



Harmonised traditional medicine policies and regularoty framework for the ECOWAS sub-region



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**HARMONISED FRAMEWORK FOR
REGULATION OF AFRICAN TRADITIONAL
MEDICINE PRACTICES, PRACTITIONERS AND
PRODUCTS IN THE ECOWAS REGION**

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For the purpose of this document, the term Traditional Medicine may be used broadly to encompass Complementary/Alternative Medicine

Preface

In 1978, the Alma-Ata Declaration, reiterated by the Ouagadougou Declaration in 2008, cited TM as an important component of Primary Health Care to respond to the expressed health needs of communities. Since then, the WHO Governing Bodies, partners and countries have adopted several resolutions and declarations on TM aimed at institutionalizing the sector in national health systems. For example in 2000, the WHO Regional Committee for Africa adopted the Regional Strategy by its Resolution AF/RC50/R3 on Promoting the Role of TM in Health Systems. The aim of the strategy is to contribute to the achievement of “health for all” in the Region, by optimizing the use of TM. The Resolution urged countries to produce inventories of effective practices as well as evidence on safety, efficacy and quality of TMs and to undertake relevant research.

Subsequently, the 61st session of the WHO Regional Committee for Africa in 2011 discussed the progress report on the implementation of the above-mentioned Regional Strategy and the Plan of Action on the Decade of African TM (2001-2010). The Committee then proposed “African TM: practices, practitioners and products” as a topic for Panel Discussion at the 62nd session of the Regional Committee.

During the course of the implementation of the Regional Strategy, several challenges were identified. These include limited data on the safety, efficacy and quality of most TM products; inadequate financial resources and infrastructure for conducting Phase III clinical trials; limited patents from research results; lack of protection of indigenous knowledge and Intellectual Property Right (IPR) resulting in rampant biopiracy of Africa’s natural resources; limited knowledge on the impact of climate change on biodiversity; limited capacity to regulate TM practices and products, limited collaboration between TMPs and conventional medicine practitioners; and low literacy levels of most TMPs.

These challenges coupled with the effects of current economic crisis and globalization, have resulted in a proliferation of TMPs with doubtful abilities and intentions in many countries, thus hampering the efforts being made to develop the sector.

Calls have therefore been made to accelerate the process for identifying, licensing and accrediting qualified practitioners, and to develop long-term training programmes and well-defined frameworks for enhancing collaboration between TMPs and conventional medicine practitioners.

It is against this background that in 2012, the WHO/AFRO brought together experts from the WHO/AFRO Member States, in Harare and subsequently in Brazzaville, to revise the documents that had given policy orientation to the promotion of TM in the Member States. Key among these documents were the Regional Framework for Regulation of African Traditional Medicine Practices, Practitioners and Products and the Regional Framework for Development of National Policies and Legislation for the Protection of Traditional Medical Knowledge and Access to Biological Resources

At the end of this regional consultation, the WHO/AFRO Regional Office called on Member States to develop effective frameworks for utilising these vital documents.

In response to this call the West African Health Organisation constituted a small committee to review these vital documents and develop a draft framework for adapting them to the unique circumstances of the ECOWAS region. The committee met in Bobo Dioulasso in May 2013, after which proposals were made for consideration by a regional meeting held in Conakry in the same month. After two days of extensive discussions the meeting validated and adopted the framework, which constitutes the subject of this document.

As a specialised agency of ECOWAS mandated to safeguard the health of the peoples of the sub-region, WAHO considers the regulation of all aspects of healthcare delivery, including Traditional and Complementary/Alternative medical services as paramount. Indeed, WAHO appreciates and upholds the principles of best practices as observed in all advanced health systems across the globe.

The development of this document is consistent with the vision of ECOWAS, and I am therefore happy to endorse it.

Dr Placido Cardoso

Director General

Introduction

Over the past two decades, the global resurgence of interest in “Alternative” forms of health care has resulted in an increased patronage of African Traditional Medicine as well as other health care services originally provided outside Africa. In our part of the world, this has also resulted in the influx of persons purporting to have the skills and competencies in so-called Complementary & Alternative medicine (CAM). Rightly, the peoples of the sub-region appreciate and understand such practices as Traditional Medicine probably due to the fact that they are based on the use of naturally occurring substances, i.e., plant and animal-based products and minerals.

Nevertheless, despite this development many countries still lack the requisite regulatory and legislative framework for the practice of TM, codes of ethics for Traditional and Alternative Medicine Practitioners (TAMPs) and strategic plans for implementation of national policies.

A situational analysis of the level of TM development in the ECOWAS Member States conducted at the first sub-regional workshop on TM held in Bobo Dioulasso in May 2007, showed that despite the Alma Atta Declaration of 1978, the resolution adopted in Ouagadougou, Burkina Faso in 2000 and the declaration of the period 2001-2010 as the Decade of African Traditional medicine in Lusaka, Zambia in July 2001, many countries still faced major challenges in the development and implementation of the regulation of Traditional, Complementary/Alternative and Herbal Medicines.

Country presentations at the workshop revealed that besides the lack of policy and/or legal framework in many countries, inadequate documentation (e.g. knowledge, use, research, practices and efficacy), inadequate regulation of the production, import and export, distribution and use of Traditional and Complementary/Alternative Medicines, lack of scientific evidence for safety, efficacy and quality, lack of safety-monitoring mechanisms in most countries and inadequate infrastructure, production, research, training, regulatory control, quality control and analysis, financial and human resources, were also highlighted as some of the great challenges facing member states in their attempts to promote TM.

It was agreed that in order for the objectives of the above resolutions to be realized, a harmonized policies and regulatory framework that will reflect the unique circumstances of all the ECOWAS Member States be developed. It was also observed that any such exercise will need to recognize the variety of model guidelines for TM institutionalization that have been developed by the WHO/AFRO Regional Office.

Delegates at this meeting, agreed that due to the differences that had been noted in the levels of TM development in each country, a harmonised system will, among other things, facilitate the efforts of countries which either lack a national policy or encountering difficulties to develop one. It was felt that even countries with advanced TM systems could benefit from a harmonised

framework; they would be encouraged to review their existing policies with a view to improving their effectiveness and efficiency.

A harmonised system was also deemed necessary because although existing WHO/AFRO documents are useful templates, they are broad guidelines, which may not always meet the peculiar circumstances of all the regional groupings on the continent. A sub-region-specific harmonised document would provide a more relevant framework suitable for use by member states. In addition, harmonisation is consistent with ECOWAS' goal of sub-regional integration and will foster collaboration among countries.

Since the eventual implementation of these important documents will have wide ranging implications for TM promotion in the sub-region, WAHO organised two meetings which enabled TM experts as well as the Directors and Coordinators of TM and some TM practitioners to review and adapt them to the circumstances of the ECOWAS region.

This document is divided into two (2) parts:

- Part One:** Guidelines for regulating traditional medical practices and practitioners: this has three chapters on guidelines for the licensing of practitioners, code of ethics and for the licensing of the practice traditional medicine clinic.
- Part Two:** Guidelines for regulating traditional medicines: this part is subdivided into five chapters on good manufacturing practices (GMP), official certification of medicines, clinical trials, pharmacovigilance and advertising.

These guidelines aim to provide Member States with a basis for the developing national regulatory framework for traditional medicine practices, practitioners and products. They are intended for competent national authorities, the private sector, Traditional Medicine Associations, technical and financial partners, NGO's, academia, and other relevant stakeholders.

Dr Kofi Busia

Professional Officer Traditional Medicine

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ACRONYMS AND ABBREVIATIONS

MA Marketing Authorisation

NMRA National Medicines Regulatory Authority

GMP Good Manufacturing Practices

CAMES *Conseil Africain et Malgache pour l'Enseignement Supérieur*

PEC Professional Ethics Committee

WHO World Health Organization

TMP Traditional Medicine Practitioner

AU/ African Union/

STRC Scientific, Technical and Research Commission

THP **Traditional Health Practitioner**

HIV/AIDS Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome

Part 1: Guidelines for regulating traditional medical practices

General Introduction

Since the adoption of the regional strategy in 2000, many Member States have made efforts to institutionalize traditional medicine. However, there are still regulatory gaps in traditional medical practices and care structures, traditional medical ethics and the identification of traditional practitioners. Furthermore, in the States where regulation exists, its enforcement is inadequate. Faced with this situation, the WHO Regional office has proposed a harmonized approach at the level of Member States for the formulation and enforcement of the regulation.

These guidelines aim to assist Member States to:

- Prepare regulatory instruments related to traditional medicine practices, traditional care structures, medical ethics and identification of traditional medicine practitioners;
- Define a procedure for enforcing the regulatory instruments.

Chapter 1:

Licensing traditional medicine practitioners

Introduction

Traditional medicine practitioners play a key role in health care delivery in Africa. However, their work and profession are not well appreciated and officially recognised in most Member States. For example, the interventions of traditional practitioners are not captured in national health statistics. This situation is due to several reasons while responsibilities may be shared by relevant stakeholders from all levels. This chapter outlines an approach for regulating traditional medicine practitioners.

I. Definitions

Traditional Medicine: the sum total of knowledge and practices, tangible or intangible, explicable or not used for diagnosing, preventing or eliminating a physical, mental and social imbalance based exclusively on knowledge transmitted orally or in writing from generation to generation, and on actual experiences.

Traditional medicine practitioner (TMP): any person recognized by the community in which he/she lives, to be competent to diagnose diseases and disabilities prevailing there, provide health care using traditional methods and products of plant, animal or mineral origin. The categories of traditional medicine practitioners are determined by an order from the competent national authority.

Naturopathist: A person who, on the basis of knowledge, uses only natural substances as a means of therapy.

Traditional birth attendant:

A person recognized to be competent to provide to a woman before and during pregnancy including delivery and her new born child, health care based on concepts prevailing in the society in which she lives.

Ritualist: A person who mainly resorts to rites (religious or otherwise) in providing care.

Chiropractor: A person who mainly practices with bare hands or with instruments, massage or modifications on the body with the aim of providing or restoring ailing or wounded parts their function.

Herbalist: A TMP who uses only herbs in his professional practice, work or therapy.

Traditional medicine dealer: a person, who on the basis of knowledge of plants, animals and minerals acquired, packages and sells them as raw materials for therapeutic purposes

Traditional medicine practices: A set of traditional techniques and resources of traditional medicine nature used to prevent, diagnose and treat diseases.

Licensing of traditional medicine practitioner: A document granted to a traditional medicine practitioner by a national competent authority to enable him/her to practice officially and legally.

II. Regulatory procedure

II. 1. Development

The development of traditional medicine regulations involves the following stages: advocacy, situational analysis and preparation of the first draft, organization of consensus workshops and adoption of the regulatory instruments.

II.1.1. Advocacy

This stage essentially consists of sensitizing political, administrative, religious and traditional authorities. The authorities must be informed and familiar with any initiatives or actions to be undertaken. This will facilitate decision-making and the enforcement of the regulations. The advocacy must be undertaken by a multidisciplinary and multi-sectoral task force (researchers, academics, doctors, pharmacists, **socio anthropologists**, legal practitioners, and modern medicine practitioners, traditional medicine practitioners, associations and NGOs involved in the promotion of traditional medicine). The advocacy can be based on the following elements: importance of traditional medicine (its economic value and contribution to health care), its shortcomings and strategies for alleviating them the assurance of better services, education, promotion and collaboration between traditional medicine and modern medicine, in accordance with international declarations, resolutions and recommendations for the development of traditional medicine, etc.

II.1.2. Situational analysis

This entails a general study of the status of traditional medicine. The study must consist of a review of:

- Traditional medicine: its organization, key stakeholders, intervention areas, resources and possible technical and financial partners
- Problems identified: in the practice, absence of appropriate regulatory frameworks, identification of traditional medicine practices, etc.; potentials, achievements strengths or, weaknesses, opportunities and threats (SWOT).

A situational analysis helps select priority problems and areas to be regulated.

II.1.3. Preparing the first draft

After identifying the problems and priority areas to be regulated, the next stage is to prepare the initial draft regulations. The work can be entrusted to a multidisciplinary and multi sectorial group which must include traditional health practitioners. The group should also comprise of national and international experts or organizations with experience in drafting legislative and regulatory instruments. It may also use existing relevant regulations. The first draft must have the consent of a representation of the traditional medicine stakeholders.

II.1.4. Organizing a consensus workshop

A consensus workshop must be organised to critically review the draft with a fair representation of traditional medicine practitioners. Where necessary, a final review meeting can be organized prior to submitting the draft to the competent national authority.

II.1.5. Adoption

The finalized draft texts, together with a summary report, should be submitted to the competent national authority for adoption. The purpose of the report is to explain the reasons leading to the preparation of the text, the context in which it was done and the drafting process. Once the

regulations have been approved, they must be translated into the local/national languages, reproduced and widely disseminated among all stakeholders.

Following its adoption, an advocacy exercise must be conducted at the level of national and regional authorities for their involvement, commitment and support in the enforcement of the regulations. The practitioners must also be sensitized and trained to enable them understand and use the regulations.

II.2 Main elements of the regulation

These elements are described below in the form of articles

- Article 1: Conditions for traditional medical practice shall be determined by these regulations
- Article 2: As defined in these regulations, traditional medicine is the sum total of knowledge and practices, tangible or intangible, explicable or not, used to diagnose, prevent or eliminate a physical, mental, psychological and social imbalance based exclusively on knowledge transmitted orally or in writing from generation to generation, or practitioner to practitioner, and on actual experiences.
- Article 3: A traditional practitioner shall be any person recognized by the community in which he/she lives and the competent national authority to be capable of diagnosing diseases and disabilities prevailing there and provide health care using traditional methods and products of plant, animal or mineral origin. The categories of traditional medicine practitioners shall be determined by the competent national authority.
- Article 4: Traditional medicine practice shall be part of:
- ✓ The national health system;
 - ✓ Community health protection and promotion;
 - ✓ National research priorities
- Article 5: No one shall practice traditional medicine in his/her country without a traditional medicine practitioner's licence issued by the competent national authority.
- Article 6: A traditional medicine practice licence may be issued to any traditional medical practitioner of good moral standing and acknowledged reputation.
- Persons from other communities or of foreign nationality may receive a traditional medicine practitioner's licence upon meeting the requirements of traditional medicine practice in that country.
- Article 7: The process for obtaining traditional medicine practitioner's licence and the titles to be used shall be determined by the competent national authority.
- Article 8: Traditional practitioners' services shall be supervised and monitored by the competent national authority.
- Article 9: Any traditional medicine practitioner must comply with the laws of the country and the Code of Ethics governing the practice as outlined in Chapter 2 of these regulations.
- Article 10: Any traditional medicine practitioner must keep a register in which the names and addresses of the patients, diagnosis, and management plan (referrals, treatment, dietary and lifestyle advice, etc.) are written.

Article 11: A traditional medicine practitioner may, as part of a contract, collaborate with another traditional practitioner, health worker, research establishment or a public or private health facility.

Article 12: Any traditional medicine practitioner who is already practising has a period of time (to be determined by the competent national authority) to comply with the terms of these regulations; beyond the set period, he/she shall be deemed to be practising illegally.

III. Enforcing regulations

III.1 Preparing and submitting an application for a traditional medicine practitioner's licence.

Any traditional medicine practitioner wishing to obtain a practitioner's licence must submit an application, which should consist of the following:

- ✓ A standard application form addressed to the competent authority.
- ✓ a national identification certificate or a copy of birth certificate
- ✓ a police criminal record of less than 3 months (variable validity period depending on the countries)
- ✓ a medical certificate
- ✓ Testimonial from the community (chief, town council, religious leader)
- ✓ a residence permit (for foreigners)
- ✓ passport photographs
- ✓ Any other document relevant to the application

Once the application is completed, it shall be submitted to the local 1st level health authority to be forwarded to the competent national authority through the administrative chain of command.

III. 2 Application assessment procedure

III.2.1. Preliminary assessment:

The application submitted to the competent national authority shall be assigned to the unit responsible for traditional medicine. It shall verify the application; prepare a summary report for subsequent assessment by the technical evaluation committee.

The committee shall be multidisciplinary or multi-sectoral (e.g. ministerial departments responsible for the enforcement of traditional medicine regulations, representatives of traditional medicine practitioners' associations/federations, general and central directorates of the relevant traditional medicine authority, health facilities and research units of universities, networks or associations of journalists and researchers).

III.2.2 Work of the Committee

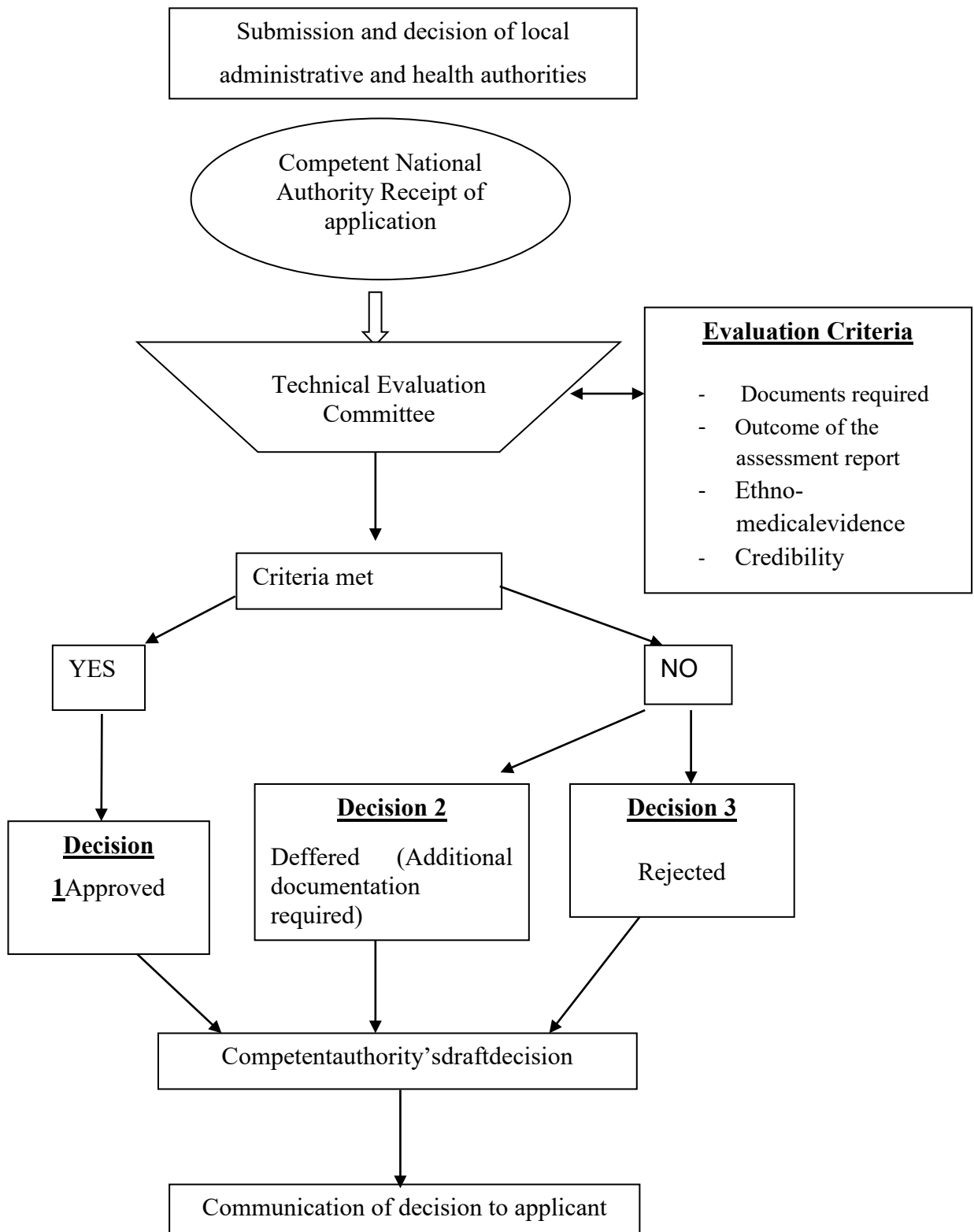
The committee shall be responsible for evaluating applications based on the following criteria: availability of required documentation, credibility of the applicant, etc. The committee shall issue one of four possible recommendations:

- ✓ approval;
- ✓ deferment (eg. for additional documentation);
- ✓ rejection.

Appealsprocess

Any person aggrieved by a decision of the competent national authority with regard to registration or licensing under these regulations shall have the right to appeal within 3 months. The competent national authority on considering such an appeal, shall sustain or reverse the decision, vary the decision, or refer to an independent committee (adhoc) for further review.

Figure 1: Flow chart of practitioner licensing decision-making process



Following evaluation of the application, the secretariat shall prepare a report and licence to be submitted to the competent national authority for signature. The decision of the competent authority shall be communicated to applicants within a specified period.

III.2.3. Main decision elements

The decision of the competent authority shall be based on the report of the technical committee.

III.3 Monitoring of traditional medicine practitioners

Any licence holder must be monitored by a competent national authority to ensure proper traditional medicine practice and avoid possible abuse and impediments. The Monitoring shall consist of; inter alia, capacity building monitoring/evaluation including ensuring the practitioner is licensed or not, has a permit to open and operate a traditional medicine clinic or a licence to market his/her products.

Monitoring should be conducted to identify and correct shortcomings and, where necessary, envisage a revision of the regulations.

Licensed traditional medicine practitioners should be trained in good traditional medicine practices as defined by the **competent national authority**. The training provided practitioners' activities and enforcement of traditional medicine regulations shall be monitored and evaluated.

Chapter 2:

Code of ethics of traditional medicine

p r a c t i t i o n e r s

Introduction

Ethics is the science of moral values. The basic foundation of ethical behavior is the basic precept, “Do good and avoid evil”. Traditional medicine has its ethical and moral requirements, and it is essential that the practitioners adhere to a code of ethics that promote good practices. Ethics, especially professional ethics, attempts to achieve its purpose in the context of this document, through the voluntary self-discipline of Traditional Medicine Practitioners. These guidelines are intended to assist Member States to develop and enforce a code of ethics for the practice of traditional medicine.

I. Definitions

Code of ethics: a set of rules governing conduct based on moral values expected by a professional association.

Professional ethics: moral principles that must guide members of traditional medicine practitioners’ association ‘in their relationships with one another, their patients, employers, the environment, government, etc. The members of the profession must be distinguished by their desire for collaboration and discipline.

Professional ethics committee: a committee at least one third of whose members come from the Traditional Medicine Practitioners’ Council duly appointed by the competent national authority to ensure the enforcement of the code of ethics.

Herbal medicine means a plant-derived material or preparation with therapeutic or other human health benefits which contains either raw or processed ingredients from one or more plants. In some societies, materials of inorganic or animal origin may also be used in preparing herbal medicine.

Herbal medicinal products are finished and labelled medicinal products containing plant materials or their preparations.

National competent authority refers to the authority at local, district, regional or national levels charged with the responsibility of regulating traditional medicine as regards practices, practitioners and products (medicines).

Herb medicinal products are finished and labelled medicinal products containing partly or entirely herbs preparations and presented as having therapeutic or prophylactic property.

Animal medicinal products are finished and labelled medicinal products containing only animal material or their preparations and presented as having therapeutic or prophylactic property.

Mineral medicinal products are finished and labelled medicinal products, and containing only inorganic material or their preparations.

Prohibited conduct: dishonourable conduct or professional or ethical misconduct that violates the code of ethics, as well as all the other acts of misconduct reasonably established as such by a competent national authority.

II. Regulatory procedure

II. 1. Development (see Chapter1)

The development of the code of ethics follows the same stages as those of the regulation of traditional medicine practitioners: advocacy, situational analysis, preparation of the initial draft, organization of a consensus workshop and adoption of the regulations by the competent national authorities.

II.2 Main elements to regulate

They are presented below in the form of articles.

Article 1: The provisions of this code shall be binding on all traditional medicine practitioners

Traditional medicine practitioners in relation to their work shall:

Article 2: first and foremost promote the health and well-being of the patient and the general public. They shall refrain from any act that can adversely influence the health of the patient.

Article 3: not practice traditional medicine unless licenced to do so.

Article 4: in the event of delegation, the practitioner must provide the necessary supervision and shall be liable for any case of negligence.

Article 5: immediately report to the competent national authority any adverse events observed and side effects noted during the treatment.

Article 6: not use conventional medicines as ingredients in their preparations and in their practice.

Article 7: limit their interventions to their scopes of practice and urgently refer any cases beyond their competency to the appropriate health professional.

Article 8: continuously update their knowledge to keep up with new developments in their area of practice and where available attend continuing education programmes.

Article 9: provide information on traditional medicine to the public or any other health professional where necessary.

Traditional medicine practitioners in relation to their patients shall:

Article 10: maintain a high sense of integrity in their interaction with their patients.

Article 11: inform their patients of the procedures involved in the treatment they intend to administer.

Article 12: respect the rights of a patient to accept or refuse traditional medicine treatment (except where the law requires that such treatment be administered to the patient).

Article 13: not abuse his relationship with the patient for personal gains.

Article 14: refrain from any act of discrimination towards patients on the basis of age, nationality, belief, colour, religion, gender, ethnicity, social status, political affiliation, etc.

Article 15: give appropriate advice to the patient, patient's family and the community to ensure the prevention, care (especially home-based care), management and promotion of health.

- Article 16: provide the necessary information and advice to ensure the proper use of traditional medicines.
- Article 17: keep a clear and complete register on all the patients treated in their clinics.
- Article 18: be reasonable in matters concerning fees or remuneration. Fees charged should be commensurate with the treatment given.
- Article 19: completely keep all the information and opinions about the patients confidential, except where:
- (a) the disclosure is clearly and justifiably in the patient's interest, or
 - (b) there is need for disclosure, e.g. when the practitioner considers referral necessary, or when disclosure is mandatory by law.
- Article 20: refrain from disclosing confidential information to the spouse of the patient or any other person, except if authorized to do so by the appropriate authority.

Traditional medicine practitioners in relation to their colleagues

In maintaining good relations with their colleagues, traditional medicine practitioners must:

- Article 21: support, respect and cooperate with fellow practitioners in addressing the needs for scientific and technical information.
- Article 22: consider other members of the Traditional Medicine Practitioners Association as colleagues and always be mindful of the need for consultation and referral.
- Article 23: adhere to procedures laid down by the appropriate national authority when referring patients or dealing with patients referred to them by other practitioners.
- Article 24: a refrain from expressing their opinions on the competence or conduct of a colleague to a third party, particularly to patients.
- Article 24: b report to the appropriate authority any act(s) of misconduct or malpractice by a fellow traditional medicine practitioner.
- Article 25: participate in the activities of their own professional associations and of other associations or organizations to promote traditional medicine.
- Article 26: refrain from expressing undue alarm or show any such reaction upon receiving a patient who has been improperly treated or referred by another traditional medicine practitioner but shall properly document patient's health status on reception.
- Article 27: refrain from making comments that undermine the integrity of colleagues.
- Article 28: not engage in negotiations or secret arrangements with any health practitioners for tenders, commissions, etc., in return for patronage, referral, etc.
- Article 29: not connive with other traditional medicine practitioners to engage in malpractice(s).
- Article 30: strive for the promotion of health, expansion of health services and the development of team spirit with other health practitioners.

Traditional medicine practitioners in relation to the public shall:

- Article 31: not use the title “Doctor”, either directly or indirectly, in a way likely to suggest being a registered conventional or orthodox medical practitioner, except if that is the case.
- Article 32: refrain from using or possessing any medical device, except where the traditional medical practitioner has received training.
- Article 33: not administer an anaesthetic or a subcutaneous, intramuscular, intravenous or any other form of injection, **except where the traditional medical practitioner is a qualified and licensed physician**
- Article 34: not use any surgical procedures to facilitate the examination of a person, except where the traditional medical practitioner is a qualified and licensed physician.
- Article 35: immediately report and document all deaths on the premises to the appropriate health authority for record purpose.
- Article 36: report all births to the appropriate health authority for record purposes.
- Article 37: abide by the law, observe strict confidentiality with regard to the patient’s disease(s), the types of traditional medicines used or any information patients may disclose in the course of the consultation.
- Article 38: be accountable and liable for any damage caused to the patient as a result of negligence or non-compliance in the discharge of professional duties or failure to report undue obstruction of duties by an unauthorized person(s).
- Article 39: participate in collaborative research involving humans and animals where ethical standards have been met and approved.
- Article 40: immediately report, to the principal investigator of the research team, any adverse findings, especially when the health or well-being of the participant is in danger.
- Article 41: be law-abiding and strictly adhere to the laws of the country and the socially accepted norms; maintain high standards of integrity; promote and show concern for social justice in the community; be enlightened and conversant with the laws in every aspect of their professional practice.
- Article 42: not prescribe medicines derived from human body parts or organs.

Traditional medicine practitioners and sexual abuse towards patients

- Article 44: refrain from prescribing or administering sexual activity as a form of treatment of any disease, be it physical or spiritual.**

Management and ethical use of traditional medicines

Traditional medicine practitioners must:

- Article 45: abide by established advertising standards of the profession. The style and content of the advertisement must aim at protecting the interests of patients.
- Article 46: refrain from any act that would denigrate other traditional medicine practitioners or other professions.

- Article 47: adhere to the legal requirements and the provisions of the national code of advertising.
- Article 48: refrain from displaying false promises about the treatment of diseases.
- Article 49: be subject to disciplinary action for contravening national regulations.
- Article 50: be personally liable for misconduct of their staff or assistants who are not registered with the competent national authority but serve under their supervision.
- Article 51: refrain from making available for sale or dispensing to patients, traditional medicines that are substandard, mislabelled or adulterated.
- Article 52: be liable for disciplinary action with the possible suspension/cancellation of license as a traditional medicine practitioner upon infringement of the Code of Ethics, as prescribed by the PEC

III. Enforcing the code of ethics

This relates to the following areas:

- Adherence to the code
- Sensitization/training
- Monitoring/evaluation of the code.

III.1 Adherence to code

The PEC is the body responsible for ensuring adherence to the code and must include experienced and respectable practitioners. The operating principles of the PEC can be defined by the competent national authority and will have power to sanction practitioners.

III.2 Sensitization/training of traditional medicine practitioners

After developing and adopting the code of ethics, it is essential to sensitize and train traditional medicine practitioners on performance and moral obligations for compliance.

III.3 Monitoring and evaluation

The mode of practice of the profession can change over time. The code of ethics must be examined and reviewed periodically to reflect this reality. The constant monitoring and evaluation of the code will help determine the extent to which the code has achieved the expected results.

Chapter 3:

Licensing a traditional medicine facility

Introduction

Traditional medicine has made significant progress in most WHO Member States. Since the declaration of the 1st Decade of African Traditional Medicine (2001-2010), traditional medicine practitioners have made considerable efforts to improve their practice and products. However, there are many challenges that need to be addressed in relation to their services, products and facilities. These guidelines propose a harmonized approach for developing and regulating the establishment and operations of traditional medicine facilities.

I. Definitions

Licence for a traditional medicine facility: a document issued by a competent national authority to a traditional medicine practitioner to open and operate a traditional medicine facility.

Traditional medicine facility: traditional medicine facility means a clinic in which the entire knowledge and practices, tangible or intangible, explicable or not, are used to diagnose, prevent, stabilize or eliminate a physical, mental, psychological and social imbalance exclusively based on actual experiences and knowledge transmitted orally or in writing.

Traditional medicine shop: a shop in which plant, animal and mineral materials are sold for treatment purposes.

Traditional medicine production unit: a unit where traditional medicines are manufactured, distributed and sold.

II. Regulatory procedures

II. 1. Developing the regulation (See Chapter 1)

The development of regulations pertaining to the opening and operation of a traditional medicine clinic follows the same processes as described in Chapter 1, namely: advocacy, situational analysis, initial draft preparation, organization of a consensus workshop and adoption by the relevant authorities.

II.2. Main elements of the regulations

They are presented below in the form of articles:

Article 1: Conditions for opening and operating traditional medicine facility shall be determined by the provisions of these regulations.

Article 2: A traditional medicine facility shall comprise of any of the following:

- ✓ Traditional medicine consultation and care facilities;
- ✓ Traditional medicine shop;
- ✓ Traditional medicine production unit.

Traditional medicine facility

Article 3: A licence to open and operate a traditional medicine facility shall be issued by a decision of the competent national authority.

Article 4: No one may open a traditional medicine facility without first obtaining a licence issued by the competent national authority.

- Article 5: A registered traditional medicine practitioner may apply for a licence to open and operate a traditional medicine facility.
- Article 6: The supervision and control of traditional medicine facilities shall be the responsibility of the relevant services of the competent national authority.
- Article 7: Any holder of a licence to open and operate a traditional medicine facility must abide by the Code of Ethics.
- Article 8: Traditional medicine practitioners are civilly liable for all their acts in the facility.
- Article 9: Opening and operating of a traditional medicine facility without a relevant licence shall be deemed illegal.
- Article 10: The illegal opening and operating of a traditional medicine facility shall attract prosecution by a competent national authority.
- Article 11: Licensed practitioners shall display their licence in a conspicuous place on the premises that is accessible to all patients. All licensed practitioners shall give unhindered access at any time to inspectors sent by the Council to ascertain the suitability of the premises for the practice of traditional medicine.
- Article 12: The licence shall expire after a stipulated period, as specified by the national competent authority, and shall be renewable, subject to fulfilment of the laid-down conditions, including a record of satisfactory practice.
- Article 13: Traditional medicine practitioners who have already opened a clinic shall have a grace period (to be determined by the competent national authority) to comply with the provisions of these regulations; failure to do so shall result in sanctions provided for in these regulations.

III Enforcing the regulations

III.1. Main elements of application

Any practitioner wishing to obtain a licence to open and operate a traditional medicine facility must make an application. The latter must comprise a number of documents including:

- ✓ a written and stamped application indicating the type and location of the clinic, including the recommendation of the president of the recognized local traditional medicine practitioners association, administrative and health authorities of the place of residence of the applicant.
- ✓ Nationally-accepted identification document, or a birth certificate;
- ✓ a certificate of residence (for foreigners);
- ✓ an undertaking to abide by the code of ethics and good practices signed by the applicant;
- ✓ a certified true copy of the practitioner's licence to practice;
- ✓ an office copy of marketing authorizations where applicable;
- ✓ a certified true copy of import permit, where applicable;
- ✓ an office copy of a housing permit or a lease agreement, where applicable;
- ✓ passport photos.

III.2. Procedure for processing of application

III.2.1. Preliminary procedures:

Application forwarded to competent national authority shall be assigned to the body in charge of regulating traditional medicine. Upon receiving the application, the body shall verify that the application is complete and all the supporting documents are authentic. It shall then make a decision on the submitted application and prepare a draft response to be signed by the competent national authority addressed to the applicant. Where necessary, the reply should indicate the missing or additional documents to be provided by the applicant. Furthermore, the body shall prepare a summary report of the application for evaluation.

The outcome of the evaluation shall be:

- ✓ approval;
- ✓ deferment (additional documentation);
- ✓ rejection.

At the end of the evaluation, the secretariat shall prepare a report and communicate the decision in writing. In case of a favourable decision, a provisional/full licence signed by the competent national authority will be issued.

III.2.2. Main decision elements

The decision of the competent national authority shall be based on the evaluation report.

Part Two: Guidelines for regulating traditional medicine products

General introduction

Since the adoption of the Alma Ata Declaration in 1978 and the regional strategy in 2000, significant steps have been taken by many countries to include traditional medicines in their national health systems. However, there are regulatory shortcomings related to registration and distribution, Good Manufacturing Practices (GMP) and evaluation of the quality, efficacy and safety of traditional medicines.

This document proposes a harmonious approach that will enable Member States to develop and enforce regulations of traditional medicines more efficiently.

Objectives

These guidelines aim to assist Member States to:

- develop regulations related to GMP, certification, clinical trials, phytovigilance and advertisement of traditional medicine, practice and products.
- Develop mechanisms for enforcing these regulations.

Chapter 4:

Good Manufacturing Practice (GMP)

Introduction

The concepts of Good Manufacturing Practices, quality assurance and control are inter-related. Good Manufacturing Practices constitute elements of quality assurance. They entail a set of measures designed to prevent errors and contaminations during production. Indeed, their enforcement helps to ensure the good quality, safety and efficacy of medicines for the population. They guarantee that the manufacture and process control of medicines are based on quality standards required for their marketing authorization.

However, current methods of herbal medicines production do not always comply with the existing guidelines on GMP developed by the WHO. As a result, it is difficult for the competent health authorities to supervise the production of herbal medicines.

This guide is therefore intended to serve as an information and training tool for producers as well as a reference document for National Medicines Regulatory Authorities (NMRAs). (make reference to the GMP standards of countries)

I. Standards of Good Practices

These standards cover the entire manufacturing process, the staff, premises, storage, transport, archiving, documentation and quality control. They are based on the need to:

- ✓ Describe what has to be done,
- ✓ Do what is stated,
- ✓ Write what has been done.

Abiding by them requires the participation and commitment of the staff at all stages of the production line.

I.1 Principles

According to GMP, the product must not only meet final specifications, but be also manufactured under the same conditions and procedures each time to bring about product standardization. The establishments, their systems, equipment and processes must be properly controlled to ensure the systematic manufacture of quality products at all times.

Thus, before starting the production, it is always necessary to understand the Standard Operating Procedures (SOPs) and:

- ✓ Follow the SOPs to the letter and, in case of doubt, seek assistance and ask questions.
- ✓ Use the same and correct ingredients.
- ✓ Use the right materials and equipment.
- ✓ Avoid contamination and adulteration.
- ✓ Always ensure accuracy and precision especially in weights and measures.
- ✓ Maintain cleanliness and orderliness.
- ✓ Observe any errors and report immediately.
- ✓ Prepare clear and accurate reports on the work done and the controls made immediately.

I.2 Standards of hygiene and cleanliness

Basic standards of hygiene must be observed at all times. Precise cleaning and hygiene procedures must be applied to eliminate potential sources of contamination. These standards must apply throughout the entire manufacturing process.

I.2.1. Staff hygiene, clothing and cleanliness

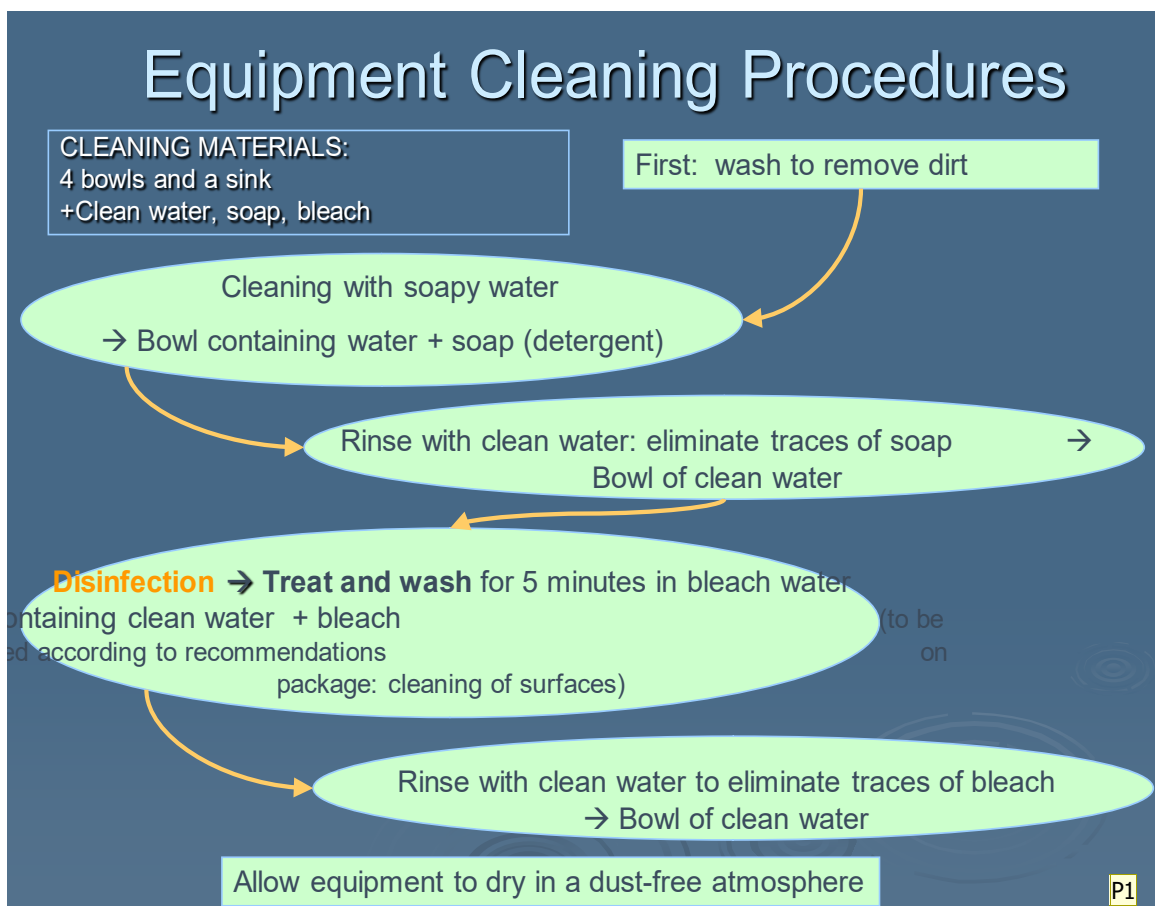
Any person handling raw materials, semi-finished and finished products must wash his/her hands, forearm with soapy water and wear clean gloves, a mask, a cap or a scarf, overall or suitable clothing for production. To reduce contamination from external sources, clothes and shoes must be changed on arrival and on leaving the production unit.

The clothing must be regularly cleaned. It is advisable to use disposable gloves, masks and caps. It is recommended to conduct a medical examination prior to recruitment of staff.

I.2.2. Equipment sanitation

Any equipment to be used for raw materials, and finished products must be clean. The equipment must be cleaned before and after each use and immediately after handling. The clean and dry equipment must be kept at a clean and dust-free place. Each piece of equipment must have a specific and exclusive use.

Figure 2: Equipment cleaning procedure



I.2.3. Premises sanitation

The entire premises should be cleaned shortly before and immediately after production (floors and work surface tops) daily. The floors should be cleaned at least 3 times a week with bleach (diluted according to the directions on the package: floor and surface cleaning).

Just before handling, clean all surfaces which will come in contact with the products with an appropriate disinfectant. Separate cleaning equipment should be used for the work surfaces and other similar areas.

Appropriate steps and precautions (eg. the use of air extraction and appropriate premises) should be taken during sampling, weighing, blending and processing of plant materials to avoid cross contamination and for staff safety.

I.2.4. Site sanitation

Waste bins must be regularly emptied in containers placed away from the production unit. Livestock, pesticides or fertilizers must be kept away from the production site (check GMP standards).

I.3. Organization

I.3.1. Premises

The premises must be suitable and sufficiently spacious. Depending on the activities, they may be divided into several compartments. It is essential to have separate shelves for storage of materials and equipment. This should be the same for stores and production areas.

The premises and equipment must be located, designed, constructed, adapted and maintained in a manner suited for the activities to be carried out. They should be clean and made of materials, which prevent infestation by insects, microorganisms and animals (rodents).

The plan, arrangement, design and use of the premises must aim at minimizing errors and facilitate free movement, effective cleaning and maintenance to avoid contamination and spoilage.

Lighting, temperature, moisture and ventilation must be appropriate to avoid directly or indirectly affecting the manufacturing process and storage.

I.3.2. Staff

Qualified and adequately trained staff is indispensable for the implementation of GMP standards. An organizational chart of the establishment defining the tasks and responsibilities of each employee must be developed. This must be accompanied by a clearly defined job description. Functions may be delegated to staff with suitable qualifications.

I.4. Manufacturing process

Any manufacturing process shall be clearly defined, systematically reviewed, standardized and should be reproducible. The process entails several stages, all of which are governed by precise instructions that will help to reduce or totally eliminate risks of verbally conveyed information, enable traceability and limit potential errors and disputes.

The procedures should be prepared in a clear and unambiguous language, and periodically reviewed. They must be used as reference and to train new staff members in the application of the methods and procedures.

I.5. Qualification and validation

In accordance with GMP, each production line must define the qualification and validation methods needed to prove that the critical aspects of the implementation of the processes are well understood and followed.

Validation studies are key elements of GMPs and must be conducted in line with predefined and approved protocols as quality assurance measures. Manufacturing processes and procedures must be evaluated on the basis of validation outcomes. Responsibility for managing the validations must be clearly assigned.

Qualification and validation must establish proof that: the premises, equipment and processes were designed in accordance with the requirements of GMPs. All aspects of the operation, including significant modifications made to the premises, installations, equipment or processes likely to directly or indirectly influence the quality of the product must be qualified and validated.

1.6. Documentation and archiving(including herbarium records)

Plants used as raw materials must be adequately documented and the information should contain:

- ✓ Full botanical name, **if not common local name**;
- ✓ Origin of the plant, harvest period, harvesting method, supplier, etc.
- ✓ Parts used;
- ✓ Description of drying methods;
- ✓ Description of the plant and its macroscopic and microscopic characteristics;
- ✓ Identification tests
- ✓ Dosage forms,
- ✓ Appropriate methods for determining possible contamination by pesticides;
- ✓ Tests to determine fungal and microbial contamination,
- ✓ Tests to identify toxic metals, contaminants and adulterants.
- ✓ Tests to identify other foreign substances.
- ✓ Pharmacopeia

Any treatment designed to reduce fungal or microbial contamination must be documented. Data on the treatment, tests and limits of the residues must be available. Instructions related to the methods for processing the raw plant material (e.g. drying, crushing and sieving), as well as methods used to determine the size of fragments or particles, must be adequately described.

To ensure the traceability of the production; batch documents, monitoring of the settings during production, measurements and observations made must be documented. It is equally advisable to have a physical trace in the form of a specimen sample for each stage.

1.7. Storage and transportation

Plants in the raw state (unprocessed) must be stored in separate areas. The storage area must be well ventilated and be protected from insects and other animals such as rodents. Effective steps must be taken to limit infestation.

The storage of plants, extracts, tinctures and other products may require special conditions related to humidity, temperature and light.

1.8. Quality control

Quality control is part of GMP. It is a process of ensuring quality from the starting material up to the finished product. It involves sampling, physical, chemical and microbiological analyses, documentation and release procedures which ensure that finished products are not released into the market without having passed the quality test. In view of the complex and variable nature of traditional medicines, quality control of the raw materials and finished products is of paramount importance.

Persons responsible for quality control must also be knowledgeable in some aspects of traditional medicines to be able to carry out identification testing for deterioration, presence and development of micro-organisms, infestations, heavy metals and pesticide contamination and batch-to-batch variations.

All control activities must follow written standard operation procedures.

Sampling for quality control test must be carefully carried out by staff with the requisite knowledge in order to minimise risks.

Quality controls must follow written Pharmacopoeial methods recognized by each country. The findings must be recorded and verified to ensure consistency, reproducibility and repeatability.

Documents related to sampling, control and recording; analytical reports and certificates; outcomes of validation of control methods for each batch must be kept for one year after the expiry date and at least five years after the release of the batch.

I.9. Quality assessment

I.9.1. Pharmaceutical assessment

This assessment should cover all the important aspects of the quality assessment of the traditional medicines. Where **an** herbal pharmacopoeia has a monograph it should be consulted. Where it does not, one should be developed using the same criteria as those for the monographs of the official herbal pharmacopoeia. All the processes used should follow GMPs.

I.9.2. Raw plant materials

The botanical definition, namely the genus name, species and the authority and family should be provided for a correct identification of the plant. A definition and description of the plant part used in manufacturing the medicine (leaf, flower, root for example), indicating if the plant is used in the fresh or dried or powdered state, or as an extract must be specified. Foreign elements and impurities as well as microbial load should be defined in terms of pharmacopoeial limits. Herbarium samples of the plant for each batch should be authenticated by a qualified botanist and kept for a minimum of 10 years. A batch number should be assigned and indicated on the label of the product.

I.9.3. Plant preparations

Plant preparations could be in the form of whole plant part, powders, tinctures, decoctions, fatty or essential oils, saps, resins, and other plant-derived constituents. The manufacturing method must be described in detail. Where a substance is added during the manufacturing process to alter the content or characteristic of a specific active ingredient, or for any purpose, it should be specified. An identification method both qualitative and quantitative, for the preparation, should be indicated. Where it is not possible to identify the active ingredient, it will be sufficient to identify a substance or a mixture of characteristic substances (eg. chromatographic profile) to confirm the quality of the preparation.

I.9.4. Finished product

The manufacturing process and formula, including the quantity of excipients should be described in detail. A method of identification, and if possible of quantification of the plant preparation in the finished product, should be defined.

I.9.5. Stability

The physical and chemical stability of the product in the container intended for marketing should be assessed in specific storage conditions and the shelf life established.

I. Applying standards: good practices inspection

This helps to ensure that the traditional medicines are produced in accordance with the regulations. Inspection should cover all production activities in the facility and must follow well-established procedure. The procedure entails the following descriptive elements:

Herbal Medicines Production/Manufacturing Facility		
National Competent Authority Logo	INSPECTION REPORT	Ref. No.
Date:	Name of Facility:	Facility Reg. No.
Parameter Assessed	Observations	Recommendations

Inspectors:

Name (Surname First) Designation signature

a)

b)

Head of facility/Authorised Representative/Facility witness

Designation.....Signature.....

Note: Refusal by a facility owner/representative to countersign an inspection report

is an offence (refusal to cooperate with inspectors) and does not invalidate the inspection report.

III.5 Methodology :

The inspection and classification are divided in fourphases:

- programming
- Preparation
- Actual inspection
- Preparing a review or report and monitoring.

III.5.1 Programming:

An annual inspection programme is established by the relevant entity. Inspections are planned according to the annual objectives defined by following an order of priority aimed at reducing key risks to health and safety.

Various kinds of inspection may be undertaken:

- **“Routine”**: they are based on a pre-established programme designed to monitor compliance withGMP standards
- **"Targeted"**: these are inspections intended to meet the demands of various contract givers. They include:
 - one-off and urgent **investigations** ordered by competent authorities **e.g. complaints**/potentially at risk;
- **monitoring** (or inspection follow-up) of establishments requiring particular vigilance;

III.5.2. Preparation:

Preparation is the most essential stage since it determines the success of an inspection.

The preparatory phase consists of:

☞ **Defining inspection objectives:**

The purpose of an inspection is to verify and oversee compliance with regulations and GMPs recognized by a country.

☞ **Creating an inspection team:**

Inspection may be conducted by two or three authorized inspectors.

An inspection team leader is appointed to coordinate the inspection.

☞ **Searching and studying reference data and methodological tools:**

Inspection entails a comparison of practices within the establishment inspected with one or more body of references. The latter comprise laws, regulations, circulars, guides, good practices and grids. They differ from country to country.

☞ **Review of administrative documents and previous inspection reports:**

Review the documentation prior to the inspection: an inspector has to check the documents of the establishment concerned and note the missing ones for subsequent queries during the inspection. The review will help the inspector have an idea about the operation of the establishment, its size and volume of activities.

Previous inspection reports: they must be used as a baseline data for the subsequent inspection; they will help identify the various weaknessesdetected at the last inspection and gain an early insight into the operation of the establishment.

☞ **Informing the manager of the unitto be inspected by telephone or fax, where the inspection is not a surprise one.**

☞ **Items required:**

The following items and materials may be taken along:

- *Mission statement and/or inspection mandate;*
- *Statement of sample taking, findings;*
- *Sample-taking equipment;*
- *Usable reference items;*

III.5.3 Actual inspection process:

The actual inspection process consists of:

Pre-inspection meeting

An inspection systematically begins with an opening meeting involving the inspection team and the person in charge of the establishment.

The purpose of the opening meeting is to:

- Establish an initial contact with the persons to be inspected;
- Spell out the purpose of the inspection;
- Outline the inspection plan;
- Determine the inspection duration;
- Gather a number of administrative, regulatory and technical information on the establishment:
 - The staff (number, qualification, training and hygiene),
 - The premises,
 - Equipment (maintenance, servicing),
 - Materials,
 - Operations conducted (procedure, control),
 - Quality management.

Field inspection

The inspection consists of verifying the conformity of the practices with the current standards and comparing them with what was described in the procedures.

On-the-spot statements may be made on punishable violations noted during the inspection.

The inspectors may request that all the documents needed for the inspection be provided, irrespective of the medium and copies made, samples taken, and any relevant information or supporting document collected on the spot or by invitation.

For computerized information, access to relevant software and data must be provided to the inspectors. The latter may request a directly usable transcription, involving any appropriate technology, of documents for the purpose of the inspection.

Post-inspection meeting

At the end of the inspection, a closing meeting must be organized between the inspection team and the head of the establishment. But, prior to the meeting the inspectors must meet in order to collate the various observations made and agree on what message to pass on to the management of the facility.

The various comments will be presented by the inspection team leader and eventually discussed in order to clarify any ambiguities or controversies. The follow up of the inspection and monitoring modalities will be explained.

III.5.4 Report preparation and despatch:

After each inspection, a report should be prepared and signed by the inspection team; the report should contain all the observations made during the inspection. It should contain comprehensive and organized details that would help ascertain the conformity of the activity, operations carried out and products with the relevant enforceable standards.

Observations that were not made at the closing meeting or later raised with the officials of the establishment should normally not be included in the report.

In the event of an investigation (enquiry, or complaints), the report should not be given to the inspected party.

Any inspection report should be subjected to quality control, both in terms of form and the content, by the unit in charge of the inspection, in order to ascertain the accuracy of the report. Quality control must also ensure that the conclusion addresses the totality of issues pursued by the inspection team and helps make a general assessment of the establishment's activity or its consequences for public health.

III.5.5 Monitoring:

Monitoring will consist of verifying during a later inspection the application of corrective measures recommended in accordance with the Action Plan for Resolving Regulatory Violations. Furthermore, additional resources or administrative measures may be envisaged and also monitored.

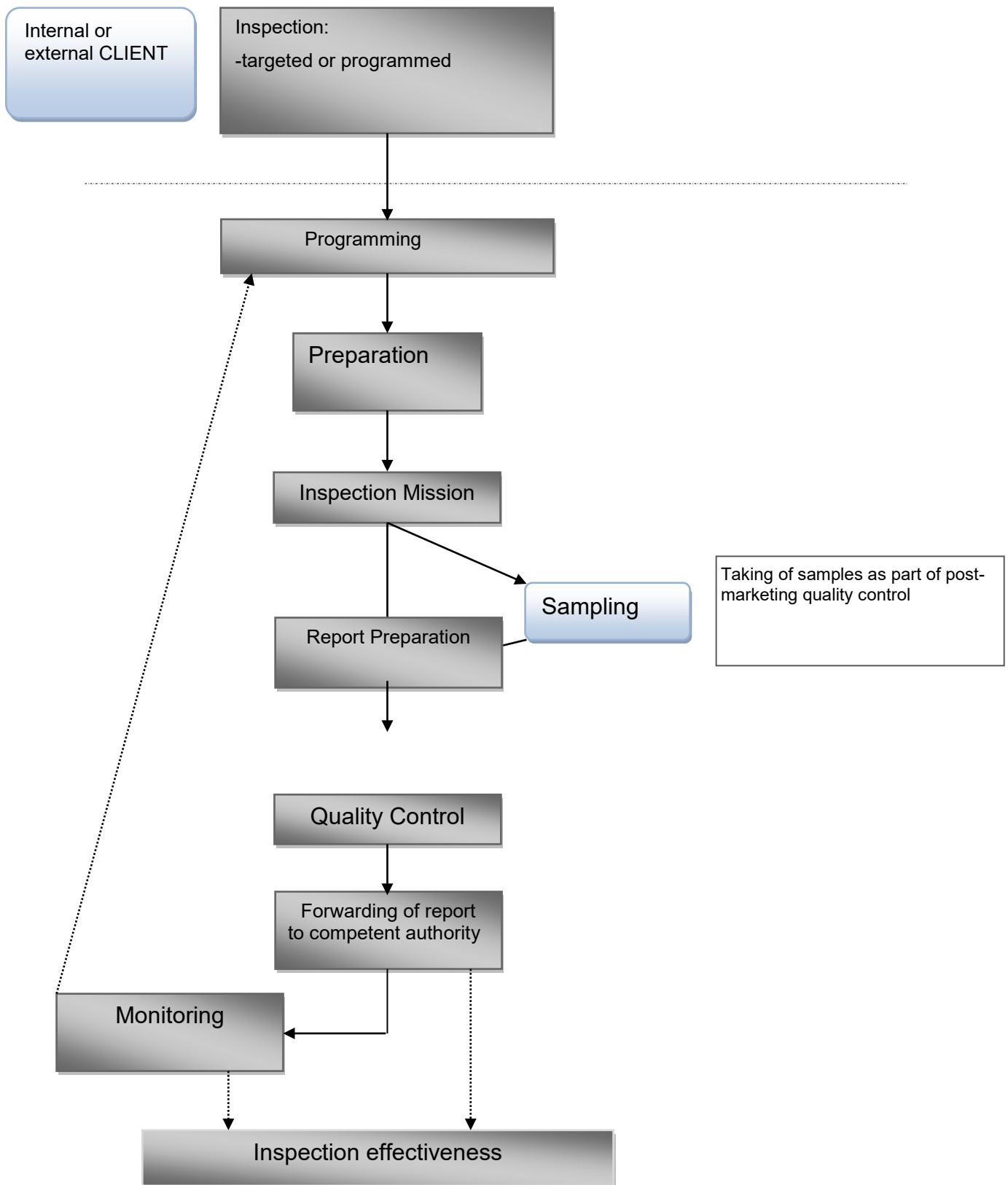
Hence for greater efficiency, the main regulatory violations should be the subject of a consensual action plan **based on a written agreement**.

III.6 Inspection effectiveness:

The monitoring and evaluation report of the inspection unit is used to prepare its annual progress report.

The findings of internal and/or external monitoring and evaluation are also taken into account. This analysis also helps assess customer satisfaction, resource needs and to modify the process, where necessary.

Figure 3: Flowdiagram of inspection procedure



Chapter 5:

Certifying traditional medicines

Introduction

The development of plant medicines constitutes a major challenge for African countries whose biogenetic resources are highly diversified. This calls for coordinated research to accumulate data needed for the validation of usable plant medicines in treating priority or emerging diseases. Research has therefore been conducted on many plants in institutes and universities throughout Africa. Some of the research has yielded tangible results and the medicines derived are currently produced on a semi-industrial or industrial scale.

Even the medicines marketed have low distribution within and between the African countries as a result of the poorly developed nature of the sector, lack of harmonised certification procedures and weak registration systems. This hinders the development of a local pharmaceutical industry for plant medicines.

These guidelines aim at providing a framework for the certification of traditional medicines for the Member States of the WHO African Region.

I. Definitions

- **Certification:** it is the procedure leading to the granting of marketing authorisation of a traditional medicine by the National Medicines Regulatory Authority.

- **Registration:** it is the consequence of the certification, namely the inclusion of a medicine on a country's list of approved medicines

- **Marketing authorization:** this is an operating right conferred on a specific product for its importation, withholding, distribution and dispensing in a given country for a given period.

II. Regulation procedure

II.1 Regulation development

This comprises of:

- ✓ Advocacy
- ✓ Consensus building
- ✓ Actual development process
- ✓ Adoption process

II.1.1 Advocacy

This aims to sensitize political, administrative, traditional and religious leaders. It is generally undertaken by a multidisciplinary and multisectoral task force (researchers, academia, legal experts, practitioners of traditional and conventional medicine, pharmaceutical industries, professional associations and NGOs operating in the area of traditional medicine). Advocacy must be based on many publications related to ethnobotanical, ethnopharmacological, ethnomedical, preclinical and clinical studies and pharmacopoeia, and their contribution to addressing the health needs of communities.

II.1.2 Consensus building

This is required to engage all the stakeholders involved in the promotion of traditional medicine. Consequently, it is essential to identify resource persons and to set up a committee to organise the workshops.

II.1.3. Actual development process

This comprises of a series of workshops to conduct a situational analysis, outline objectives and strategies, and to reach consensus on the document, which will be submitted to the competent national authority for validation.

II.1.4. Adoption

The draft document must be submitted to the competent authority for adoption.

Following the adoption, advocacy must be undertaken with the national and local authorities for their involvement, commitment and support in the enforcement of the regulations. Hence, practitioners must be sensitized for the purpose of familiarization and ownership of the regulations. At the end of the advocacy, awareness and training, the enforcement of the regulations must become effective.

II.2 Main elements to be regulated

II.2.1 Classification of traditional medicine products

Traditional medicine products are classified into 4 categories based on the method of preparation, indications for use and the extent of development.

II.2.1.1. Category 1 medicine

The criteria for Category 1 medicine are as follows:

- ✓ It is prepared extemporaneously (generally following consultation in a herbal clinic);
 - ✓ It is prepared following traditional methods of production and standardization (the formula and method of preparation are chosen by the traditional practitioner);
 - ✓ Its safety and efficacy are guaranteed by the long period of use (over 20 years);
 - ✓ Raw materials are well-known to traditional practitioners and may be fresh or dried;
 - ✓ Aqueous preparations usually have a short shelf life which, generally, does not exceed one week;
- It is distributed on an individual basis.

II.2.1.2 Category 2 medicine

The criteria for Category 2 medicines are as follows:

- ✓ It is prepared in advance, packaged with a batch number;
- ✓ Raw materials used in its composition are well known by the community;
- ✓ It is produced by methods that guarantee its stability and standardization;
- ✓ It is produced industrially or semi-industrially;
- ✓ Its safety and efficacy are guaranteed by ethno-medical evidence from a long period of use or by open clinical trials where this is deemed necessary by the competent authority;
- ✓ The constituent ingredients are raw materials;
- ✓ Main chemical groups of the raw material are known;
- ✓ The shelf life is determined through stability tests.

II.2.1.3. Category 3 medicine

The criteria for Category 3 medicine are as follows:

- ✓ It is prepared in advance and packaged with a batch number;
- ✓ Its production is semi-industrial or industrial;
- ✓ Its shelf life period is determined by stability tests;
- ✓ The active ingredients are standardized extracts;

- ✓ It takes into consideration the biological properties of raw materials, new therapeutic indications, galenical formulations with dosage specification and knowledge about biologically active molecules;
- ✓ Its standardization and production are based on GMPs;
- ✓ Its efficacy and safety are proven by preclinical and clinical trials based on standard protocols.

II.2.1.4. Category 4 medicine

The criteria for Category 4 medicine are as follows:

- ✓ It is imported
- ✓ It should be registered in the country of origin
- ✓ It meets all the requirements of Category 3 medicines

II.2.2. Documents for registration

Any traditional medicine may be retailed or wholesaled if it has a marketing authorization (MA). The conditions for obtaining an MA must be determined by a competent national authority.

Only Category 1 medicines are exempted from this requirement. Properly enforced regulation of traditional medicine practice in an approved facility is sufficient guarantee for the safety of these remedies.

For Categories 2, 3 and 4, an MA must be obtained through an application to the competent authority. The MA is granted by the competent authority following the decision of a national committee of experts.

II.2.2.1. Applying for Category 2 medicines:

This application is still called simplified application and consists of 3 parts:

II.2.2.1.1. Administrative application

- ✓ An application form addressed to the competent national authority;
- ✓ Record of the production unit;
- ✓ A copy of the licence permitting the establishment of the production unit;
- ✓ Samples of the final product to be sold;
- ✓ Proof of payment of application fee;
- ✓ Proposed wholesale price excluding taxes;

II.2.2.1.2. Pharmaceutical documentation

- ✓ Raw materials
 - Complete monographs of plants used as raw materials;
 - Scientific name and synonyms of each (family, gender, species and varieties) as well as the author and family of the scientific binomial;
 - Names in main local languages;
 - Brief description of plant;
 - Organoleptic, macroscopic and microscopic features;
 - Geographical distribution, habitat and harvesting information;
 - Stability and quality control data (purity, general characterization tests and physical and chemical properties).
- ✓ Manufacturing process
 - Formula, including excipients;
 - Manufacturing procedures;
 - Quality control;

- GMPs report.
- ✓ Finished product
 - Labelling: information indicated on the label should contain manufacturer's details, name, strength and composition of the product; dosage and directions for use, category of medicine, expiry date and batch number, auxiliary labels ("keep away from children", storage conditions, route of administration, etc.)
 - Packaging: highlights of prescribing information (package inserts); indications and usage; dosage and administration; dosage forms and strengths; contraindications; warnings and precautions; adverse reactions; drug interactions; use in specific populations; overdose and management; clinical pharmacology; references; how supplied/storage and handling; patient counselling information
 - Results of quality control of finished product;
 - Results of stability tests of the finished product in relation to the organoleptic and active constituent characteristics.

II.2.2.1.3. Clinical Toxicology documentation

- ✓ A technical report (such as ethno medical information) certifying the long period of use of the medicine in its current or previously-used form (a minimum of 20 years). The known and potential toxicological risks related to the misuse must be presented in detail (dose dependent/independent toxicity). Risks related to misuse of the medicine as well as the possibilities of physical or psychological dependence must also be indicated.
- ✓ Investigations by research institutes and verifiable statements by conventional and traditional medicine practitioners, who have already marketed the product will be taken into account. A comprehensive bibliography (publications, theses, dissertations, WHO, WAHO, CAMES and AU/STRC reports etc.) toxicity tests already conducted on plants used or on species belonging to the same family.

II.2.2.2 Documentation for Category 3 medicines

It consists of 4 parts:

II.2.2.2.1. Administrative documentation

- ✓ An application form addressed to the competent authority;
- ✓ Record of the production unit;
- ✓ A copy of the licence authorizing the establishment of the production unit;
- ✓ A copy of memorandum of understanding, notably a partnership agreement (where applicable) between the producer/traditional medicine practitioner and a research institute (where applicable);
- ✓ Samples of the final product to be sold;
- ✓ Proof of payment for application determined by the competent national authority.

II.2.2.2.2. Pharmaceutical documentation

- ✓ Raw materials (extracts)
 - Complete monographs of plants used as raw materials;
 - Scientific name of each plant, and synonyms (family, genus, species and variety) as well as the author and family of the scientific binomial;
 - Names in the local languages;
 - Brief description of the plants;
 - Organoleptic, macroscopic and microscopic features;
 - Geographical distribution, habitat and harvesting information;
 - Method of standardization of the extracts;

- Quality control methods; Stability and quality control data (purity, general characterization tests and physical and chemical properties).
- ✓ Manufacture
 - Formula, including excipients;
 - Manufacturing procedures;
 - Quality control;
 - GMPs report.
- ✓ Finished product
 - Labelling: information indicated on the label should contain manufacturer's details, name, strength and composition of the product; dosage and directions for use, category of medicine, expiry date and batch number, auxiliary labels ("keep away from children", storage conditions, route of administration, etc.)
 - Packaging: highlights of prescribing information; indications and usage; dosage and administration; dosage forms and strengths; contraindications; warnings and precautions; adverse reactions; drug interactions; use in specific populations; overdose and management; clinical pharmacology; references; how supplied/storage and handling; patient counselling information
 - Results of the quality control of the finished product;
 - Results of the stability tests of the finished product.

II.2.2.2.3. Preclinical data

- ✓ Efficacy data;
- ✓ Safety (acute and sub-chronic toxicity) in animal experiments;
- ✓ Literature review (ethnographic and scientific records);
- ✓ Technical report on the tests conducted.
- ✓ Observational studies report (if available)

II.2.2.2.4. Clinical data

- ✓ Approval of clinical trials by a competent national authority (recognised ethical committee or board);
- ✓ Clinical trials protocol based on standard methods (Phases I and II);
- ✓ A technical report of the clinical trials conducted.

II.2.2.3. Category 4 medication documentation:

It consists of 4 parts:

III. Procedure for applying for Category 4 certification

The granting of an MA by the competent national authority must be based on the quality, safety and therapeutic efficacy of the product. The procedure for assessing an MA application involves the following stages:

III.1. Receipt of application

The application is received by the National Medicines Regulatory Authority, and a receipt is issued to the applicant. An analysis and administrative assessment is then conducted to determine the completeness of the application. The application is then forwarded to the committee of experts.

III.2. Assessment

The technical expert committee appointed by the competent national authority reviews the submission, and compares the product with similar medicines that have already been certified.

III.3. Decision

The technical expert committee is responsible for validating the application using the following criteria:

- ✓ Therapeutic significance and efficacy;
- ✓ Safety;
- ✓ Quality;
- ✓ Proposed wholesale price excluding taxes

The marketing licence is granted or refused by the competent authority in accordance with the recommendation of the technical expert committee. The decision could be one of the following:

- ✓ approval;
- ✓ conditional approval;
- ✓ deferment (additional documentation) ;
- ✓ rejection

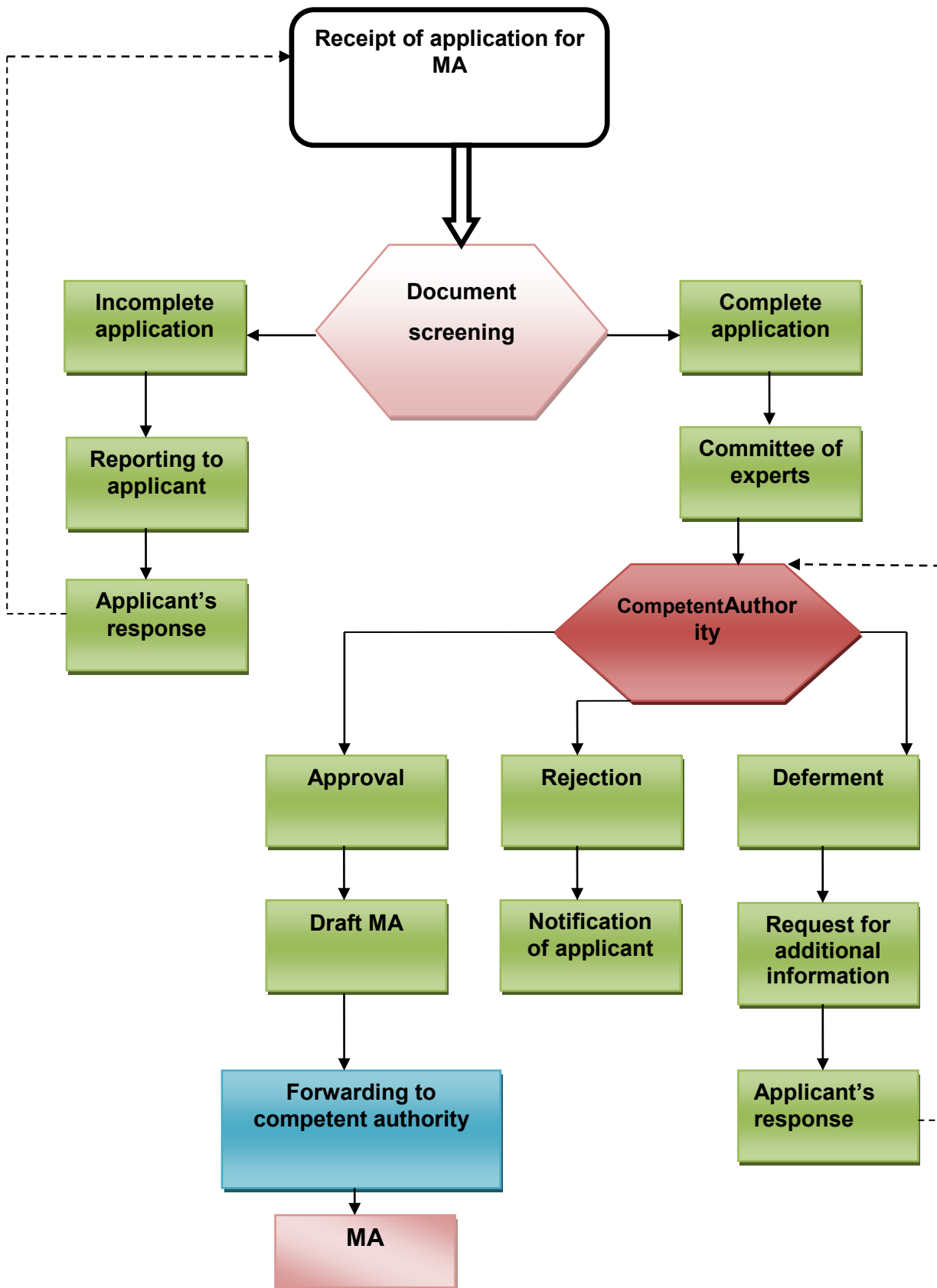
A rejection must be justified and the applicant notified in writing. In the event of a rejection, the applicant has a right of appeal.

III.4. Duration and renewal of MAs

The marketing licence is valid for at least ten (10) years from the date of registration. The renewal is subject to the submission of an application comprising of:

- ✓ An application addressed to the competent authority
- ✓ certification written testimony indicating that no modification has been made to the product since the last registration
- ✓ A copy of a valid certification from the country of origin, e.g. evidence that the product has not been withdrawn. In case of voluntary withdrawal, a case-by-case decision can be made;
- ✓ Proof of payment of renewal fees

Figure 4: Flow diagram of certification decision



Chapter 6:

Clinical Trials / Efficacy and safety assessment

Introduction

The use of plant-based medicines is traditionally recognized in many African countries. The wealth of the African flora has helped in the development of many remedies used for the treatment of diseases such as malaria, sickle-cell disease, HIV/AIDS, diarrhoeal diseases etc.

However, there is insufficient scientific data to validate their use. This is due to inadequate funding, which makes it almost impossible to conduct scientific studies, on the same scale as conventional medicines. In addition, the majority of the few clinical studies that have been conducted in the region do not meet the required standards. This could, in part be explained by the lack of regulatory framework for the conduct of clinical trials.

These guidelines seek to address this problem.

I. Definitions

Clinical trial: is any research conducted on a human being aimed at discovering, identifying and/or ascertaining the effects of a prophylactic, therapeutic or diagnostic agent. Clinical trials are based on rules of good practices, called Good Clinical Practices (GCP).

Controlled clinical trials: it aims at establishing a causal link between the administration of a medicine and the appearance of an event. Comparison is made between the group that takes the medicine and the one that takes a placebo or a reference substance; this group is called the control group.

Randomization: Randomization is a process that assigns research participants by chance, rather than by choice, to either the treatment group or the control group.

II. Clinical trial

Any clinical trial must be conducted in accordance with a protocol drafted and previously approved by health authorities. Most good protocols are designed by a team of experts. Protocols must include the justification of the study and define the issues to be addressed.

The population studied must also be clearly defined with an inclusion and exclusion criteria, as well as the recruitment process used to assign the participants to various groups. The protocol must define the clinical and biological parameters needed to detect toxicity and efficacy, and provide a plan to address any emergencies and adverse events of the medicine.

For each study participant, informed consent, medical history, information on the treatments followed and brief reports of all the examinations and controls undertaken as well as the results of laboratory tests should be documented.

Efficacy must be determined on the basis of defined criteria such as improvement in clinical symptoms or signs and change in biological markers. Safety should be monitored in accordance with development of symptoms or signs, by paying particular attention to organs that are likely to be affected, such as the liver, kidney, heart and blood. In addition, a good knowledge of statistics is essential for planning and data analysis. Well-established, randomized and controlled clinical trials provide evidence of efficacy. However, the use of placebo, controlled clinical trials is not always possible because of ethical or technical problems.

III. Safety assessment

This must cover all aspects of the safety of the product. The basic principle stipulates that: if the product is used in a traditional way without any harmful effect having been reported for 100s of years, no special restrictive regulatory action needs to be taken unless fresh data requires a revision of the risk/benefit assessment. Such fresh data is generally provided through toxicological testing and clinical trials.

In the absence of detailed toxicological studies, risk assessment should be based on review of the documentation showing safe use of the remedy over a long period. However, even in some cases of prolonged use of a medicine, it is possible for chronic toxicity to occur without being detected. Known toxicological risks, specifying direction for use, should be documented and presented. The possibility of misuse, abuse or dependence must also be documented and presented.

Where prolonged traditional use cannot be shown or where there are doubts regarding the safety of the product, toxicity data should be submitted.

IV. Efficacy assessment

The assessment should cover all key aspects of efficacy. This requires a review of existing literature. The pharmacological and clinical effects of the product and, where the active ingredients are known, they should be specified or described.

Evidence for efficacy depends on the type of indication and for less serious disease conditions and for prophylaxis, the traditional use of the product can be considered. The reports by doctors, traditional medicine practitioners or patients treated describing the use of the product could also be taken into account.

Where traditional use has not been established, appropriate pharmacological and/or clinical data should be provided through clinical trials.

V. Regulatory procedure

V.1 Development (see previous chapter)

The development of regulations related to the granting of clinical trials authorization for traditional medicine follows the same stages as that of the regulations of traditional medicine practitioners: advocacy, situational analysis, **initial draft preparation**, organization of a consensus workshop and adoption of the regulations by competent national authorities.

V.2. Main elements to be regulated

V.2.1: Clinical trial authorization

Clinical trials constitute a mandatory step for granting a Marketing Authorisation for category 3 and 4 medicines.

Any clinical trial is subject to granting of an authorization. The following articles are therefore proposed as essential elements of the regulations.

Article 1: No clinical trial shall be undertaken in a country without a written authorization from the competent authorities.

Article 2: Authorization for clinical trial confers on a person or legal entity the right to undertake a specific clinical trial.

- Article 3: Granting of an authorization shall be subject to the payment of an application fee. The application costs shall be determined by the competent national authority.
- Article 4: The sponsor is an individual, an organization, a group or any other legal or research entity that initiates, organizes and/or finances a clinical trial. Where several persons take the initiative for a clinical trial, they shall appoint a person or legal entity as the sponsor and assume the relevant obligations.
- Article 5: The principal investigator shall be the person who will direct and oversee the clinical trial at a specified venue.
- Article 6: An application for clinical trial comprising of the following documents must be sent to the competent national authority:
- ✓ An application form duly completed and signed by the sponsor
 - ✓ Clinical trial protocol
 - ✓ Investigator's brochure (CV) of the investigator(s)
 - ✓ Information leaflet of participants and the informed consent form
 - ✓ GMP certificates of the medicines
 - ✓ Statement forms completed and signed by the investigators
 - ✓ Evidence of the approval by the ethics committee; for international collaboration, the protocol must be cleared by all participating countries.
 - ✓ Evidence of payment of application fees
 - ✓ Indemnity insurance cover
 - ✓ Written confirmation of the budget for the study
- Article 7: The competent national authority has a maximum period of 90 days to make a decision and communicate it to the applicant. The decision may be an approval, deferment or rejection. **Beyond this delay, the authorization is considered granted.**
- Article 8: The sponsor and principal investigator must ensure that the clinical trial is conducted in accordance with current good clinical practices guidelines defined by the competent national authority or internationally-acceptable guidelines.
- Article 9: The principal investigator shall inform the competent national authority, Institutional Review Board and the Data Safety Monitoring Board of any serious adverse events in the course of the study in accordance with established procedures. In a multi-centre study, adverse events must be communicated to the relevant competent national authority by the sponsor.
- Article 10: A mid-term and a final report of the trial results should be submitted to the competent national authority in accordance with the framework described in the clinical trial protocol.
- Article 11: Any duly mandated clinical trial may be subjected to inspection by the competent national authorities to ensure compliance with the protocol.
- Notwithstanding legal lawsuit, the inspection report may provide reasons for the suspension or immediate discontinuation of any on-going trials.

V.2.2: The clinical trial authorization technical review committee

The committee shall be responsible for assessing the clinical trial application and make recommendations for the national competent authority to take an informed decision.

Its establishment and functions must be approved by the competent national authority. The following articles provide details of the main elements to be considered for the establishment of the technical review committee.

Article 1: A technical committee for reviewing applications for clinical trial authorization is hereby established.

Article 2: The committee comprises of the following members:

- Chairperson: who may be nominated by the relevant national competent authority
- Secretary: who may be the person responsible for regulation at the NMRA
- Members:
 - Pharmacist
 - Epidemiologist
 - Pharmacologist
 - Toxicologist
 - Herbalist/phytotherapist
 - Clinician
 - Ethicist
 - Pharmacognocist
 - Pharmaceutical technology expert
 - Other relevant researchers

Article 3: The members of the clinical trial technical review committee shall be appointed by the competent national authority for a three-year period, subject to renewal.

Article 4: The technical review committee may co-opt any other experts where necessary, with the approval of the competent national authority

Article 5: Members of the technical committee must not have any interest in the clinical trial being reviewed, or must disclose the existence of such interest.

Article 6: A meeting of the technical committee can be convened if two-thirds (2/3) of the members are present.

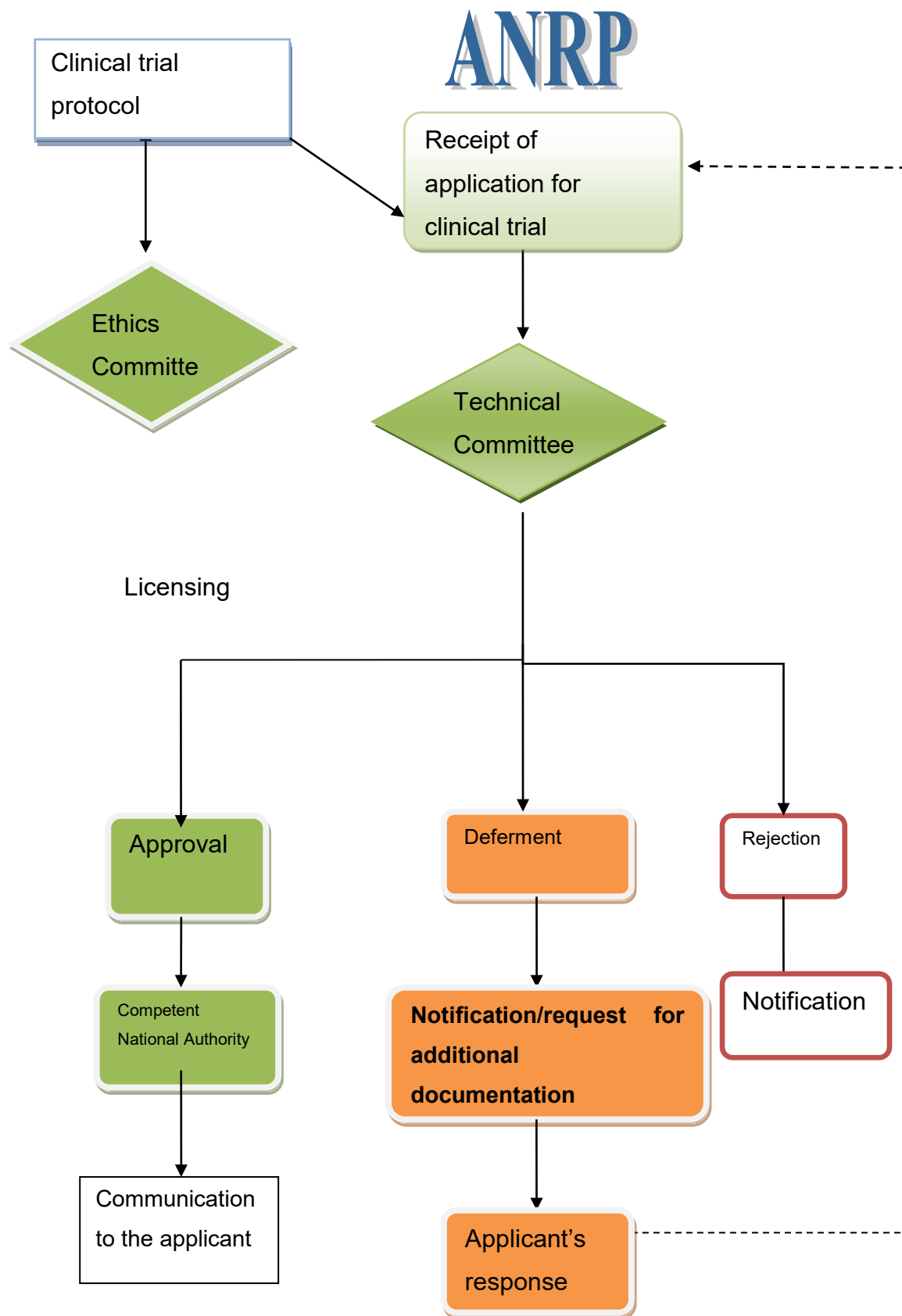
Article 7: The operation of the technical committee shall be governed by written procedures and the operating costs included in the budget of the competent national authority.

V.3. Application procedure

It consists of three stages, which may be adapted to the unique circumstances of Member States:

- Assessment by the ethics committee of a given health research
The committee is responsible for the ethical assessment of any research project. Approval by the committee is one of the elements of the application for authorization
- Assessment by the technical committee
- The protocol approved by the ethics committee is forwarded by the applicant to the competent national authority who in turn forwards it to the technical committee for assessment and decision
- Decision by the competent national authority

Figure 5: Flow diagram of clinical trial decision



Chapter 7:

P o s t .

Marketing surveillance/ phytovigilance

Introduction

For a long time medicinal plants and phytomedicines were considered safe because they are natural. Currently, there is an increasing interest in the use of traditional medicines for the treatment of diseases such as malaria, HIV/AIDS, cancer etc. Besides, some patients often combine conventional medicines with medicinal plants for their health care with potential herb-herb interaction eventualities.

Although plant medicines are assumed to be safe, it must be noted that they contain several chemical compounds that are often pharmacologically active and likely to have adverse side effects or interactions with conventional medicines. In view of this, their use requires continuous vigilance for patient safety.

The aim of these guidelines is to assist the WHO African Regional Member States to develop enforceable regulations on pharmacovigilance of medicinal plants and plant products.

I. Definitions

Pharmacovigilance: it is the system of surveillance that enables a health authority to detect, assess, understand and prevent risks of side effects as well as any incident or hazard related to the use of health products for humans after their release on the market.

Phytovigilance: this is a surveillance system that enables a health authority to detect, evaluate, understand and prevent risks of adverse effects, as well as any other incident or hazard related to the use of medicinal plants and their products.

Adverse event: any harmful and unintended manifestation occurring to a person during or after treatment which may or may not be related to one or more of the medicinal plant in a product(s);

Side effects: Any unwanted non therapeutic effect caused by a drug

Adverse effect: a harmful and unintended reaction due to a medicinal plant product resulting from its normal use for prophylaxis, diagnosis or treatment of a disease or modification of a physiological function. It also comprises any incident or hazard resulting from misuse or the poor quality of the medicinal plant product;

Imputability: individual analysis, for a given notification, of the causal relation between the taking or use of a medicinal plant product and the occurrence of an adverse event;

Reporting: the mandatory reporting of the presumed adverse effect of a medicinal plant product; this is done by completing a reporting form which is sent to a pharmacovigilance centre;

II. Phytovigilance regulation

II.1. Creating a system of vigilance on the medicinal plants and products

Each country must develop its own phytovigilance system, which should be part of the National Pharmacovigilance system. The role of phytovigilance is to:

- ✓ Ensure that the risks related to the use of medicinal plant product are anticipated and well managed.
- ✓ Provide the regulatory officials with the necessary information to change the recommendations concerning the use of that traditional medicine;
- ✓ Improve communication between health professionals and the public
- ✓ Assist health professionals to better understand the risks/efficacy of medicines.

The development of an operational and effective phytovigilance system is a protracted process.

Phytovigilance must be supported and accommodated by the national medicines regulatory authority (NMRA).

Collaboration and coordination between the NMRA and the health centers, traditional health practitioners and professional associations are necessary for coherent development and prevention of duplication of efforts. To create a phytovigilance system, the following steps must be taken.

- ✓ Consultation with all the health authorities, traditional health practitioners, professional associations and all other entities involved in the process.
- ✓ Preparation of reporting forms and making them available
- ✓ Sensitization of all health professionals about the definitions, objectives and methods used in phytovigilance.
- ✓ Creation of the centre (recruitment of staff, purchase of the necessary materials and equipment)
- ✓ Staff training
- ✓ Creation and maintenance of a database
- ✓ Promotion of the importance of the reporting of adverse effects of medicines through medical journals and other professional publications.
- ✓ Establishing relations with international institutions working in the area of pharmacovigilance.

Moreover, in order for the system to be functional, it must be supported by a legal framework comprising of the following articles:

Article 1: A phytovigilance system is hereby created as part of the national health products vigilance system under the supervision of the Ministry of Health or competent national authority.

Article 2: The aim of the national phytovigilance system is to monitor the adverse effects and events related to the use of medicinal plants and products to guarantee their safe use.

Article 3: Phytovigilance comprises of:

- detection of adverse effects;
- collection of information and reporting of the adverse effects in accordance with the reporting system defined by the Ministry of Health;
- collation and assessment of the information;
- Recommendation for studies to be conducted or for safe use or banning of such products.

Article 4: The operating costs of the centres shall be covered from the government budget.

II.2. The phytovigilance technical committee

This committee shall be responsible for data assessment and interpretation and publication of information. Its creation and operation must be regulated by the competent authority. It must be multidisciplinary:

- ✓ Medicine,
- ✓ pharmaceutical sciences,
- ✓ clinical pharmacology,
- ✓ epidemiology,
- ✓ pathology,
- ✓ phytotherapy
- ✓ toxicology
- ✓ traditional medicine

The committee shall be responsible for:

- preparing the meetings of the national phytovigilance technical committee;
- proposing investigations to the national pharmacovigilance committee in the event of an alert;
- documenting and assessing the information collected through reports, surveys and related studies;
- proposing risk management plan related to the use of plant medicines.

-II.3. Reporting system

To ensure greater effectiveness, reporting must be regulated. The channel varies depending on the organization of the country's health system. The major elements of such regulation have been formulated hereunder in the form of articles.

Article 1: Reporting may be made by traditional medicine practitioners, practicing physicians, pharmacists, dentists, mid-wives, nurses, and any other health professionals mandated to prescribe or dispense medicines.

Article 2: Adverse effect observed from a plant product should be reported to the phytovigilance centre or nearest health care institution.

Article 3: A phytovigilance focal point shall be created in the regions as well as health care institutions, and shall be in charge of:

- Collecting information provided by reporting officers;
- Supporting and advising the reporting officers to complete the reporting forms;
- Investigations where necessary;
- Archiving the documents;
- Providing feedback to the reporting officers;
- Contributing to the training and raising the awareness of the reporting officers;
- Forwarding the reporting forms to the national phytovigilance centre,

Article 4: The national centre shall be responsible for:

- Receiving reports of serious adverse effects directly from the reporting officers;
- Collecting information on adverse effects from the focal points, health programmes, national research centres, the private sector, or any national or international organization operating in the area of health.
- Conveying data to the national phytovigilance committee

III. Regulation enforcement

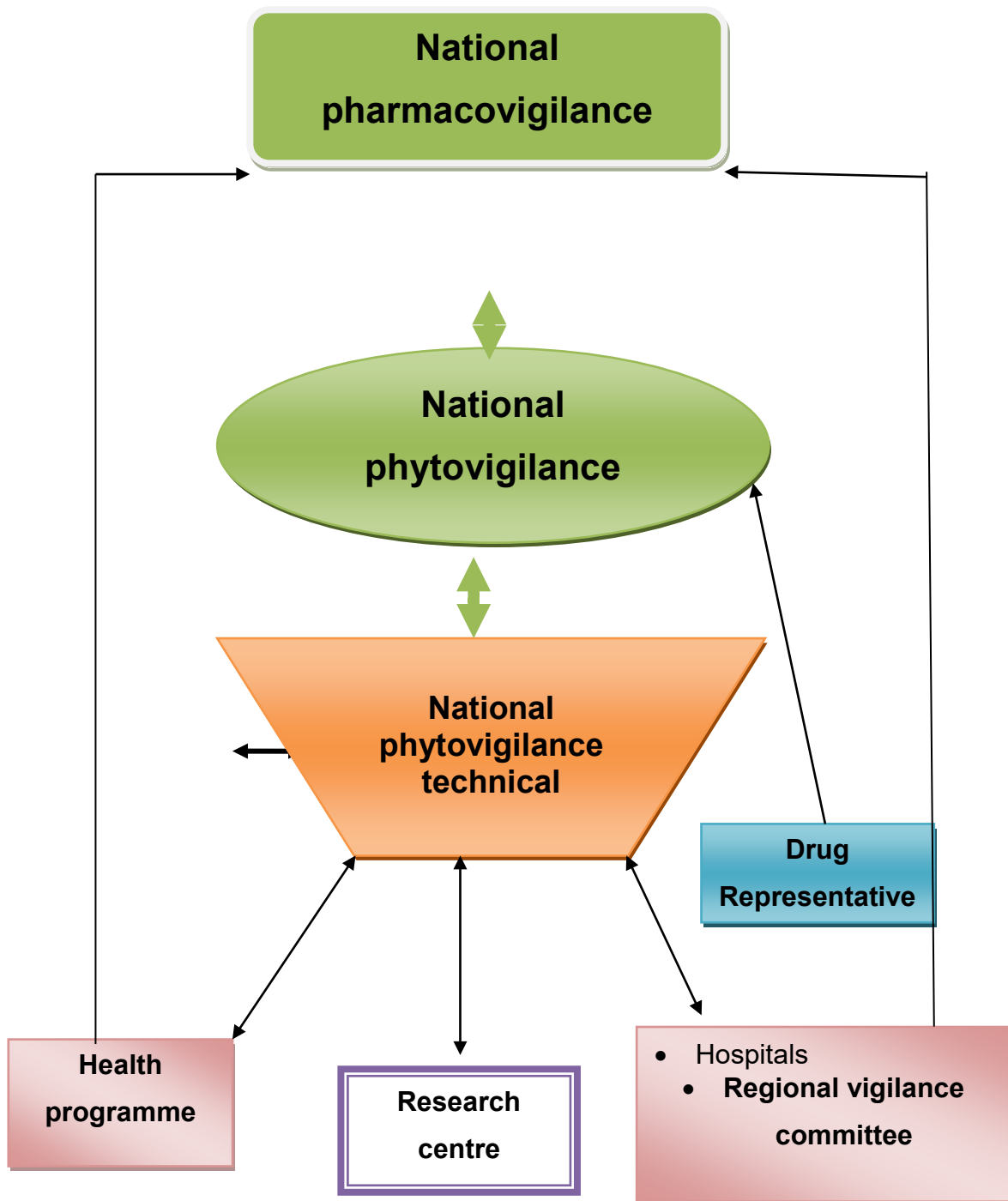
To ensure the effectiveness of the system, collaboration and constant interaction between all the relevant entities is indispensable.

Spontaneous reporting is currently the major source of information on pharmacovigilance. This can be improved by:

- ✓ Readily available reporting forms;
- ✓ Toll free hotline
- ✓ Acknowledgement of receipt of reports ;
- ✓ Providing feedback to the reporting officer;
- ✓ Providing necessary training to the staff of the centres;
- ✓ Collaboration with local drug committees;
- ✓ Collaboration with professional associations;

The decision procedure may be represented in the form of a diagram:

Figure 6: Flow diagram of phytovigilance system decision



Chapter 8:

Advertising control

Introduction

Advertising in this context is a marketing tool used by a manufacturer or a traditional medical practitioner to promote their products and services. While this activity is in principle not prohibited, it must be regulated in order to avoid abuse. The aim of this framework is to assist member states of the ECOWAS Region to regulate advertising of traditional medicine practice and products.

I. Advertising regulation

I.1 Advertising Certificate

Advertising may be accepted only for medicines that have obtained a marketing authorization and must be consistent with the information contained in the summary of the characteristics of the product.

Any advertisement must be approved by the national medicines regulatory authority, which will issue a permit. Following the granting of the permit, the advertisement must:

- ✓ Convey a message that is not misleading;
- ✓ Contain accurate information on the proper use of the medicine.

The articles below provide a summary of the main elements of this regulation

- Article 1: Only traditional medicines with marketing authorization may be advertised.
- Article 2: Any public advertisement on traditional medicines shall be subject to the granting of advertising permit
- Article 3: An application for an advertising permit must be addressed to the competent national authority. The application to be submitted to the NMRA shall comprise of:
- A dated application signed by the applicant
 - Name and address of the applicant or manufacturer
 - Name or name(s) of the traditional medicines to be advertised and evidence of marketing authorisation
 - Dissemination media and methods
 - Places of dissemination
 - A copy of the draft advert (conveying an accurate information about the drug)
 - Evidence of payment of advertising permit application fee.
- Article 4: The permit issued may be suspended or withdrawn in the event of violation of the regulations.
- Article 5: A traditional medicine's advertisement must be verifiable and comply with the ethical standards
- Article 6: It is prohibited to make misleading advertisements on for example nature, composition, quality, strength, active ingredients, use, prices and conditions of sale.

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Appendix 1: Preliminary assessment of applications for certification

<p><i>Name of National Medicines Regulatory Authority</i> ADDRESS TELEPHONE FAX E-MAIL COUNTRY</p>	<p>ASSESSMENT OF APPLICATIONS FOR CERTIFICATION</p>
---	--

I. Information on the product^o

Name of the product:

Name and address of the manufacturer:.....

Location of the manufacturing unit.....

Dosage form and composition of the product:

Category of medicine:

Indications.....

Directions for use

Pharmacological properties.....

Side effects/adverse reactions

Precautions/contraindications.....

Particular risks.....

II. Physical inspection of the stock

Primary packaging information:

.....

The packaging comprises the following information

Product name	YES	NO
Generic name	YES	NO
Dosage	YES	NO
Batch N° (correspondence with analysis certificate)	YES	NO
Manufacturing date	YES	NO
Expiry date	YES	NO
Labelling	YES	NO
Name/address of manufacturer	YES	NO
Method of administration	YES	NO

III. Check list for the application

- Copy of licence authorizing the establishing the production unit
- Application addressed to the Ministry of Health
- Proof of payment of application fee

Supporting documents

- Pharmaceutical documentation
- Pharmacological and toxicological documentation
- Clinical documentation

Samples of the stock

Date:

Full name and address of applicant:

Full name and signature of the person responsible for the preliminary assessment of the application:

Additional comments:.....

.....

Appendix 2: Application evaluation guide

<i>Name of National Medicines Regulatory Authority</i> ADDRESS TELEPHONE FAX EMAIL COUNTRY	APPLICATION EVALUATION GUIDE
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I. Manufacturing process

- Determination of the product characteristics
- Description of methods for identifying and determining impurities in the raw materials, intermediate products, vehicles and the final product characterization of the impurities

Comments:

.....
.....
.....

II. Analytical procedures

- Validation of analytical methods
- Has the following information been provided on:
 - ✓ Sample and its treatment,
 - ✓ Standards and reference materials used,
 - ✓ Method of preparation of reagents,
 - ✓ Apparatus and method of use etc.?
- Are the methods described adequate for a routine verification of the product? YES NO

Comments:

.....
.....
.....

III.Data on stability

- Were stability studies conducted according to recommended standards?
- Were results provided?
- Were deviations noted? Were such deviations justified?
- Was the pre-test period justified?
- Was the justification acceptable?
- Did the analytical methods chosen provide adequate information on stability?

Comments:

.....
.....

IV.FINISHED PRODUCT

- Verification of the data on chemical, biological and pharmaceutical studies
- Description and composition of the product

Description:

- Qualitative and quantitative composition of the product with indication about the role of its components.
- Description of the primary packaging

Comments:

.....
.....

V. Methods of preparation

- Batch manufacture formula
- Detailed manufacturing methods and in-process controls
- Is the formulation of the product the same as used for the clinical tests

Comments:

.....
.....

VI.Packaging

- Is the packaging suitable?
- Did the material meet the required specifications?

Comments:

.....
.....

VII. Manufacturer(s)

- Have the names, addresses and responsibilities of each member of the production team been indicated?
- Have sub-contractors been included?
- Has information been provided on the production sites/areas involved in the manufacture including packaging and quality control?

Comments:

.....
.....

VIII. Control of finished product

- Specifications and routine tests
- Methods of control and standards in the analysis of the finished product

Comments:

.....
.....
.....

IX. Stability studies

- Stability studies of active ingredient in real time
- Stability studies of finished product in real and accelerated time
- Stability study results
- Proposed validity duration

Comments:

.....
.....

X. Review of the expert’s report on the toxicological and pharmacological documentation

.....
.....
.....

Clinical experience

- Clinical trials
- Post-marketing surveillance (for re-registration)Published and unpublished data

Comments:

.....
.....

Appendix 3: Technical assessment of application for certification

<p><i>Name of National Medicines Regulatory Authority</i></p> <p>ADDRESS</p> <p>TELEPHONE</p> <p>FAX</p> <p>EMAIL</p> <p>COUNTRY</p>	<p>TECHNICAL ASSESSMENT OF APPLICATION FOR CERTIFICATION</p> <p>TECHNICAL ASSESSMENT OF DOCUMENTATION FOR QUALITY CONTROL</p>
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I. Active substance

I.1. References of the active substance (if known)

- Does the information presented make reference to a monograph?
- Have the main physical and/or chemical properties been described?
- Have properties that may be critical at the development, manufacturing or control stages been identified?
- Nomenclature of the active ingredient: description, summary of the extraction method with solvents used, impurities and their methods of detection?
- Have the residual solvents and their methods of analysis been documented?

Comment:

.....

I.2 Information on the origin of the active substance

- Have GMPs been followed?
- Has the manufacturing site been clearly identified?
- Has information on the manufacturer been provided?

Comments:

.....

I.3 Description of the manufacturing and in-process control

- Has quality control for materials been described?
- Has verification of the critical stages and intermediate products been done?
- Has a table of specifications for controlling the active substance been provided?

Comments:

.....

.....

.....

Appendix 4: Model ReportingForm

NATIONAL MEDICINES REGULATORY AUTHORITY			
ADVERSE EFFECT REPORTING FORM			
Date :/...../...../			
1- Identification of the area and health facility:			
Region/Division/Health District:.....			
2-Identification of prescriber:			
Family Name:.....	First	Names:
Qualification :.....			
3-Product Identification:			
Description:			
Dosage form :.....			
Route of administration :..... Marketing Authorization No:.....			
Expiry Date:.....			
Manufacturer's Address:.....			
Therapeutic Indications:.....			
Expected Side Effects:.....			
Other relevant information:.....			
4-Patient Identification:			
Family Name:.....	First	Names:
Gender:..... Age:.....			
Weight:..... Height:.....			
Medical History:.....			
Address:	Region:.....	Province.....	
Department.....	City/Village	District or Area	
..... Contact Address.....			
5- Adverse Effects:			
Clinical diagnosis:.....			
Date of start of treatment:..... Date of end of treatment:.....			
Dosage:.....			
Adverse effectsobserved:.....			
Start of adverse effects:..... Development of adverse effects: disappeared/___/			
worsened/___/ death/___/ recurred/___/			
6- Reporter Identification			
Family Name:.....	First	Names: Profession
:.....			
Address:.....			
Signature of Reporting officer			
<i>NB : The completed form must be sentto the national phytovigilance centre.</i>			
<i>Centre Address</i>			