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Government Gazette No. 31265 is hereby withdrawn and substituted by the following: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

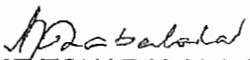
The draft policy on African Traditional Medicine comes at a time when the public health care system is in a dire need to reflect the diverse health disciplines which the citizen utilize for their healthcare needs in South Africa.

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

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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 Health 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 world's 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 Health 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 Commission 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 Commission E Monographs