

3. Global experiences of traditional medicine



3.1 The WHO African Region

About 80% of the population living in the African Region use traditional medicine for their health care needs (AFR/RC50/R3/2001), however the development of traditional medicine varies widely in different countries in the WHO African Region. Most countries do not have national policies and regulations on traditional medicines. Generally, the use of herbal medicine in the region is not adequately documented. Most traditional medicines which are claimed to provide “effective cures” for various diseases lack scientific evidence for safety, efficacy and quality. These herbal medicines are sold in the open markets, stores, homes, etc. to the public with possible adverse consequences. Furthermore, most countries in the region have not established safety monitoring mechanisms for traditional

medicines (i.e.

both imported and locally produced) in the market.

About two thirds of AIDS patients in the developing countries use traditional medicines to obtain symptomatic

relief and manage opportunistic infections (UNAIDS Report 2002). Traditional medicines are used in the WHO African Region for many other diseases such as sickle cell anaemia, diarrhea, microbial infections, diabetes, hypertension, etc.

A number of countries in the WHO African Region have made important strides in the area of traditional medicine in terms of policies and regulations. Countries like Nigeria, Mali, Ghana, Uganda, Zambia, Zimbabwe, to mention a few, have made major breakthroughs in the area of regulation of traditional medicine and have put in place legislative machinery to officially recognize and empower traditional medicine as part of the public health care delivery system. However, the majority of countries in the region are still trying to formulate the legal status of traditional medicine.

3.2 Other regions

The use of traditional medicines is not only limited to Africa. Traditional medicines usually have a long history of use and are linked with the culture of a specific group e.g. Chinese, Indians etc. Traditional medicines used today are mainly of plant origin.

Some countries have a long history and rich heritage of traditional medicine use and practice, and have gone further to develop appropriate and practical regulatory framework for traditional medicine.



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Pharmacopoeia and monographs have also been developed and documented for some medicinal plants. The experiences of these countries (some of which are mentioned below), and the efforts of the WHO regionally and globally, continue to inform and guide the South African regulatory initiatives as spelled out in the National Reference Centre for African Traditional Medicines strategy.

3.2.1 China

China has possibly the greatest amounts of documentation concerning herbal plants of almost any country in the world. The knowledge about Chinese medicine had accumulated over thousands of years, and had been confirmed through both empirical experience and scientific evaluation.

Diagnosis and treatment are based on the holistic view of the patient and the patient's symptoms. Chinese medicine encompasses a range of practices, including acupuncture, herbal medicines, manual therapy exercises, breathing techniques, and diets. Chinese

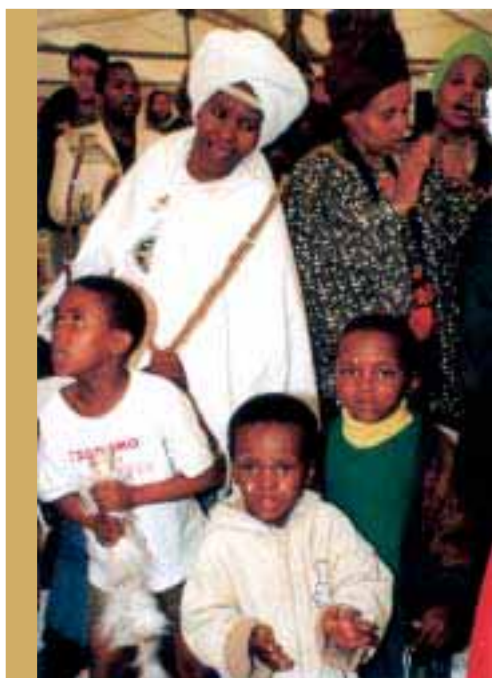
medicine, especially acupuncture, is the most widely used traditional medicine.

Traditional medicines account for 30% to 50% of total consumption. There are well-established manufacturers of herbal products, farms for cultivation and production of materials for traditional medicines, and research institutions.

The integration of traditional medicine into the national health care system and the integrated training of health practitioners are both promoted by the People's Republic of China. The government has reinforced its commitment to the integration of traditional and allopathic medicine on a number of occasions. The Constitution of China promotes both allopathic and Chinese medicine. Both systems cooperate with each other, learning from each other's merit to make up their own shortcomings.

Early publications on herbal medicines appeared during the Shang-Zhou dynasties (2000-220 BC). The earliest work on Chinese herbs (about 101BC) covered 365 agents and some of the entries had been given some credence by as a result of recent scientific investigations. Later herbal publications followed, with the appearance of the first world pharmacopoeia in 659AD.

Chinese medicine continued to develop with the establishment of traditional



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medicine colleges and institutions. The medical education is integrated in China with every medical school containing a department of traditional medicine and vice versa.

3.2.2 India

Traditional medicine is used by over 70% of the population. For centuries, ayurveda, siddha, and unani-tibb systems of medicine have coexisted with yoga, naturopathy, and homeopathy. All these systems are well integrated into the national health care system. There are state hospitals and dispensaries for both traditional medicine and homeopathy.

The traditional Indian system of medicine is recognized by the government of India through a proper regulatory framework in the form of the creation of the Central Council of Indian Medicine Act of 1970 and Central Council of Homeopathy, constituted in 1973, which prescribe minimum standards of education in traditional medicine; advise government in matters relating to qualifications in traditional medicine; to maintain register of Indian medicine; provide standards for professional conduct; and develop code of ethics for practitioners of traditional medicine.

The Department of Indian Systems of Medicine and Homeopathy is primarily responsible for, among others, education,

standardization of medicines, enhancement of availability of raw materials, and research and development. Traditional medicine formularies and pharmacopoeias have been developed.

The government is presently working to standardize the training of traditional medicine practitioners and homeopaths.

3.2.3 Indonesia

Traditional medicine provides an important resource of for self-care within the health services and through traditional medicine practitioners. Forty percent of the population uses traditional medicine, 70% in rural areas. Over 350 monographs for herbal medicines have been produced in Indonesia and standards for good manufacturing practice for all such products have been applied since 1991.

Traditional medicine practitioners are divided into four groups: herbalists, skilled practitioners, including traditional birth attendants, circumcisers, bonesetters, masseuses, and traditional dentists, spiritualists, and supernaturalists. Health Law Act 23 – 1992 places traditional medicine as an integral part of curative and nursing care, and also provides for supervision of traditional medicine to ensure its safety and efficacy; and for development and improvement of forms of traditional medicine deemed safe and efficacious. The center for Traditional

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medicine research offers training in traditional medicine.

3.2.4 Thailand

Traditional medicine practitioners represent an important resource for the Thai health care strategy. The Thai traditional medicine draws from Indian and Chinese systems. It encompasses a holistic philosophy and is based principally on plants, including the use of herbal saunas, herbal medicines, herbal steam baths, and hot compresses; traditional massage; acupuncture; and reflexology.

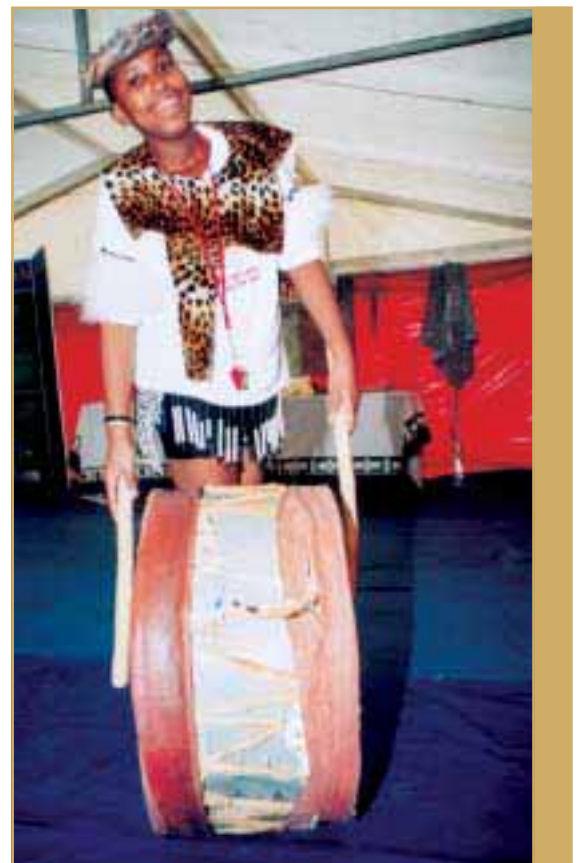
The Thai traditional medicine has a well-recorded history dating as far back as 1182. Traditional medicine formularies have long been compiled and received official endorsement.

The Thai Government has a policy to promote traditional treatments within the national public health care system, and also develop research into medicinal herbs, train traditional medicine practitioners, and make use of medicinal herbs and traditional medicine practitioners in an official capacity. The National Institute of Thai Traditional Medicine, established in 1993, was charged with facilitating the integration of Thai traditional medicine into the public health services, and also establishing the Thai Traditional Medicine Training Centre, where a variety of programmes from pharmacy to Thai traditional healing and reflexology are offered. All types of

traditional medicine practitioners are registered with the Medical Registration of the Ministry of Public Health.

3.3 The WHO initiatives on African Traditional Medicines

The World Health Organization (WHO) advocates the reversal of the culturally biased notion that traditional health practitioners are quacks and charlatans who should be discouraged. In 1977, the 30th World Health Assembly adopted a



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resolution to promote traditional medicine worldwide. A year later at Alma Ata it was declared that African Traditional Practitioners should be part of the primary health team. In the spirit of these resolutions there have been numerous attempts at collaboration between traditional health practitioners and biomedicine personnel throughout the world. A WHO Africa Regional Expert Panel on traditional medicine was set up in 1975 to undertake consultations and prepare working documents.

The WHO works to provide its Member States with technical guidance to ensure the safety, quality control, and efficacy of herbal medicines as well as the rational use by health practitioners and the general public. A number of guidelines, monographs and related documents covering several issues relevant to the production, quality control and use of herbal medicinal products have been issued over the years.

In order to support Member States to facilitate the evaluation of traditional

medicines for registration purposes, a meeting was held in April 2003 in Johannesburg, South Africa, to discuss and amend a draft document entitled “*Guidelines for Registration of Traditional Medicines in the WHO African Region*”. During the workshop, the minimum regulatory requirements for registration of traditional medicines were determined. Guidelines for control of advertisements for traditional medicines were also reviewed. As far as ethics is concerned, the international ethical guidelines for biomedical research involving human subjects should be implemented in each clinical trial, and amended accordingly.

Recommendations have also been made to the WHO African Region member states to establish or review national regulation of traditional medicine; strengthen existing drug regulatory agency to cover traditional medicines; set up structures to regulate traditional medicine practice; support scientific research of traditional medicines; speed up the integration of traditional medicine into national health system.

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4. A model for South Africa: The National Reference Centre for African Traditional Medicines



4.1 Identification of needs

There is wide agreement amongst stakeholders that the status of African Traditional Medicines in South Africa is highly unsatisfactory. The Department of Health took the initiative to coordinate a process of establishing the National Reference Centre for African Traditional Medicines in 1997. Considerable preliminary work has already been done to date in this regard.

A number of meetings involving interest groups and stakeholders in traditional medicines from all areas of the country have been held. Stakeholders have comprised, among others, the Medicines Control Council, universities, traditional healer organizations, research institutions, Agricultural Research Council, Medical Research Council, and Council for Scientific and Industrial Research. A way forward in terms of strategies has been mapped out, resulting in the establishment of working groups and special committees to look at key areas of utmost interest in African Traditional Medicines. These areas include claims for cure; intellectual property rights and patents; research and development; education and training; database development; and propagation and conservation.

There is a plethora of issues that must be addressed before the therapeutic potential

of medicinal plants can be used to create health, social and economic benefits for people of the region. A number of Government Departments contribute to addressing these issues, categorized as follows:

4.1.1 Policy and a regulatory framework for controlling African Traditional Medicines

The National Drug Policy and the draft Traditional Healers Bill of the **Department of Health** address certain aspects relating to traditional medicines. However, there is a need to have a focal point on African Traditional Medicines in the Department of Health, to develop policy and a regulatory framework specifically for African Traditional Medicines

4.1.2 Conservation of medicinal plant species

The draft National Environmental Management Biodiversity Bill of the **Department of Environmental Affairs and Tourism** addresses the conservation of biodiversity of the country. The draft Bill proposes a permit system to control access to biodiversity, such as medicinal plants, for commercial purposes. The successful development and regulatory approval of a traditional medicine will create a high demand for the medicinal plant. Resources will therefore be required to control access to scarce medicinal plants

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in the wild, and to establish suitable propagation techniques such as tissue culture.

4.1.3 Protection of the intellectual property rights of Traditional Healers

The **Department of Science and Technology** has drafted an Indigenous Knowledge Systems Bill that is aimed at protecting the rights of owners of indigenous knowledge. The knowledge Traditional Healers have on the medicinal properties of indigenous plants is of particular relevance.

The **Department of Trade and Industry** is amending the Patents Act to bring it into line with the provisions of the international Convention on Biological Diversity(CBD) and the National Environmental Management Biodiversity Bill. The Patents Amendment Bill aims to protect and empower holders or owners of indigenous knowledge by introducing compulsory disclosure requirements on the origin of the genetic or biological resource or traditional knowledge upon which a patent is based.

4.1.4 Availability of resources to scientifically validate the efficacy, quality and safety of

African Traditional Medicines, facilitate regulatory approval of medicines and establish businesses for the supply of approved medicines

The **Department of Health** proposes the establishment of a National Reference Centre for African Traditional Medicines to coordinate the scientific and technological resources required to develop, register and produce traditional medicines of guaranteed efficacy, safety and quality. The strategy, objectives, participants and structure of the NRCATM are discussed in greater detail below.

4.2 A proposed strategy for the National Reference Centre for African Traditional Medicines (NRCATM)

The **vision** of NRCATM is to advance the contribution of African Traditional Medicines to the health and well being of people of the region.

The **mission** of NRCATM is to promote the scientific validation and production of high quality, safe, and effective medicines based on African Traditional Medicines, thereby contributing to health care, job creation, education and training,

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conservation of medicinal plants and equitable benefit sharing with owners of Indigenous Knowledge.

4.2.1 The NRCATM will conform to the following guiding principles:

- **Accessibility.** The NRCATM will be accessible to all stakeholders in traditional medicines, including Traditional Healers, Government Departments, regulatory authorities, scientists, medical professionals, toxicologists, conservation authorities, communities and the manufacturing sector.
- **A virtual centre without walls.** The Centre will aim to establish a national network of experts and facilities that provides access to education and training, and scientific and technological capabilities required to fulfill its mandate.
- **Environmental responsibility.** The NRCATM will collaborate closely with conservation authorities to ensure opportunities for improving the conservation status of medicinal plant species are pursued.
- **Intellectual property rights of owners of indigenous knowledge.** The NRCATM undertakes to safeguard the intellectual property rights of Traditional Healers and communities and promote opportunities for equitable benefit sharing.

- **International best practices.** The NRCATM will whenever possible, investigate and adopt existing technology for the validation and production of herbal medicines available elsewhere in the world.
- **Focus on traditional medicines.** The Centre will focus on promotion of scientifically validated African Traditional Medicines.
- **Transparency of research activities and dissemination of validated data.** There are many stakeholders in traditional medicines in South Africa, therefore the NRCATM will develop policy and protocols for the dissemination of its research findings. The Centre, together with other partners, will ultimately aim to publish a Pharmacopeia of African Traditional Medicines, based on traditional medicines that have been validated in



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controlled scientific and ethical clinical trials and approved by the MCC. In addition, information that is of importance to the public, such as toxicological properties found in indigenous plants, will be made accessible. The NRCATM will be informed by the specific strategic guidelines listed here and by medical ethics in general, when providing an opinion on the possible therapeutic value of specific traditional medicines.

4.2.2 The primary specific objectives of the NRCATM

- Establishment of an information system on African Traditional Medicines;
- Promotion of research and development focused on standardization and authentication of products based on medicinal plants using best international practices such as WHO guidelines;
- Identification of education and training needs of traditional medicine in South Africa;
- Protection of indigenous knowledge and trade promotion through patents and intellectual property rights;
- Establishment of agro-processing businesses based on propagation, cultivation and processing of medicinal plants in a way that promotes sustainability, job creation and trade.

4.2.3 Other specific objectives

- Promoting research into life-threatening, chronic and common diseases that are prevalent in the region
- Fostering and identifying areas of collaboration in African Traditional Medicines research amongst research institutions, academics, parastatals, traditional practitioner associations, non-government organizations, and government departments.
- Facilitating and obtaining maximum returns for the financial investment by Government through various departments, in African Traditional Medicines research.

4.3 Partners/participants in the National Reference Centre activities

The National Reference Centre for African Traditional Medicines will consist of recognized experts in their individual fields to help coordinate data and make it readily accessible in order to facilitate mutually beneficial interaction between all parties concerned. Partners involved in the activities of the NRCATM will largely comprise the following:

4.3.1 Government departments

- Department of Health (Medicines Control Council, Medical Research Council)
- Department of Environmental Affairs and Tourism (National Botanical Institute)

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- Department of Agriculture (Agricultural Research Council)
- Department of Science and Technology (Council for Science and Industrial Research, National Research Foundation)
- Department of Water and Forestry
- Department of Education
- Department of Trade and Industry

4.3.2 Non-Governmental Organizations

4.3.3 Universities - almost all South African universities are pursuing some research into traditional medicines

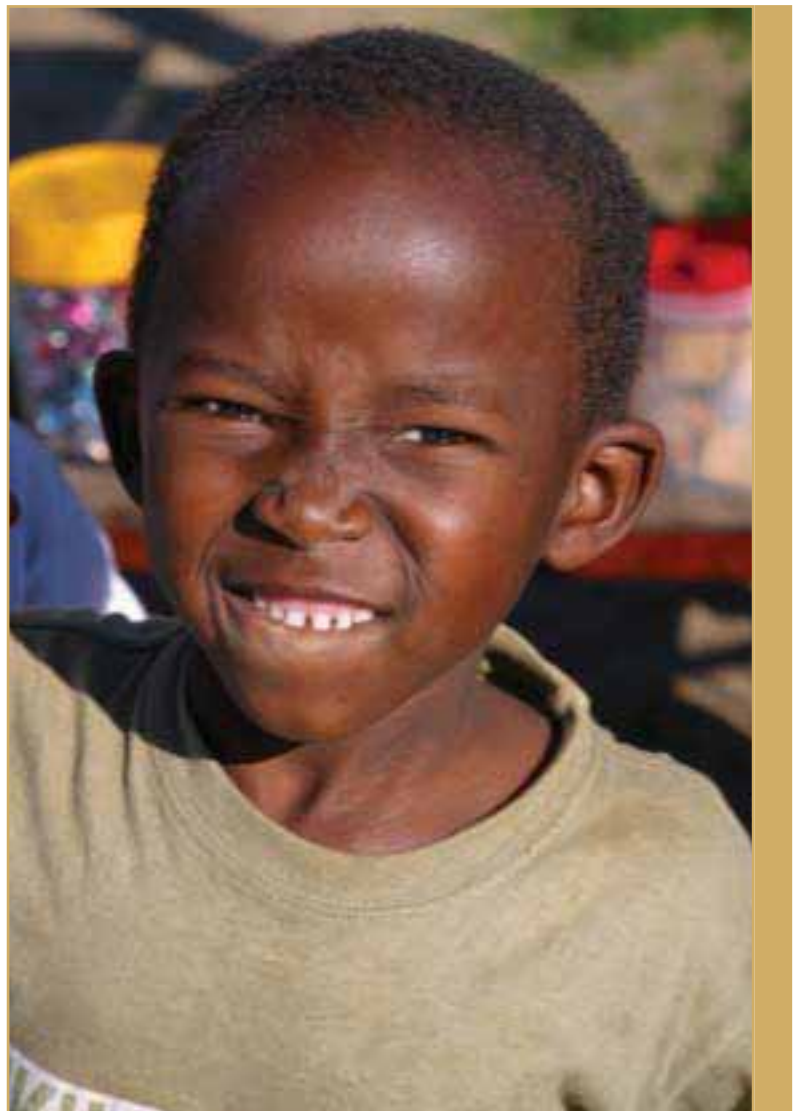
4.3.4 Research Institutions

4.3.5 Traditional Healers

4.3.6 Traditional Healer Organizations

4.4 Trade and poverty alleviation

The National Reference Centre for African Traditional Medicines offers a huge potential for trade promotion and job creation. The natural resources of South Africa constitute a national asset which is essential for the economic welfare of present and future generations. With scientific support, application of sound business principles and political will, a



wider potential for trade in medicinal plants is created.

The cultivation of medicinal plants provides opportunities for establishing agro-processing businesses, job creation and poverty alleviation, particularly for rural communities. Local production of

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traditional medicinal products of proven quality and efficacy may present an affordable alternative to some expensive, imported synthetic drugs. It is essential that development of this important natural resource takes place locally and not at the hands of overseas entrepreneurs, as has happened with many of the most horticulturally valuable species. The IKS Health Centre has a 19ha piece of land earmarked for development and cultivation of scientifically validated medicinal plants. The CSIR has established facilities required to develop and produce world-class medicinal products based on indigenous plants. The organization has already successfully established small agro-processing businesses in the formal as well as community farming sectors in most of the Provinces of South Africa.

Traditional medicines are also an important source of drug leads. Conventional medicine also relies on plant-derived drugs to the extent that about 30% of prescription drugs have their origins in the plant kingdom. Only a small percentage of all known plant species have ever been investigated for medicinal potential and there is currently a worldwide resurgence of interest in the screening of plants for new pharmaceuticals. The development of new drugs offers both economic and health benefits, as the costs of drugs produced by the pharmaceutical industry are often prohibitive in developing countries. The

NRCATM will endeavour to optimise the economic value inherent in African Traditional Medicines.

4.5 The Proposed structure of the National Reference Centre for African Traditional Medicines

4.5.1 Management

The National Reference Centre for African Traditional Medicines is being launched as a virtual Centre drawing on multi-disciplinary expertise throughout South Africa. The Department of Health, CSIR and MRC will establish a Management Board for the NRCATM. The CSIR and MRC will be contracted to manage the NRCATM on behalf of the Department of Health. The main responsibilities of the Management Board will be as follows:

4.5.1.1 Develop and implement an operational plan for the successful implementation of the vision, mission and goals of the Centre (cf. paragraph 4.2). Advise Department of Health on strategic issues that affect the NRCATM, such as local and international developments in traditional medicines, appropriate structure for NRCATM, funding requirements, etc.

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4.5.1.2 Establish networks and collaboration with stakeholders in Traditional Medicines (cf. paragraph 4.3)

4.5.1.3 Ensure that the outputs of the NRCATM are optimised in favour of promoting trade and poverty alleviation (cf. paragraph 4.4)

4.5.2 Operations

The planned operations of the Centre and the way it interacts with stakeholders are depicted in Table 2.

4.5.3 Operational outputs of the NRCATM

4.5.3.1 Database of Traditional medicine: a novel information management system

The database will be populated with all known anecdotal information on African Traditional Medicines, including claims for cure and suspected toxicity of medicinal plants. The database construction allows the capturing of confidential, previously undisclosed indigenous knowledge on use of medicinal plants.

Table 2. Summary of Functions of the NRCATM

NRCATM Management Board (Department of Health, CSIR, MRC)	Operations Manager	Functions	Collaborators/Contractors/Resources
		1. Database of Traditional Medicines	<ul style="list-style-type: none"> Traditional Healers CSIR, MRC and National Botanical Institute (NBI) existing databases Publications
		2. Selection of candidates for research (Product definition)	<ul style="list-style-type: none"> CSIR/MRC Health professionals Government priority areas
		3. Biological and chemical studies	<ul style="list-style-type: none"> CSIR/MRC Universities CRO
		4. Good Manufacturing Practice (GMP) supplier of Products, including Good Harvesting and Good Farming Practices	<ul style="list-style-type: none"> CSIR Community Farmers Commercial Farmers Government Departments (Agriculture, Conservation)
		5. Pre-clinical studies on Products	<ul style="list-style-type: none"> CSIR CRO Universities
		6. Clinical studies on Products	<ul style="list-style-type: none"> MRC Universities Private clinicians
		7. Submission of Product dossiers to Regulatory Authorities for approval	<ul style="list-style-type: none"> MRC/CSIR
8. Education and training	MRC/CSIR, Universities		

The database will also be a repository for scientific information found during execution of the operational tasks listed in Table 1. The database will have training modules to assist transfer of such information to Traditional Healers. The database will also be a tool to enhance collaboration amongst stakeholders in different organizations.

Notes:

1. The Department of Health will contract CSIR and MRC to manage the NRCATM
2. CRO is 'Contract Research Organization', typically contracted to undertake efficacy and toxicity studies
3. The Operational tasks 1-7 follow a logical sequence. The Operational Management responsibilities include the contracting of experts to conduct specific tasks

Monographs will be published on traditional medicines that were successfully developed and approved by MCC. The database will make these monographs, as well as scientific publications on

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traditional medicines, easily accessible. The database will also function as a register of traditional medicine projects to prevent duplication of research efforts in different organizations.

4.5.3.2 Selection of candidates for research (Product definition)

A considerable number of indigenous plants are used as traditional medicines. The management of the research programmes of NRCATM will require an ongoing process of selection and prioritisation, based on the needs of all stakeholders. In addition, there is a requirement to define the therapeutic use of the traditional medicine. In many cases the nature and origin of the plant material makes the development of a registered traditional medicine not feasible (e.g. the bark of a very scarce tree, or plant species threatened by extinction).

It is important to note that the NRCATM will not attempt to investigate the safety, quality and efficacy of traditional medicines in the form of roots, bark or any other form currently traded on the street. The Centre will develop minimally processed herbal medicine versions of African Traditional Medicines,

typically in the form of tea bags, milled plant material or simple extracts in capsules or tablets (referred to as 'Products' in this document).

The information and decisions relating to Product definition will be of great importance to all stakeholders, for example Traditional Healers and conservation officials. It can be reasonably expected that certain traditional medicines will be found by the NRCATM to have unacceptable side effects, in which case Traditional Healers will be encouraged to use substitutes with proven safety profile. A further example is the case of popular but very scarce medicinal plants. The development of an approved traditional medicine by the NRCATM in such cases will require technology for the propagation, such as tissue culture.

4.5.3.3 Biological and chemical studies

This work entails the collection, extraction and biological testing of plant extracts. The CSIR's ongoing chemical and biological studies on its extract collection of 11 000 plant species is a significant resource for NRCATM, but it is envisaged that much of this work will also be



conducted at universities, NBI , and CROs.

The outputs include results of biological assays of plant extracts, which give a first indication of efficacy of the traditional medicine. Chemical studies are undertaken to identify possible classes of chemical substances that are known to be biologically active, either contributing to efficacy or possible toxicity. In addition the chemical studies identify the therapeutically useful metabolites in the medicinal plant for the purpose of quality control.

4.5.3.4 GMP supplies of Products

High-quality medicinal products will be manufactured in the GMP compliant facilities of CSIR, for evaluation in pre-clinical and clinical studies. This work involves the management of supplies of plant material from the wild or through cultivation under Good Farming and Good Harvesting Practice. Related outputs will be the establishment of propagation systems for medicinal plants using modern techniques such as tissue culture. Once the efficacy and safety of a specific traditional medicine have been proved, communities may participate in the supply of

harvested or cultivated medicinal plants.

The outputs expected from this activity is reproducible supply of material with approved specifications, in the first instance for clinical studies and later for production of the approved Product.

4.5.3.5 Pre-clinical studies on Products

The output of this work is information on possible toxicity and *in vivo* efficacy of the Product. During this stage of the development work, the dosage of the traditional medicine is also determined in suitable *in vivo* models.

Significant infrastructure for testing of plant medicines in animal models and non-human primates is located at MRC in Cape Town area, and available at CROs.

The information gained during preclinical studies will form an invaluable part of the regular feedback NRCATM will provide to Traditional Healers.

4.5.3.6 Clinical studies on Products

The MRC will supervise clinical trials that will produce data

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indicating the efficacy, dosage and safety of the products derived from the traditional medicines. Early clinical studies will include maximum tolerance study in a small number of human volunteers. The design of clinical studies will depend on the nature of the therapy under development.

The output of the clinical trials is a dossier to be presented to the MCC for regulatory approval of the product.

4.5.3.7 Submissions of Product dossiers to Regulatory Authorities for approval

The NCRATM will approach the MCC to obtain regulatory approval for the production and distribution of products. Once approval is obtained a monograph on the product will be published.

4.5.4 Other outputs of strategic importance to the medicinal plant trade in South Africa

It can be expected that during the course of scientific investigations described in paragraph 4.5.3, valuable opportunities for economic and social upliftment of the country will be generated. These spin-off opportunities can be categorised as follows:

- 4.5.4.1 Creation of commercially valuable intellectual property that can be licensed to the pharmaceutical industry;**
- 4.5.4.2 Opportunities for benefit sharing with Traditional Healers as defined in the draft IKS Bill;**
- 4.5.4.3 Stimulating industry through establishment of new manufacturing businesses for the production of high quality Products based on traditional medicines;**
- 4.5.4.4 Poverty alleviation and job creation through cultivation and propagation of proven medicinal plants;**
- 4.5.4.5 Diversification of agriculture through creation of opportunities for value-added agro-processing;**
- 4.5.4.6 Opportunities to implement conservation plans for important medicinal plants that are currently under environmental pressure.**

4.5.5 Budget

The NRCATM will propose a business plan for the development of a minimum number of African Traditional Medicines over the following five years. The Department of Health will collaborate with NRCATM in efforts to obtain funding for the activities from government sources.

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