# REPUBLIC OF RWANDA



# MINISTRY OF HEALTH P.O. Box 84 KIGALI

www.moh.gov.rw

# NATIONAL POLICY OF TRADITIONAL, COMPLEMENTARY AND ALTERNATIVE MEDICINE

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#### **FOREWORD**

The Government of Rwanda through the Ministry of Health is committed to achieve the Universal Health Coverage through strengthening primary health care with evidence based policies and strategies including the National Policy of Traditional, Complementary and Alternative Medicine in Rwanda.

The development of National policy of traditional, complementary and alternative medicine was in line with the national and international guiding documents such as Vision 2050, the National Strategy for transformation (NST), National Health Policy (2015) Health Sector Strategic Plan (HSSP IV 2018-2024), the Sustainable Development Goals (SDGs) and; the WHO Traditional, Complementary and Alternative Medicine Strategy 2014-2023.

The policy aims at defining the Traditional, Complementary and Alternative Medicine framework in Rwanda. The various elements examined under the policy include, legislation and regulatory control, registration, manufacture, procurement and supply chain management, rational use of medicines, quality assurance, co-ordination, conservation and protection, research, monitoring and evaluation of Traditional, Complementary and Alternative Medicine practices.

The policy has also been formulated with an inherent flexibility to accommodate future developments and changes in the overall vision of attaining health for all.

The policy of traditional, complementary and alternative medicine was being developed through several stakeholders 'consultations in the Traditional, Complementary and Alternative Medicine area in order to ensure a coherent and a multi-sectoral platform for achieving the main goal of the policy. I wish to express my sincere appreciation to all stakeholders for their contribution and support towards the elaboration of this policy. it will therefore provide the strategic guidance on the better practice of Traditional Medicine in Rwanda, thus ensuring social welfare of Rwandans

I call upon all stakeholders to make joint efforts towards ensuring a safe and sustainable Traditional, Complementary and Alternative Medicine practice and use in Rwanda.

Dr. Diane GASHUMBA Minister of HealtH

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## ACRONYMS AND ABBREVIATIONS

CAM: Complementary and Alternative Medicine(CAM)

CM: Complementary medicine

CURPHAMETRA: Centre Universitaire de Recherche en Pharmacopée et Médicine

Traditionnelle

**EDPRS:** Economic Development and Poverty Reduction Strategy

FAO: Food and Agricultural Organization/Fonds Agro-Alimentaire

HSSP: Health Sector Strategic Plan
INES: Institute of Applied Sciences

IRST: Institut de Recherche Scientifique et Technologique

KOIKA: Korea International Agency

MDGs: Millennium Development Goals

NAPRECA: Natural Product Research Network for Eastern and Central Africa

NGOs: Non-Governmental Organizations

NIRDA: National Industrial Research and Development Agency

OMT: Osteopathic Manipulative therapy(OMT)

Rwanda FDA: Rwanda Food and Drug Authority

SDGs: Sustainable Development Goals

SWAP: Sector Wide Approach

T, C&AM: Traditional, Complementary and Alternative Medicine

TK: Traditional Knowledge

TM: Traditional Medicine

TRIPS: Trade-Related Aspects of Intellectual Property Rights

TWG: Technical Working Group

UNESCO: United Nations Educational, Scientific and Cultural Organization

**UR:** University of Rwanda

WHO: World Health Organization

#### **GROSSARY OF TERMS**

For the purpose of this policy the following terms definitions may apply:

#### Alternative Medicines:

Is treatments that are used instead of standards medical treatments.

## Acupuncture:

This describes a family of procedures involving stimulation of anatomical points on the body by a variety of techniques. American practices of acupuncture incorporate medical traditions from China, Japan, Korea, and other countries. The acupuncture technique that has been most studied scientifically involves penetrating the skin with thin, solid, metallic needles that are manipulated by the hands or by electrical stimulation.

## Aromatherapy:

This involves the use of essential oils (extracts or essences) from flowers, herbs, and trees to promote health and well-being.

## Chiropractic:

This is an alternative medical system which focuses on the relationship between bodily structure (primarily that of the spine) and function, and how that relationship affects the preservation and restoration of health. Chiropractors use manipulative therapy as an integral treatment tool

## Complementary and Alternative Medicine(CAM):

The terms "complementary medicine" or "alternative medicine" refer to a broad set of health care practices that are not part of that country's own tradition or conventional medicine and are not fully integrated into the dominant health-care system.

## Herbalism:

is the study of botany and use of plants intended for medicinal purposes. Plants have been the basis for medical treatments through much of human history, and such traditional medicine is still widely practiced today.

## Homeopathic medicine:

This is an alternative medical system. In homeopathic medicine, there is a belief that "like cures like," meaning that small, highly diluted quantities of medicinal substances are given to cure symptoms, when the same substances given at higher or more concentrated doses would actually cause those symptoms.

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## Massage therapy:

These manipulate muscle and connective tissue to enhance function of those tissues and promote relaxation and well-being.

## Reflexology:

Reflexology is the application of appropriate pressure to specific points and areas on the feet, hands, or ears. Reflexologists believe that these reflex points correspond to different body organs and systems, and that pressing them creates real benefits for the person's health.

## Traditional Medicine (TM):

TM is the sum total of the knowledge, skills and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.<sup>1</sup>

## Complementary medicine (CM):

The terms "complementary medicine" or "alternative medicine" refer to a broad set of health care practices that are not part of that country's own tradition or conventional medicine and are not fully integrated into the dominant health-care system. They are used interchangeably with traditional medicine in some countries.<sup>2</sup>.

#### 1. INTRODUCTION

The Government of Rwanda recognizes the importance of regulating and guiding the Traditional, Complementary and Alternative Medicines, to ensure the safety of its population. This is in alignment of the National Vision for "ensuring the High Standards of Living for all Rwandans". <sup>3</sup> The T,C&AM policy develop the key priorities defined in the national Guiding documents such as National Strategy for Transformation and Health Sector Policy.

In the Alma-Ata Declaration of 1978, recognition was given to the role of traditional medicine and its practitioners in achieving health for all. The WHO Regional Committee for Africa by its resolution AFR/RC34/R8 of 1984, urged Member States to prepare specific legislation to govern the practice of traditional medicine as part of national health legislation and ensure an adequate budget allocation that will make for effective development of traditional medicine.

<sup>&</sup>lt;sup>1</sup> http://www.who.int/medicines/areas/traditional/defnitions/en/, consulted on 26/October 2018

<sup>&</sup>lt;sup>2</sup> http://www.who.int/medicines/areas/traditional/defnitions/en/, consulted on 26/October 2018

<sup>3</sup> http://www.minecofin.gov.rw/fileadmin/user\_upload/Hon\_Gatete\_Umushyikirano\_Presentation\_2016.pdf

Traditional medicine is used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses. The importance of T, C&AM and its potential for the achievement of health for all in the African Region is a fact; about 80% of the rural population living in the African Region depend on T, C&AM to meet their health care needs<sup>4</sup> (WHO 2003); but also, it should accelerate the development of local production of traditional medicines and other natural products to meet their health care needs and contribute in achieving the attainments of SDGs.

Some countries in the region such as Tanzania, Zanzibar, Ghana, and South Africa<sup>5</sup>, have established national agencies responsible for management of activities in the field of traditional medicine, formulated policies of T, C&AM, passed legislation and developed codes of ethics and of conduct for the practice of T, C&AM and created associations. Further noting that some countries in the region are doing research in the field of T, C&AM and those aspects have been included in the program of some training institutions<sup>6</sup>.

According to research conducted by IRST in 1997, 80% of Rwandan people consulted traditional practitioners. Therefore, even though Traditional Medicine is not yet institutionalised, in some legal<sup>7</sup>, and national guiding documents, the need by the Government of Rwanda to ensure access to safe healthcare and products provided by Traditional Medicine Practitioners has been highlighted<sup>8</sup> in the National Health policy and strategic plan. Although, incorporating it into the national health system with the objective of ensuring that traditional, complementary and alternative medicine treatment is available, safe, efficient is needed.

The Traditional, Complementary and Alternative Medicine policy provides for clear goals, and guiding principles and actions for its institutionalisation. This will facilitate the establishment of a legal and regulatory framework on T, C&AM practices. The policy seeks to promote collaboration and partnership with all relevant partners. It also aims at promoting appropriate methods and technologies in the development of T, C&AM practices that will improve the quality, safety and efficiency of T, C&AM products.

## 2. SCOPE AND RATIONAL OF TRADITIONAL MEDICINE IN RWANDA

## 2.1. Scope of traditional medicine in Rwanda

<sup>\*</sup>Promoting the Role of Traditional Medicines in Health Systems; A strategy for African Region, p.1

<sup>&</sup>lt;sup>5</sup> South Africa: The Rise of Traditional medicine, 2015

<sup>6</sup> WHO Traditional Medicine Strategy 2014-2023 page 23.

<sup>9</sup> WHO Traditional Medicine Strategy 2014-2023 page 15

- To protect traditional medicine knowledge, preservation of biodiversity and intellectual property rights
- Promote research for traditional medicines and collaboration between different stakeholders (regulators, practitioners, researchers, and academia...)

## 3. SITUATION ANALYSIS

## 3.1. Traditional, Complementary & Alternative Medicine practice worldwide

Many countries have already their own traditional medicine practices which are firmly linked to their own culture. Health systems around the world are experiencing increased levels of chronic illness and escalating health care costs. This includes expanding access to T, C&AM products, practices and practitioners. Over 100 million Europeans are currently T, C&AM users, with one fifth regularly using T, C&AM and the same number preferring health care which includes T, C&AM. There are many more T,C&AM users in Africa, Asia, Australia and North America<sup>11</sup> also. But available data shows that the market is substantial. The output of Chinese material medical was estimated to amount of US\$83.1 billion in 2012, an increase of more than 20% from the previous year. In the Republic of Korea, annual expenditures on T, C&AM were US\$4.4 billion in 2004, rising to US\$7.4 billion in 2009<sup>12</sup>.

The global uptake of T, C&AM shows that significant momentum has been achieved over the past decade. It is important to highlight the ongoing demand for T, C&AM products, practice and practitioners. It is also necessary to describe patterns of use, identify the need for regulation to protect consumers and describe the importance of integrating T, C&AM into universal health coverage as well as the difficulties and challenges related to its integration in national health system.

The demand for T, C&AM products, practices and practitioners increase significantly over the world. Examples are given in Australia and China. In Australia visits to complementary health professionals such as acupuncturists, chiropractors and naturopaths have been growing rapidly with an increase of over 30% between 1995 and 2005. In China, according to a national survey, the number of traditional Chinese medicine (TCM) visits was 907 million in 2009, which accounts for 18% of all medical visits to surveyed institutions; the number of TCM inpatients was 13.6 million, or 16% of the total in all hospitals surveyed. <sup>13</sup>The use of T, C&AM is attributed to 4 main factors:

<sup>&</sup>lt;sup>13</sup>Abdoullahii AA, Trends and challenges of Traditional Medicine in Africa, African Journal on Traditional Medicine, Complementary and Alternative Medicine 2011,



<sup>&</sup>lt;sup>14</sup> WHO Traditional Medicine Strategy, 2014-2023, Page 25

<sup>12</sup> Idem, page 26

According to the World Health Organization (WHO), traditional medicine is "the total combination of knowledge and practices, whether explicable or not, used in diagnosing, preventing or eliminating physical, mental or social diseases and which may rely exclusively on past experience" The terms "complementary medicine" or "alternative medicine" are used inter-changeably with traditional medicine in various countries. They refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system<sup>10</sup>.

Various traditional medicine practices have been developed in different cultures and in different regions in Rwanda. For the sake of this policy lays out the strategic directions of Traditional medicine from plants, herbs, animal's materials and mineral. While Alternative and Complementary medicine will consider diverse medical, practices and products that are not generally considered as part of convention medicine including the homeotherapy, chiropractic, Medication therapies, acupuncture, aromatherapy, manual therapy (reflexology) and any other which will be covered in the definition of C&AM.

## 2.2. Rationale of traditional, complementary and alternative medicine in Rwanda

Long historical use of many practices of traditional medicine, including experience passed on from generation to generation, has demonstrated the safety and efficacy of traditional medicine. The products used can be easily found naturally and are easily affordable and accessible by majority of the community. Apart from that, cultural acceptability on Traditional medicine is high since it applies a holistic approach to treatment. However, research and monitoring systems are needed to provide additional evidence of its safety and efficacy.

A National Policy on T, C&AM is substantiated by the following:

- The use of Traditional, Complementary and Alternative medicines (T, C&AM) is widespread in Rwanda therefore it is necessary to regulate and encourage better practice in an organized way.
- To define the role of traditional medicine in health care service delivery systems
- To provide for legislation and regulations of tradition and alternative medicines practitioner to ensure safety, efficacy and quality of services rendered
- To encourage the proper conservation and cultivation of traditional medicines products
- To promote local manufacturing of traditional medicines

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<sup>9</sup> WHO Traditional Medicine Strategy 2014-2023 page 15

<sup>10</sup> http://www.who.int/medicines/areas/traditional/defnitions/en/

- ✓ Inaccessibility/availability of conventional medicine-based health services: For instance, the ratio of traditional healers to population in Africa is 1:500 whereas the ratio of physicians to population is 1:40,000. For millions of people in rural areas, native healers therefore remain their health care providers:14
- ✓ Cultural and historical influences: In some countries such as Singapore and the Republic of Korea where the conventional health-care system is quite well established, 76% and 86% of the respective populations still commonly use TM; Complementary therapy. This is common in developed countries where the health system structure is typically well developed, e.g. North America and many European countries;
- ✓ Failure of treatment: It has been shown, for instance, that patients attend the Royal London Hospital for Integrated Medicine because other treatments have failed or because of their personal or cultural preference, or because they have experienced adverse effects with other treatments. In Australia, interviews with T, C&AM users also showed that the failure of conventional medicine treatments and a desire for a healthy lifestyle were the main motives for using T, C&AM.
- ✓ In many developing countries, T, C&AM plays an important role in meeting the primary health care needs of the population, and specific types of T, C&AM have been used for a long time: Potential cost savings are an important reason for individuals to opt for T, C&AM services. However, T, C&AM regulation remains a country's responsibility by ensuring the safety of T. C&AM practice and managing its described risks more effectively.

Globally, traditional medicine (TM) is either the mainstay of health care delivery or serves as a complement to it. T, C&AM is an important and often underestimated part of health care. It is found in almost every country in the world and the demand for its services is increasing. TM, of proven quality, safety, and efficacy, contributes to the goal of ensuring that all people have access to care.

#### Traditional, Complementary & Alternative Medicine practice in Rwanda 3.2.

The current situation of T, C&AM in Rwanda indicates that, majority of the population uses T. C&AM for treatment of various diseases. According to the research conducted by IRST 15 in 1997, approximatively 80% of Rwandan population consulted tradipracticians rather than medical products. Different T, C&AM methods, which have been practiced in Rwanda, include herbal medicine, massage/manipulation, steam/heat, diet and supplements, exercise, spiritual

<sup>14</sup> Idem note 1,

<sup>15</sup> Examples of development of pharmaceutical products from medicine plants, 1997,

and mental therapy. Unfortunately, up to now, there are limited studies that prove the effectiveness, efficacy and safety of active substances used in traditional practices. Here below is current status on each component of T, C&AM management in Rwanda.

#### Institutional Framework

Traditional, Complementary and Alternative medicine practices are recognized worldwide so does in Rwanda; however, they need to be streamlined, regulated and improved.

The Ministry of Health in its mandate to ensure the access and quality of health care services including the safety and efficacy of T, C&AM use and practices. Some components of T, C&M are regulated by its affiliated institutions such as Rwanda FDA which has the responsibility to regulate, through registration and licensing, inspection, pharmacovigilance and post marketing surveillance of herbal and alternative medicines. However, the MOH faces the challenges including the lack of regulation and institutionalized system of T, C&AM practices.

There is a need to revise the MOH structure to incorporate the responsibilities of T, C&AM regulation.

## Research and Development

The Government of Rwanda recognized the importance of research and development by creation in 1980 of CURPHAMETRA within National University of Rwanda (actually University of Rwanda), a University Centre for Research on the Pharmacopoeia and Traditional Medicine. This center had mandate to study the use of traditional medicine; phytochemical research of drugs from medicinal plants and other economic products from local raw materials.

The center was later transferred to the Institute of Scientific and Technological Research (Institut de Recherche Scientifique et Technologique – IRST), established by law nº 06 / 1989 of 15 March 1989, which currently is in the National Industrial Research and Development (NIRDA). Among the achievements of IRST in this area, some researches have been conducted in Herbal medicine. The IRST has produced Seven improved tradition medicine through research. Those are batankor syrup, Gifurina Syrup, Catamibe capsule, Rusendin ointment, calendelar ointment, Tembatemba ointment, umuravumva capsule. Unfortunately, all those medicines have not been registered to be in the standards treatment guidelines and in the list of essential medicines, because there was not an organ to regulate them.

Other researchers conducted in area of herbal medicine include:

Rwandese Plants used in treatment of diarrhoea in which a series of 20 medicinal plants used to treat diarrhoea diseases has been screened for antibacterial activity against several salmonella and shigella and for antidiarrhoea activity on mice<sup>16</sup>.

A study to document the Traditional phytotherapy remedies used in Southern Rwanda for the treatment of liver diseases where 68 multi-components and 65 single-component herbal recipes were identified for the treatment of liver diseases with a total of 86 different herbs from 34 families identified.<sup>17</sup>

There is very little interaction between scientists and practitioners and generally, there is a worrying lack of recognition of the need for the benefits of research and development towards improving traditional medicine practices. Existing laboratories in which laboratory studies can be done are not well equipped and traditional medicine practitioners do not formally take part in passing on knowledge at different levels. This might be linked to the fact that the frameworks for joint national, sub-regional and international collaboration between different structures involved in research and education in different aspects of Traditional Medicine are always formalized. There is a need to develop a research agenda to coordinate the T. C&AM related researches and make it more relevant to the country policy and decision making process.

# Legislation and regulation;

In Rwanda, there has not been any comprehensive legislation and regulation of T, C&AM. Few laws and Ministerial Orders were established but were not covering all aspects regarding legislation and regulation of T, C&AM.

Among others we can cite the Ministerial Order No 007/2008 of 15/08/2008 establishing the list of protected animal and plant species which include some endangered medicinal plants and the Law No 47/2012 dated 14/01/2013 relating to regulation and inspection of food and pharmaceutical products including regulation of herbal medicines.

Even though the herbal medicine is regulated, the others product and practice of the T, C & AM has been performed informally without any control of the Government. The main problems affecting the practice of Traditional Medicine in Rwanda, include the lack of information on practitioners including their qualification, registration, educational background, location, number and the products used in their practices. Other problems include inappropriate premises

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<sup>&</sup>lt;sup>16</sup> Rwandese Plants used in treatment of diarrhoea: journal of Ethnopharmacology, 1989, p?

<sup>&</sup>lt;sup>17</sup> Traditional phytotherapy remedies used in Southern Rwanda for the treatment of liver diseases. Journal of ethno pharmacology, 2011. Page 415

for practice, inadequate record keeping by practitioners, inadequate facilities for diagnosis and the use of un-standardized products.

Furthermore, there are varied and unknown T, C&AM practices in the country. Some of these practices particularly T, C&AM, are confined to families and the practice is home-based. These practices are not organized for training purposes. There are, also too many hawkers and peddlers practicing in the system.

Alternative Medicines in particular are mainly foreign and imported. In most cases there are no recognized locally accredited training institutions and/or professional bodies.

To ensure quality of Traditional, Complementary & Alternative medicines, there is a need for a law enactment to regulate the T, C&AM practices.

## Capacity building

A Number of efforts are being made by the government of Rwanda to strengthen the capacities in traditional medicine subsector:

- The University of Rwanda through The Faculty of Medicine, School of Pharmacy offer pharmacognosy, as a course related to pharmacological and toxicological properties of herbal products.
- A five-year project in collaboration with Belgium Universities (ULg and ULB) on Belgium side and UR and NIRDA on Rwanda side. This project started in 2016 and financially support 3 PhD studies in the area of traditional medicine.
- Training of Traditional healers and establishment of Traditional Healers Builder team (from NIRDA, UR, MoH and INES, CNRU( Commission Nationale Rwandaise pour l'UNESCO)<sup>18</sup>

However, there are no established institutions for training T, C&AMPs and their trainers. There is no T, C&AM component in the existing programs and curricula for the training of traditional practitioners and lack of motivation for traditional practitioners who embark upon TMP training programs.

Traditional Medicine in Rwanda is currently individualized in the hands of Traditional healers.

Their knowledge is handed-over from generation to generation. Complementary and Alternative Medicine is practiced by practitioners who acquired knowledge through developed

\* www.mirda.gov.rw/index/pnp/id=6&ex

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<sup>18</sup> www.nirda.gov.rw/index/php?id=8&tx

curricula and trainings. However, education, training and research in this area have to be adequately developed in Rwanda like many other developing countries.

## Information:

Although there is some information on T, C&AM, some ignorance on the nature and scope of T, C&AM still exists in some members of the Rwandan community. The perceived negative aspects of T, C&AM have often tended to obscure the real benefits.

Currently, there is no established system for information dissemination and sharing of T, C&AM systems and products. This has hindered the development of this sub-sector. The development of information, education and communication strategies on Traditional Medicines for traditional practitioners, consumers and the general public should be encouraged.

#### Registration

The registration of traditional and alternative medicine practitioners, working premises and products used in their daily practices should be properly and legally completed and settled. The aim is to ensure that T, C&AM practices are conducted in accordance to the provisions of the law and prescribed regulations and standards in order to attain the good quality of the products used as well as the better quality of healthcare services to patients.

Therefore, there is still need to develop all T, C&AM regulatory framework in accordance to National, regional and International Standards including registration procedures to ensure the safety, efficacy and quality of herbal medicines used in Rwanda.

## Production and use

The products used in the traditional medicine practices in Rwanda are produced on small scale, various plants-based preparations for some disease conditions and the assurance of their safety and quality is still doubtful. For sustainability and safe environment for the production of herbal medications at local and at industrial levels, the policy objectives are to improve the quality and quantity of traditional and alternative medicines for internal and commercial use. Different stakeholders will have an important role to play in the production and conservation of medicinal plants while promoting the local production of herbal medicines used in the traditional medicine.

## **Intellectual Property Rights Protection**

Traditional medicine practitioners' dynamics are developing in different regions of Rwanda. A change in attitudes and awareness of traditional medicine practitioners is occurring with regard to protecting their profession, legal protection, conservation of cultural legacy, protecting and conserving medicinal species and collaborating with conventional medicine practitioners as

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well as different partners. A deep reflection on the transmission of traditional knowledge and on the application of intellectual property rights begins to take shape among sensible and clearsighted traditional medicine practitioners at different levels and they have acquired a lot of experience from trainings. As TM is considered as traditional knowledge, it is regulated by intellectual property rights Law No. 31/2009 of 26/10/2009 which concerns: Competition, Copyright and Related Rights (Neighbouring Rights), Industrial Designs, Industrial Property, Layout Designs of Integrated Circuits, Patents (Inventions), Trade Names, Trademarks, Traditional Cultural Expressions, Traditional Knowledge (TK). For its implementation following regulation are in place, Ministerial Order No. 05/10/Minicom of 25/08/2010 determining the Timeframe provided for Granting of Unilateral Licence, a Compulsory Licence and Opposition to Registration of Intellectual Property (RW025), Ministerial Order No. 07/10/Minicom of 25/08/2010 determining the structure and functioning of the Council of Appeal in charge of settling disputes related to intellectual property (RW026), Ministerial Order No. 06/10/ Minicom of 25/08/2010 determining the fees payable for registration services of an intellectual property (RW027) and Ministerial Order No. 01/10/MINISPOC of 20/08/2010 determining the content of the application for suspension of procedures of clearing goods suspected to have been pirated (RW028) which relates. Traditional Medicine Practitioners do not share information on their knowledge (practice and preparation) due to the lack of trust, fear of losing their live hood, oath of secrecy, maintenance of their status and reputation.

However, the law still need to be promoted and its enforcement need to be more comprehensive to balance the need to protect the intellectual property rights of traditional hearer's peoples and local communities and their health care heritage while ensuring access to T, C&AM and fostering research, development and innovation.

## **Processing and Marketing**

The processing of herbal medicine is done locally and are being dispensed to patients. Some products are being sold to the public without established evidence of safety and efficacy and quality in terms of production/preparation of traditional/plant medicine product. This is due to lack of appropriate technology, equipment's and expertise in the area. The marketing situation is not reliable as the TM in use are not registered. The Traditional, Complementary &Alternative products are known to have poor packaging, labelling information and absence of standardization which hamper their commercialization.

There is a need to develop appropriate and profitable marketing, pricing and post harvesting systems so that traditional medicine practice can match with world market trends.



## International collaboration and information sharing

In the T,C&AM sector, national regulatory authorities responsible for the regulation of herbal medicines have been meeting annually since 2006 as part of the global regulatory network of the International Regulatory Cooperation on Herbal Medicine (IRCH). One of the recommendations gathered was to improve regional collaboration and harmonisation of T,C&AM medicines regulation. Rwanda regulatory authority has been working on harmonizing the regulation of medicine and medical devices and there is a need to do same for herbal medicines within the region.

There is collaboration between national and foreign Universities, Organizations and research centers with regard to joint continuous and post-university education and research. E.g. CAMES, ACTC, KOICA, WHO, and others and a need to harmonize medicines regulations procedures which will include regulation of herbal medicines and Protection of Traditional knowledge.

Therefore, there is a need for more networking, collaboration and exchange of information, locally and internationally among stakeholders, in a coordinated manner. The research and training institutions on Traditional, Complementary &Alternative Medicine practices should intervene mainly in organizing the relevant local and international courses, workshops and conferences to upgrade knowledge and skills for traditional medicine practitioners.

## Integration into health care system

The potential of traditional medicine practice using products or preparations from plants, animals and parts of animals, and mineral based medicines is recognized but its integration into the health care delivery system while protecting traditional knowledge, intellectual property, consumer and other rights as well as medicinal resources in the country is not yet achieved.

The integration of T,C&AM within national healthcare system will be reached steadily by developing the law regulating the T, C&AM and implementing the programmes aiming at improving the quality, safety and efficacy of T,C&AM and raise capability as well as the efficiency of the T,C&AM practitioners for the better health care of the population.

# **Biodiversity Conservation and Sustainable Harvesting**

Rwanda is a signatory and has ratified several international treaties and conventions promoting biodiversity conservation. Amongst these is the Convention on Biological Diversity (CBD), with three main goals including the conservation of biodiversity including plants, sustainable use of the components of biodiversity, and sharing the benefits arising from the commercial and other utilization of genetic resources in a fair and equitable way. In that way Rwanda

adopted OAU Model Law on Access to biodiversity in (2013 Official Gazette n° 38 of 23/09/2013) and developed Biodiversity Policy related to the protection of and access to biodiversity available since 2011 including medicinal plants.

Through this policy, the traditional medicine practice shall consider to develop or to respect the existing laws on the protection, conservation, preservation and sustainable use of natural resources for sustainable traditional medicinal plants. There is also a need to prepare and maintain a botanical garden for selected species especially those that are either rare or are becoming so because of overharvesting or other threats.

# Networks of Health Traditional medicine practitioners

Traditional medicine practitioners' dynamics is developing in different regions of Rwanda. A change in attitudes and awareness of traditional medicine practitioners with regard to protecting their profession, legal protection, conservation of cultural legacy, protecting medicinal species and collaborating with conventional medicine practitioners is needed. A deep reflection on the transmission of traditional knowledge and on the application of intellectual property rights begins to take shape among sensible and clear-sighted traditional medicine practitioners and traditional medicine practitioners at different levels have acquired a lot of experience from training.

On the other side, traditional medicine practitioners' cooperatives are not well established and coordinated all over the country. The Ministry of Health still has had to do more with regard to organization, services and logistics of TM. The coordination of traditional therapists' cooperatives is at the embryonary stage. There are no code of practice and ethics adapted to the organization of the health traditional Medicine practitioner's profession and fight against quackery. The existing forum/networks of T, C&AM like AGA Rwanda network need to be formalized and well-coordinated.

## 3.3. Challenges and gaps

The institutionalisation of T, C&AM is still inadequate; there has not been any comprehensive legislation and regulation of T, C&AM in Rwanda and the practice in this sector has been performed with limited regulation by the Ministry of Health. Knowledge generation and management do not have a clear framework. The preparation of T, C&AM is not also standardized to ensure safety of products. This is due to the lack of regulation and registration of T, C&AM practices and practitioners. The formulation of medicinal products from plant, animal and mineral material combinations is the intellectual property of the traditional medicine practitioner which he/she keeps as a secret. Although an experienced practitioner has

the ability to formulate the product in a reproducible manner, the secrecy of the composition makes it difficult to subject such products to quality control according to international standards. There is a limited coordination of research development in the area of T, C&AM.

## 4. POLICY ORIENTATION

#### 4.1. Vision

The Rwandan population's health is improved where traditional medicine is properly regulated to ensure the quality and safe healthcare services provision to the population.

## 4.2. Mission

To ensure the quality of traditional, complementary and alternative medicine through its regulation and integration into the national healthcare system; ensure conservation and protection of traditional, complementary and alternative medicinal resources and promoting research and development:

## 4.3. Guiding Principles

The T, C&AM policy is based on the guiding principles of the National Health Policy of the Ministry of Health (MOH), promoting integrated, people-centered and sustainable services. This T, C&AM policy will adhere to the following values and principles:

## Integrated services:

- T, C&AM services providers will be integrated and collaborate with other health services providers in all level of the health systems from Community Health level.
- Sustainable linkages and collaborations with other health professional's councils to improve overall service delivery.
- Broad involvement and participation of all relevant health sector stakeholders

## People-centered services:

- Service delivery based on client needs and established norms and standards in order to protect clients;
- Professional practices, conduct and performance oriented towards the client needs;
- Promotion of universal health coverage, highlight demand of services, improvement of
  access, community participation and linkages between health sector and communities.

#### Sustainable services:

- Quality and cost effectiveness in T, C&AM management, research and development;
- Promôte research and Strengthen capacity of T, C&AM practitioners to deliver expected and desired services by clients;

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• Efficiency and effectiveness in delivery of quality health care services.

#### 4.4. Goal

The Policy's overall goal is to guide and coordinate T, C&AM practice while protecting indigenous knowledge, intellectual property, consumer and other rights as well as medicinal resources. The aim is to improve the quality, efficacy, rational use of T, C&AM and raise capability and efficiency of the T, C&AM practitioners for the better health of the community.

## 4.5. Policy Objectives

- ✓ To provide appropriate evaluation methods to facilitate the development of legislation and regulation in traditional, complementary and alternative medicine;
- ✓ To enhance national capacity management, coordination and use of information related to T, C & AM at all levels
- ✓ To ensure appropriate, safe and effective use of traditional, complementary and alternative medicines;
- ✓ To improve the quality and value of research in traditional, complementary and alternative medicine;
- ✓ To ensure proper conservation and protection of traditional, complementary and alternative medicinal resources

## 4.6. Policy Directions

The policy shall be used to implement the Rwanda traditional, complementary and alternative medicine and shall focus on effective management processes and mechanisms that promote Traditional, complementary and alternative medicines.

1. To provide appropriate evaluation methods to facilitate the development of legislation and regulation in traditional, complementary and alternative medicine

## Policy directions

- 1.1 Capitalize on the potential contribution of T, C&AM to improve the coverage and access to health care services;
- 1.2 Create and enable a regulatory and conducive environment for local production of medicines;
- 1.3 Recognize and develop practice and practitioner regulations for T, C&AM Education and training, skills development, services and therapies;

- 1.4 All TMPs shall be required to register in the TM Council with the view to enhancing the practice and eliminating quacks in the system.
- 1.5 To assist the genuine practitioners, the umbrella association of TM shall be encouraged to organize training and educational programs on good manufacturing practices.
- 1.6 TMPs shall keep accurate records of all their practices and monitor management of patients.
- 1.7 Appropriate standards of practice shall be set as and when facilities improve to make it easier for enforcement of legislation.
- 2. To enhance the national capacities in management, coordination and use of information related to T, C & AM at all levels

## Policy directions

- 2.1. To have a comprehensive and functional administrative structure of T, C&AM in Rwanda to coordinate, oversee and advise practitioners and other beneficiaries in the sector
- 2.2. Strengthen collaboration between and within local and international organizations dealing with Traditional, Complementary and Alternative Medicine.
- 2.3. Ensure consumers of T. C&AM can make informed choices about self-health care
- 2.4. To increase herbal medicines at sustainable levels, and improve the efficiency and profitability of herbal medication and complementary & alternative medicines services for both national and international consumption
- 2.5. Generate and disseminate useful information about nature and use of traditional, complementary and alternative medicine.
- 3. To ensure appropriate, safe and effective use of traditional, complementary and alternative medicine

## Policy directions

- 3.1. To establish a suitable management and regulatory measures to ensure the safe practice of T, C&AM activities
- 3.2. Recognize the role and importance of product regulation
- 3.3. To build capacity among traditional, complementary & alternative medicine practitioners and other practitioners in health sector

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- 3.4. Ensure appropriate information sharing among practitioners and other stakeholders including consumers
- 3.5. To ensure the safety practices and products of T, C&AM
- 3.6. To establish effective monitoring procedures

# 4. To improve the quality and value of research and investment in T, C& A medicine

## Policy directions

- 4.1. Encourage knowledge generation, translation and dissemination by establishing a comprehensive and inclusive approach to TM research and development including into quality, safety and cost-effectiveness
- 4.2. Strengthen the knowledge management, build evidence and sustain resources
- 4.3. Strengthen research and development to improve the quality, safety and efficiency of traditional and complementary medicines by supporting research institutions working with T, C&AM
- 4.4. Improve the quality of the products, producers and skills in marketing systems.
- 4.5. Strengthen the information system of T, C&AM by encouraging the TM practitioners to document and report regularly about the T, C&AM services
- 4.6. Promote the Investment in research and development of T,C&AM

## 5. To ensure proper conservation and protection of traditional medicinal resources

## Policy directions

- 5.1. Ensure protection and conservation of Traditional Medicines (TM) resources, in particular knowledge and natural resources
- 5.2. Provide for sustained availability of traditional medicinal resources in Rwanda
- 5.3. Collaborate with other institutions in providing adequate measures to protect production sites, farms, natural forests and parks against destructive agents such as fire, insects, parasites, pollution, degradation etc.
- 5.4. Ensure availability and protection of botanical gardens and cultivate arboreta for selected medicinal plants.