooibos tea and hoodia). Explicit details should be given on the allowed indications and dosages.

6.1 Recommendations

It is recommended that a national pharmacopoeia of African Traditional Medicine in South Africa be developed. It is further recommended that the following strategy should be adopted in developing such pharmacopoeia:

- Develop the legal framework for producing an official, national pharmacopoeia.
- Appoint a pharmacopoeia commission, with all necessary disciplines represented (similar to the composition of the German Commission E).
- Evaluate indigenous medicinal products and develop monographs.

- Appoint an international panel of experts to review the monographs and recommend improvements.

- Translate the pharmacopoeia into the other official languages.

- Publish the pharmacopoeia (as individual monographs or as a single volume).

CHAPTER SEVEN

GENERAL RECOMMENDATIONS

7.1 Information and Communication

Information and communication tools should be put in place to promote African Traditional Medicine in South Africa and facilitate its acceptance and inclusion in the National Healthcare System. Activities to realize this objective will entail amongst other things the following:

Development of National information and communication strategies in African Traditional Medicine in South Africa.

An Interministerial Committee on African Traditional Medicine may need to be established in order to ensure coordination between government departments in growing, developing and institutionalising African Traditional Medicine. The Ministry of Health would chair such a committee.

Establishment of an appropriate Journal on African Traditional Medicine to deal with issues and trends, current and emerging in the area of African Traditional Medicine.

Sensitization of the society on African Traditional Medicine through campaigns for recognition and legitimacy of African Traditional Medicine and Knowledge.

Protocols or guidelines for communication on African Traditional Medicine to all sectors.

7.2 National African Traditional Medicine Strategy / Implementation Plan

It is recommended that a national implementation plan be developed by the National Department of Health.

It is recommended that a resource mobilisation plan be devised to facilitate and ensure the implementation of all aspects of the African Traditional Medicine policy.

It is recommended that there should be regulation of initiation, circumcision and virginity testing practices for the purpose of benchmarking (traditional surgeons and circumcision schools).

REFERENCES

1. WHO Policy Perspectives on Medicine No. 2 May 2002, Traditional Medicine – Growing Needs and Potential

2. The Alma-Ata Declaration of 1978

3. Regional Strategy for Traditional Medicine in the Western Pacific, World Health Organization, Western Pacific Region, Manila, 2002, pp. 9-10

4. Van Wyk, B-E., Van Oudtshoorn, B., Gericke, N. *Medicinal Plants of South Africa*, Briza Publications, (1997) Pretoria, SA.

5. SA Health Review 2007

6. Government Gazette No. 29288, 2006

7. WHO 2001, Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review

8. Patents Amendment Act No. 20/2005

9. Van Wyk, B.E. and Gericke, N. People's plants: A guide to useful plants of Southern Africa. Briza Publications, (2000) Pretoria, p7.

10. Evans, W.C., Trease & Evan's Pharmacognosy, 13th Ed., Alden Press, Oxford, UK (1989), p.617.

11. www.statssa.gov.za. Mortality and causes of death in South Africa from 2003-2004. Statistical release P0309.3.

12. Mbewu A. D. Introductory remarks: African Perspective on Natural Products and Molecular Medicine. Annals of the New York Academy of Science. Vol. 1056 Page 15 November 2005.

13. Mander, M. (1998) Marketing of Indigenous Medicinal Plants in South Africa:

A Case Study in KwaZulu-Natal. Food and Agriculture Organization of the United Nations.

14. Bannerman R, Burton J, Chen WC, eds. *Traditional Medicine and Health Care Coverage*. Geneva, Switzerland:World Health Organization; 1983

15. Hutchings, A., Scott, A.H., Lewis, G., Cunningham, A. *Zulu Medicinal Plants, An Inventory*, University of Natal Press, (1996) Scottsville, SA.

16. Wiese, M., Kruszewska, S., Kolacinski, Z. (1996) Acute poisoning with Diffenbachia picta. Vet. Hum. Toxicol., 38, 356-358.

17. Schneider, F., *et al*. (1996) Plasma and urine concentrations of atropine after the ingestion of cooked deadly nightshade berries. J. Toxicol. Clin. Toxicol., 34, 113-117.

18. Chan, T.Y.K. (1997) *Monitoring the safety of herbal medicines*. Drug Saf., 17, 209-215.

19. Awang DVC (1997). Quality control and good manufacturing practices: safety and efficacy of commercial herbs. *Food and Drug Law J*., 52, 341-344.

20. World Health Organization (2000). General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine. World Health Organization, Geneva.