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WHO Definitions, Policy and Regulation of Traditional Medicine: Practitioners, practices and products/Herbal medicines

INTRODUCTION

Traditional medicine includes a diversity of health practices, approaches, knowledge, and beliefs incorporating plant, animal, and/or mineral-based medicines; spiritual therapies; manual techniques; and exercises, applied singly or in combination to maintain well-being, as well as to treat, diagnose, or prevent illness. The comprehensiveness of the term "traditional medicine" and the wide range of practices it encompasses make it difficult to define or describe, especially in a global context. Traditional medical knowledge may be passed on orally from generation to generation, in some cases with families specializing in specific treatments, or it may be taught in officially recognized universities. Sometimes its practice is quite restricted geographically, and it may also be found in diverse regions of the world. However, in most cases, a medical system is called "traditional" when it is practised within the country of origin.

Various types of traditional medicine (TM) and medical practices referred to as complementary or alternative medicine (CAM), have been increasingly used in both developing and developed countries. One of the major components of the WHO Traditional Medicine Strategy is to promote the integration of TM and CAM into national health care systems where appropriate. Development of national policy and regulations are an essential indicator of the level of integration of such medicine within a national health care system.

1. DEFINITIONS

Certain definitions in the field of traditional medicine have been presented in other WHO guidelines and have been selected and adapted from other WHO documents and guidelines that are widely used by the WHO Member States, such as the *General guidelines for methodologies on research and evaluation of traditional medicine*[1] and *Guidelines for the assessment of herbal medicines.* These definitions may differ from those included in national regulations, and are therefore, for reference only.

Traditional medicine: is the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health and in the prevention, diagnosis, improvement or treatment of physical and mental illness. ***(http://www.who.int/medicines/areas/ traditional/definitions/en/).*** This definition encompasses Traditional medicine products or finished herbal products; practitioners and practices.

Complementary/Alternative medicine: The terms are used to refer to a broad set of health care practices that are not part of that country's own tradition or conventional medicine and are not fully integrated into the dominant health-care system. These terms are used interchangeably with traditional medicine in some countries. Other terms sometimes used to describe these health care practices include "natural medicine", "nonconventional medicine" and "holistic medicine" **(http://www.who.int/medicines/areas/traditional/definitions/en/).**

[1]World Health Organization (2000) General guidelines for methodologies on research and evaluation of traditional medicine. Geneva, WHO/EDM/TRM/2000.1

A traditional Health Practitioner (THP): Has been defined by the Regional Committee of the WHO African Region (1976) as being "a person who is recognized by the community in which he lives as competent to provide health care by using vegetable, animal, and mineral substances and certain other methods based on the social, cultural and religious background as well as on the knowledge, attitudes and beliefs that are prevalent in the community regarding physical, mental and social well-being and the causation of disease and disability"[2].

Traditional use of herbal medicinesrefers to the long historical use of these medicines. Their use is well established and widely acknowledged to be safe and effective, and may be accepted by national authorities.

Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products, which contain as active ingredients parts of plants, or other plant materials, or combinations. In some countries herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (e.g. animal and mineral materials). Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products.

Herbs include crude plant material, such as leaves, flowers, fruit, seeds, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.

Herbal materials include, in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting or stir-baking with honey, alcoholic beverages or other materials.

Herbal preparationsare the basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures,essential oils, expressed juices and processed exudates. These are preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation.

Herbal substances: All mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).

Finished herbal productsconsist of herbal preparations made from one or more herbs. If more than one herb is used, the term "mixture herbal product" can also be used. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished products or mixture herbal products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal.

Therapeutic activity: refers to the successful prevention, diagnosis and treatment of physical and mental illnesses; improvement of symptoms of illnesses; as well as beneficial alteration or regulation of the physical and mental status of the body.

Active ingredient: refer to ingredients of herbal medicines with therapeutic activity. In herbal medicines where the active ingredients have been identified, the preparation of these medicines should be standardized to contain a defined amount of the active ingredients, if adequate

[2]Sofowora A, 1982. Medicinal plants and traditional medicine in Africa.Available at http://www.amazon.com/s/ref=la_B001JS6RS6_B001JS6RS6_sr?rh=i%3Abooks&field author =Abayomi+ Sofowora&sort=relevance&ie=UTF8&qid=1398977318).

analytical methods are available. In cases where it is not possible to identify the active ingredients, the whole herbal medicine may be considered as one active ingredient. Additional definitions (if needed), are appended in Annex 1.

2. WHO POLICY ON TRADITIONAL MEDICINE

Recognizing the widespread use of traditional medicine/Complementary and alternative medicine (TM/CAM) and the tremendous expansion of international markets for herbal products, it is all the more important to ensure that the health care provided by TM/CAM is safe and reliable; that standards for the safety, efficacy, and quality control of herbal products and traditional and TM/CAM therapies are established and upheld; that practitioners have the qualifications they profess; and that the claims made for products and practices are valid. These issues have become important concerns for both health authorities and the public. National policies are a key part of addressing these concerns.

The WHO policy on traditional medicine is reflected in the various resolutions adopted by the World Health Assembly and the WHO Regional Committee for the African Region as indicated in Annex 2 and can be summarized as follows:

(a) To facilitate integration of traditional medicine into the national health care system by assisting Member States to develop their own national policies on traditional medicine. National policies are the basis for defining the role of TM/CAM in national health care programmes, ensuring that the necessary regulatory and legal mechanisms are created for promoting and maintaining good practice; assuring authenticity, safety and efficacy of TM/CAM therapies; and providing equitable access to health care resources and information about those resources.

(b) To promote the proper use of traditional medicine by developing and providing norms and standards, technical guidelines and methodologies.

(c) To facilitate information exchange in the field of traditional medicine.

3. REGULATION OF TRADITIONAL MEDICINE: PRACTITIONERS, PRACTICES AND PRODUCTS

3.1 Regulation of practitioners and practices: These are regulated by a national professional body. A Traditional Medicine Practitioner's Council (THPC) whose powers are vested by the Traditional Health Practitioners (THPs) Bill which provides for establishment of the THPC. The Bill must be adopted by Cabinet and promulgated into law for it to be enforced. The THPC has to ensure safety, efficacy and quality of services provided by THPs through the enforcement of the Code of Ethics and conduct particularly in relation to the provisions related to Their work, Their patients, Their colleagues and to the public among other provisions. The Code of practice provides for disciplinary procedures in case of dishonourable conduct, professional and ethical misconduct; minimum standards for THPs in terms of modes of practice, categories, qualification and skills required of TM practitioners. Details regarding regulation of TM practitioners and practices are outlined in various WHO documents[3],[4],[5]. Regulation of

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[3]World Health Organization (2004) Model legal framework for the practice of traditional medicine: A THPs Bill. In: Tools for institutionalizing traditional medicine in health systems; Regional Office for Africa, Brazzaville. AFR/EDM/TRM/2004.1.

[4]World Health Organization (2004) Model codes of ethics and practice for traditional health practitioners. In: Tools for institutionalizing traditional medicine in health systems; Regional Office for Africa, Brazzaville. AFR/EDM/TRM/2004.1.

traditional medicine practitioners and their practices and main elements to be regulated are found in Annex 3, The Code of ethics of TM practitioners in Annex 3.1 and Licensing a TM facility in Annex 3.2.

3.2 Regulating traditional medicine products/herbal medicines: Regulation of herbal medicines is a key means of ensuring safety, efficacy and quality of herbal medicinal products. Traditional medicine products/herbal medicines are regulated by national medicines regulatory authorities (NMRAs) which issue a marketing authorization (product license, registration certificate) that authorizes the marketing or free distribution of a herbal medicine in the respective country after evaluation for safety, efficacy and quality. In terms of quality NMRAs establishes inter alia the detailed composition and formulation of the herbal medicine and the quality requirements for the product and its ingredients. It also includes details of packaging, labelling, storage conditions, shelf-life and approved conditions of use. To facilitate the registration, marketing and distribution of traditional medicines of consistent quality in the WHO African Region by the national medicines regulatory authorities, WHO has published *Guidelines for Registration of traditional medicines in the African Region*[6] and *Regional Framework for regulation of traditional medicine, practices and products*[7]for countries adaptation to their specific situation. Details on regulating TM products/Herbal medicines and main elements to be regulated are found in the following Annexes: Regulating Traditional medicine products/herbal medicines, Annex 4, pharmacovigilance/phytovigilance regulation in Annex 4.1, Regulation of clinical trials/efficacy and safety assessment in Annex 4.2.

[5]World Health Organization (2014) Regulatory framework for traditional medicine practice, practitioners and products.Regional Office for Africa, Brazzaville (publication process).

[6]World Health Organization (2004) Guidelines for registration of traditional medicines.Reprinted in 2010.Regional Office for Africa, Brazzaville. AFR/EDM/TRM/2004.2

[7]World Health Organization (2014) Regulatory framework for traditional medicine practice, practitioners and products. Regional Office for Africa, Brazzaville (in press).

ANNEX 1. ADDITIONAL DEFINITIONS ON TRADITIONAL MEDICINE

Ayurveda: Ayurveda originated in the 10th century BC, but its current form took shape between the 5th century BC and the 5th century AD. In Sanskrit, ayurveda means "science of life". Ayurvedic philosophy is attached to sacred texts, the Vedas, and based on the theory of Panchmahabhutas - all objects and living bodies are composed of the five basic elements: earth, water, fire, air, and sky. Similarly, there is a fundamental harmony between the environment and individuals, which is perceived as a macrocosm and microcosm relationship. As such, acting on one influences the other. Ayurveda is not only a system of medicine, but also a way of living. It is used to both prevent and cure diseases. Ayurvedic medicine includes herbal medicines and medicinal baths. It is widely practised in South Asia, especially in Bangladesh, India, Nepal, Pakistan, and Sri Lanka.

Chinese traditional medicine: The earliest records of traditional Chinese medicine date back to the 8th century BC. Diagnosis and treatment are based on a holistic view of the patient and the patient's symptoms, expressed in terms of the balance of yin and yang. Yin represents the earth, cold, and femininity. Yang represents the sky, heat, and masculinity. The actions of yin and yang influence the interactions of the five elements composing the universe: metal, wood, water, fire, and earth. Practitioners of Chinese traditional medicine seek to control the levels of yin and yang through 12 meridians, which bring energy to the body. Chinese traditional medicine can be used for promoting health as well as preventing and curing diseases. Chinese traditional medicine encompasses a range of practices, including acupuncture, moxibustion, herbal medicines, manual therapies, exercises, breathing techniques, and diets. Surgery is rarely used. Chinese medicine, particularly acupuncture, is the most widely used traditional medicine. It is practised in every region of the world.

Chiropractic: Chiropractic was founded at the end of the 19th century by Daniel David Palmer, a magnetic therapist practising in Iowa, USA. Chiropractic is based on an association between the spine and the nervous system and on the self-healing properties of the human body. It is practised in every region of the world. Chiropractic training programmes are recognized by the World Federation of Chiropractic if they adopt international standards of education and require a minimum of four years of full-time university-level education following entrance requirements.

Homeopathy: Homeopathy was first mentioned by Hippocrates (462-377 BC), but it was a German physician, Hahnemann (1755-1843), who established homeopathy's basic principles: law of similarity, direction of cure, principle of single remedy, the theory of minimum diluted dose, and the theory of chronic disease. In homeopathy, diseases are treated with remedies that in a healthy person would produce symptoms similar to those of the disease. Rather than fighting the disease directly, medicines are intended to stimulate the body to fight the disease. By the latter half of the 19th century, homeopathy was practised throughout Europe as well as in Asia and North America. Homeopathy has been integrated into the national health care systems of many countries, including India, Mexico, Pakistan, Sri Lanka, and the United Kingdom.

Unani: Unani is based on Hippocrates' (462-377 BC) theory of the four bodily humours: blood, phlegm, yellow bile, and black bile. Galen (131-210 AD), Rhazes (850-925 AD), and Avicenna (980-1037 AD) heavily influenced unani's foundation and formed its structure. Unani draws from the traditional systems of medicine of China, Egypt, India, Iraq, Persia, and the Syrian Arab Republic (5). It is also called Arabic medicine.

ANNEX 2. TRADITIONAL MEDICINE RESOLUTIONS ADOPTED BY THE WORLD HEALTH ASSEMBLY AND WHO REGIONAL COMMITTEE FOR AFRICA, 1969-2014

Year	Resolution	Subject
1969	WHA22.54	Establishment of pharmaceutical production in developing countries
1974	AFR/RC24/R14	Decision to include "traditional medicine and its role in the development of health services in Africa" in the technical discussions at its twenty-sixth session in 1976
1976	WHA29.72	Health manpower development
1976	AFR/RC26/R14	Traditional medicine and its role in the development of health services in Africa
1977	WHA30.49	Promotion and development of training and research in traditional medicine
1978	WHA31.33	Medicinal plants
1978	AFR/RC28/R3	Use of essential medicines and the African Pharmacopoeia
1984	AFR/RC34/R8	Launching or development of a programme of traditional medicine
1987	WHA40.33	Traditional medicine
1986	AFR/RC36/R9	The use of traditional medicines
1988	WHA41.19	Traditional medicine and medicinal plants
1989	WHA42.43	Traditional medicine and modern health care
1990	AFR/RC40/R8	Promotion of traditional medicine, development of traditional medicine systems and its role in the development of health services in Africa
1991	WHA44. 34	Traditional medicine and modern health care
1999	AFR/RC49/R5	Essential drugs in the WHO African Region: Situation and trend analysis
2000	AFR/RC50/R3	Promoting the role of traditional medicine in health systems: A strategy for the African Region
2003	WHA56.31	Traditional medicine
2008	WHA61.21	WHO Global strategy and plan of action on public health, innovation and intellectual property
2009	WHA62.13	Traditional medicine
2013	AF/RC63/R6	Enhancing the role of traditional medicine in health systems: A strategy for the African Region
2014	WHA67.18	Traditional Medicine

ANNEX 3: REGULATING TRADITIONAL MEDICINE PRACTITIONERS AND PRACTICES

Licensing Traditional Health Practitioners.Main elements to be regulated

The elements are described below in the form of articles.

Article 1: The 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 health practitioner shall be any person recognized by the community in which he/she lives or the competent national authority to be capable of diagnosing diseases and disabilities prevailing there and providing health care using traditional methods and products of plant, animal or mineral origin. The categories of traditional health practitioners shall be determined by the competent national authority.

Article 4: Traditional medicine practice shall be part of:

(a) the national health system;
(b) community health protection and promotion;
(c) national research priorities.

Article 5: No one shall practise traditional medicine in his/her country without a traditional health practitioner's licence issued by the competent national authority.

Article 6: A traditional medicine practice licence may be issued to:

(a) any traditional health practitioner of good moral standing and acknowledged reputation;
(b) persons from other communities or of foreign nationality who meet the requirements of traditional medicine practice in that country.

Article 7: The process for obtaining a traditional health practitioner's licence and the titles to be used shall be determined by the competent national authority.

Article 8: Traditional health practitioners' services shall be supervised and monitored by the competent national authority.

Article 9: Every traditional health practitioner must comply with the laws of the country and the code of ethics governing the practice of traditional medicine as outlined in Chapter 2 of these regulations.

Article 10: Every traditional health practitioner must keep a register in which the names and addresses of patients, diagnoses carried out, and management plans (referrals, treatment, dietary and lifestyle advice, etc.) are entered.

Article 11: Any person who practises traditional medicine without a licence or with fraudulently acquired documents shall be deemed to engage in illegal traditional medical practice.

Article 12: A traditional health practitioner may, as part of a contract, collaborate with another traditional health practitioner, health worker, research establishment or a public or private health facility.

Article 13: Every traditional health practitioner who is already practising shall have a period of time (to be determined by the competent national authority) within which to comply with the terms of these regulations; beyond the set period,

he/she shall be deemed to be practising illegally.

Enforcing regulations

Preparing and submitting an application for a traditional health practitioner's licence

Any traditional health practitioner wishing to obtain a practitioner's licence must submit an application comprising the following:

(a) a standard application form (see Figure 1: Flow chart of traditional health practitioner licensing decision-making process below) addressed to the competent authority;

(b) a copy of birth certificate;

(c) a national identification certificate;

(d) a police criminal record of less than 3 months old (variable validity period depending on the country);

(e) a medical certificate;

(f) a testimonial from the community;

(g) a notary act (issued by the administrative authority of the place of residence of the traditional health practitioner);

(h) a residence permit (issued by the administrative authority of the place of residence of the traditional health practitioner);

(i) an undertaking to abide by the code of ethics signed by the traditional health practitioner (available at the local 1st level health authority);

(j) passport-size photographs;

(k) applicant's information sheet (available at the local 1st level health authority).

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.

Application procedure

Preliminary assessment

The application submitted to the competent national authority shall be assigned to the unit responsible for traditional medicine which shall verify it and prepare a summary report for subsequent assessment by the technical evaluation committee.
The committee shall be multidisciplinary or multisectoral (comprising e.g. ministerial departments responsible for the enforcement of traditional medicine regulations, representatives of traditional health 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).

Work of the committee

The committee shall be responsible for evaluating applications based on the following criteria: availability of required documentation, recommendation of the summary report on ethno-medical evidence, credibility of the applicant, etc. The committee shall issue one of four possible decisions:

(a) approval;
(b) conditional approval;
(c) deferment;

(d) rejection.

Appeals process

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. The competent national authority shall, on considering such an appeal, sustain or reverse the decision, vary the decision, or refer it to an independent committee for further review.

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

Main decision elements

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

Supervision of traditional medicine practitioners

Every licence holder shall be supervised by a competent national authority to ensure proper traditional medicine practice and to avoid possible abuse and impediments. The supervision shall consist, inter alia, of capacity building monitoring/evaluation including ascertaining that 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.
Supervision should be conducted to identify and correct shortcomings and, where necessary, envisage a revision of the regulations.
Licensed traditional health practitioners should be trained in good traditional medicine practices as defined by the component national authority. The training provided, the practitioners' activities and enforcement of traditional medicine regulations shall be monitored and evaluated.

ANNEX 3.1: CODE OF ETHICS OF TRADITIONAL HEALTH PRACTITIONERS

Main elements to be regulated

They are presented below in the form of articles.

Traditional health practitioners and their work

Article 1: The provisions of this code shall be binding on all traditional health practitioners.
All traditional health practitioners shall:

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

Article 3: Engage in traditional medicine practice only after obtaining a licence.

Article 4: Provide health services as part of their profession.

Article 5: Refrain from delegating personal tasks to a subordinate or an assistant. In the event of delegation, the practitioner must provide the necessary supervision and shall be liable for any case of negligence.

Article 6: Immediately report to the competent national authority any adverse events observed and side-effects noted during treatment.

Article 7: Refrain from using conventional medicines as ingredients in their preparations.

Article 8: Limit their interventions to their scopes of practice and urgently refer any cases beyond their competency to the appropriate health professional.

Article 9: Continuously update their knowledge to keep up with new developments in their area of practice.

Article 10: Provide information on traditional medicine to the public or any other health professional, where necessary.

Traditional health practitioners in relation to their patients

Traditional health practitioners shall:

Article 11: Maintain a high sense of integrity in their interaction with their patients.

Article 12: Inform their patients of the procedures involved in the treatment they intend to administer.

Article 13: Respect the right of a patient to accept or refuse traditional medicine treatment (except where the law requires that such treatment be administered to the patient).

Article 14: Refrain from abusive use of the relationship with a patient for personal gains.

Article 15: 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 16: 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 17: Provide the necessary information and advice to ensure the proper use of traditional medicines.

Article 18: Keep a clear and complete register on all the patients treated in their clinics.

Article 19: Be reasonable in matters concerning fees or remuneration. Fees charged should

be commensurate with the treatment given.

Article 20: Completely keep all information and opinions about patients confidential, except where:

- the disclosure is clearly and justifiably in the patient's interest, or
- there is need for disclosure, e.g. when the practitioner considers referral necessary, or when disclosure is mandatory by law.

Article 21: 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 health practitioners in relation to their colleagues

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

Article 22: Support, respect and cooperate with fellow practitioners in addressing needs for scientific and technical information.

Article 23: Consider other members of the Traditional Health Practitioners' Association as colleagues and always be mindful of the need for consultation and referral.

Article 24: Adhere to procedures laid down by the appropriate national authority when referring patients or dealing with patients referred to them by other practitioners.

Article 25a: Refrain from expressing their opinion on the competence or conduct of a colleague to a third party, particularly to patients.

Article 25b: Report to the appropriate authority any act(s) of misconduct or malpractice by a fellow traditional health practitioner.

Article 26: Participate in the activities of their own professional associations and of other associations or organizations to promote traditional medicine.

Article 27: Refrain from expressing undue alarm or showing any such reaction upon receiving a patient who has been improperly treated or referred by another traditional health practitioner.

Article 28: Refrain from making comments that undermine the integrity of colleagues.

Article 29: Refrain from engaging in negotiations or secret arrangements with health practitioners for tenders, commissions, etc., in return for patronage, referral, etc.

Article 30: Refrain from any connivance with other traditional health practitioners to engage in malpractice(s).

Article 31: Strive for the promotion of health, expansion of health services and the development of team spirit with other traditional health practitioners.

Traditional health practitioners in relation to the public

Traditional health practitioners shall:

Article 32: Refrain from using 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 33: Refrain from using or possessing any medical equipment, except where the traditional health practitioner has received accredited formal training.

Article 34: Refrain from administering an anaesthetic or a subcutaneous, intramuscular, intravenous or any other form of injection except where the traditional health practitioner has received accredited formal training.

Article 35: Refrain from using surgical procedures to facilitate the examination of a person, except where the traditional health practitioner is a qualified and licensed

physician.

Article 36: Immediately report all deaths on his/her premises to the police for record purposes.

Article 37: Report all births to the appropriate authority.

Article 38 Abide by the law, observe strict confidentiality with regard to the patient's disease(s), the types of traditional medicines used or any information the patient may disclose in the course of consultation.

Article 39: 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 40: Participate in collaborative research involving humans and animals where ethical standards have been met and approved.

Article 41: 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 42: 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 43: Refrain from prescribing medicines derived from human body parts or organs.

Traditional health practitioners in relation to sexual abuse of patients

Traditional health practitioners shall:

Article 44: Refrain from prescribing or administering sexual activity as a form of treatment of any disease, be it physical or spiritual. In the course of treatment, they must not require a client to undress or be exposed in an indecent manner.

Management and ethical use of traditional medicines

Traditional health 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 health practitioners or other professions.

Article 47: Refrain from falsehood, and from making fraudulent, misleading, deceptive, self-laudatory, extravagant or exaggerated claims.

Article 48: Adhere to the legal requirements and the provisions of the national code of advertising.

Article 49: Refrain from displaying materials and objects likely to bring the profession into disrepute and from making false promises about the treatment of diseases.

Article 50: Be subject to disciplinary action for contravening national regulations irrespective of membership of multiple associations.

Article 51: Be personally liable for the malpractice of their staff or assistants who are not registered with the competent national authority but practise under their supervision.

Article 52: Refrain from making available for sale or dispensing to patients, traditional medicines that are substandard, mislabelled or adulterated.

Article 53: Report any case of malpractice to a Professional Ethics Committee (PEC), whose establishment shall be determined by a competent national authority.

Article 54: Be liable to disciplinary action by the Professional Ethics Committee (PEC) with the possible loss of privileges and benefits of registration as a traditional health practitioner upon infringement of the code of ethics.

Enforcing the code of ethics

This relates to the following areas:

(a) adherence to the code;
(b) sensitization/training;
(c) monitoring/evaluation of the code.

Adherence to the code

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

Sensitization/training of traditional health practitioners

After developing and adopting the code of ethics, it is essential to sensitize and train traditional health practitioners.

Monitoring and evaluation

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

ANNEX 3.2: LICENSING A TRADITIONAL MEDICINE FACILITY

Main elements of the regulations

They are presented below in the form of articles.

Article 1 — The conditions for opening and operating a traditional medicine facility shall be determined by the provisions of these regulations.

Article 2 — A traditional medicine facility shall be:

(a) traditional medicine consultations and care facilities;
(b) traditional medicine shop;
(c) traditional medicine production unit;
(d) traditional medicine facility.

Article 3 — A licence to open and operate a traditional medicine facility shall be issued by 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 health 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 — Every holder of a licence to open and operate a traditional medicine facility must abide by the code of ethics.

Article 8 — Traditional health practitioners are civilly liable for all their acts.

Article 9 — The opening and operation of a traditional medicine facility without a relevant licence or with fraudulently acquired documents shall be deemed illegal.

Article 10 — The illegal opening and operation of a traditional medicine facility shall be punishable by a fine whose amount shall be fixed by the competent authority. In the event of a repeat offence, the premises and equipment of the practitioner shall be confiscated and a fine whose amount shall be fixed by the competent authority imposed.

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 Traditional Medical Practitioners' Council to ascertain the suitability of the premises for the practice of traditional medicine.

Article 12 — The licence shall expire after a period to be specified by the competent national authority (preferably 12 months). It shall be renewable, subject to fulfilment of the laid-down conditions, including a record of satisfactory practice.

Article 13 — Traditional health practitioners who have already opened a clinic shall have a grace period (to be determined by the competent authority) to comply with the provisions of these regulations; failure to do so shall result in sanctions provided for in these regulations.

Enforcing the regulations

Main elements of application

Any practitioner wishing to obtain a licence to open and operate a traditional medicine facility must file an application comprising a number of documents, including:

(a) a written and stamped application indicating the type and location of the clinic, including the decision of the president of the local traditional health practitioners' association and the administrative and health authorities of the place of residence of the applicant;
(b) a nationally-accepted identification document;
(c) a police criminal record of less than 3 months old (period variable according to country);
(d) a certificate of residence;
(e) an inspection and counter-inspection certificate of less than 3 months old (period variable according to country);
(f) an undertaking to abide by the code of ethics and good practices signed by the applicant;
(g) a certified true copy of the practitioner's licence;
(h) an office copy of marketing authorizations, where relevant;
(i) a certified true copy of an import permit, where relevant;
(j) an office copy of a housing permit or a lease agreement;
(k) Passport-size photographs.

Application evaluation procedure

Preliminary procedures

An application forwarded to the competent national authority shall be assigned to the body in charge of regulating traditional medicine. Upon receiving the application, the body shall ascertain that the application is complete and that 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 on the application for evaluation.
The outcome of the evaluation shall either be:

(a) approval;
(b) conditional approval;
(c) deferment; or
(d) rejection.

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

Main decision elements

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

ANNEX 4: REGULATING TRADITIONAL MEDICINE PRODUCTS

Main elements to be regulated

Classification of traditional medicines

Traditional medicines are classified into four categories based on the method of preparation, indications for use and the extent of development.
The criteria for Category 1 medicine are as follows:

(a) It is prepared extemporaneously (generally following consultation);

(b) It is prepared following traditional methods of production and standardization (the formula and method of preparation are chosen by the traditional health practitioner);

(c) Its safety and efficacy are guaranteed by the long period of use (over 20 years);

(d) Raw materials are well-known to traditional health practitioners and may be fresh or dried;

(e) Aqueous preparations usually have a short shelf life which, generally, does not exceed one week;

(f) It is distributed on an individual basis.

The criteria for Category 2 medicine are as follows:

(a) It is prepared in advance, packaged with a batch number;

(b) Raw materials used in its composition are well-known to the population;

(c) It is produced by methods that guarantee its stability and standardization;

(d) It is produced industrially or semi-industrially;

(e) Its safety and efficacy are guaranteed by ethnomedical evidence from a long period of use or by open clinical trials where this is deemed necessary by the competent authority;

(f) The constituent active ingredients are raw materials;

(g) The main chemical groups of the raw material are known;

(h) The shelf life is determined through stability tests.

The criteria for Category 3 medicine are as follows:

(a) It is prepared in advance and packaged with a batch number;

(b) Its production is semi-industrial or industrial;

(c) Its shelf life is determined by stability tests;

(d) The active ingredients are standardized extracts;

(e) It takes into consideration the biological properties of raw materials, new therapeutic indications, galenical formulations with dosage specification and knowledge about biologically active molecules;

(f) Its standardization and production are based on GMPs;

(g) Its efficacy and safety are proven by preclinical and clinical trials based on standard protocols.

The criteria for Category 4 medicine are as follows:

(a) It is imported;
(b) It should be registered in the country of origin;
(c) It meets all the requirements of Category 3 medicines.

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 authority. Only Category 1 medicines are exempted from this requirement. Properly enforced regulation of traditional medicine practice 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.

Applying for Category 2 medicines

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

Administrative application

(i) An application letter addressed to the competent national authority;
(ii) Record of the production unit;
(iii) A copy of the licence permitting the establishment of the production unit;
(iv) Samples of the final product to be sold;
(v) Proof of payment of application fee;
(vi) Proposed wholesale price, excluding taxes.

Pharmaceutical documentation

(a) Raw materials;
(b) Complete monographs of plants used as raw materials;
(c) Scientific name and synonyms of each (family, gender, species and varieties) as well as the author of the scientific binomial;
(d) Names in local languages;
(e) Brief description of plants;
(f) Organoleptic, macroscopic and microscopic features;
(g) Geographic distribution, habitat and harvesting information;
(h) Stability and quality control data (purity, general characterization tests and physical and chemical properties).

Manufacturing process:
(i) Formula, including excipients;
(ii) Manufacturing procedures;
(iii) Quality control;
(iv) GMP report.

Finished product

(a) 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.);

(b) 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; overdosage and management; clinical pharmacology; references; how supplied/storage and handling; patient counselling information;

(c) Results of quality control of finished product;

(d) Results of stability tests of the finished product in relation to the organoleptic characteristics.

Clinical toxicology documentation

(a) A technical report 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 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.

(b) 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, CAMES and AU/STRC reports, etc.) and toxicity tests already conducted on plants used or on species belonging to the same family.

Documentation for Category 3 medicines

It consists of four parts:

1. Administrative documentation

(a) An application letter addressed to the competent authority;

(b) Record of the production unit;

(c) A copy of the licence authorizing the establishment of the production unit;

(d) A copy of memorandum of understanding, notably a partnership agreement between the producer/traditional medicine practitioner and a research institute;

(e) Samples of the final product to be sold;

(f) Proof of payment for application determined by the competent authority.

2. Pharmaceutical documentation

(a) Raw materials (extracts)

(i) Complete monographs of plants used as raw materials;
(ii) Scientific name of each plant, and synonyms (family, genus, species and variety) as well as the author of the scientific binomial;
(iii) Names in the local languages;
(iv) Brief description of the plants;
(v) Organoleptic, macroscopic and microscopic features;
(vi) Geographic distribution, habitat and harvesting information;
(vii) Method of standardization of the extracts;
(viii) Quality control methods;
(ix) Stability and quality control data (purity, general characterization tests and physical and chemical properties).

(b) Manufacture

(i) Formula, including excipients;
(ii) Manufacturing procedures;
(iii) Quality control;
(iv) GMP report.

(c) Finished product

(i) 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.);

(ii) 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; overdosage and management; clinical pharmacology; references; how supplied/storage and handling; patient counselling information;

(iii) Results of the quality control of the finished product;

(iv) Results of the stability tests of the finished product.

3. Preclinical data

(a) Efficacy data;
(b) Safety (acute and sub-chronic toxicity);
(c) Literature review;
(d) Technical report on the tests conducted.

4.Clinical data

(a) Approval of clinical trials by a competent national authority;
(b) Clinical trials protocol based on standard methods (Phases I and II);
(c) A technical report of the trials conducted.

Category 4 medication documentation

It consists of four parts:III. Procedure for applying for Category 4 certification:

The granting of an MA by the competent 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:

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.

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.

Decision

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

(a) Therapeutic significance and efficacy;
(b) Safety;
(c) Quality;
(d) 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:

(a) approval;
(b) conditional approval;
(c) deferment;
(d) 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.

Duration and renewal of marketing authorization

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:

(a) an application addressed to the competent authority;

(b) certification written testimony indicating that no modification has been made to the product since the last registration;

(c) 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;

(d) proof of payment of renewal fees.

ANNEX 4.1 REGULATION OF CLINICAL TRIALS/EFFICACY AND SAFETY ASSESSMENT

Main elements to be regulated

Clinical trial authorization

Clinical trials constitute a mandatory step for granting a marketing authorization for Categories 3 and 4 medicines. Every clinical trial is subject to the 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: The 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 of a clinical trial shall be an individual, an organization, a group or any other legal entity that initiates, organizes and/or finances the 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 directs and oversees the clinical trial at a specified venue.

Article 6: An application for clinical trial comprising the following documents must be sent to the competent national authority:

(a) an application form duly completed and signed by the sponsor;

(b) a clinical trial protocol;

(c) an investigator's brochure;

(d) the CV of the investigator(s) ;

(e) information leaflet of participants and the informed consent form;

(f) GMP certificates of the medicines;

(g) statement forms completed and signed by the investigators;

(h) evidence of approval by the ethics committee; for international collaboration, the clinical trial protocol must be cleared by all participating countries;

(i) evidence of payment of application fees;

(j) an indemnity insurance cover;

(k) a written confirmation of the budget for the study.

Article 7: The competent national authority shall have a maximum period of 90 days to make a decision and communicate it to the applicant. The decision may be approval, deferment or rejection.

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, the Institutional Review Board and the Data Safety Monitoring Board of any 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 a lawsuit, the inspection report may provide reasons for the suspension or immediate discontinuation of any ongoing trials.

The clinical trial authorization technical review committee

The committee shall be responsible for assessing the clinical trial application and making recommendations to enable the competent national 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 shall comprise the following:

(a) Chairperson: who may be nominated by the relevant competent national authority;
(b) Secretary: who may be the person responsible for regulation at the NMRA;
(c) Members, namely:

(i) a pharmacist;
(ii) an epidemiologist;
(iii) a pharmacologist;
(iv) a toxicologist;
(v) a herbalist/phytotherapist;
(vi) a clinician;
(vii) an ethicist
(viii) a pharmacognosist;
(ix) a pharmaceutical technologist;
(x) 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 renewable.

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 government budget.

Application procedure

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

(a) Assessment by the ethics committee of a given health research.

(b) 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.

(c) Assessment by the technical committee.

(d) 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.

(e) Decision by the competent national authority.

ANNEX 4.2PHARMACOVIGILANCE/PHYTOVIGILANCEREGULATION

Creating a system of vigilance of medicinal plants and plant products

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

(a) ensure that the risks related to the use of traditional medicines are anticipated and well managed;
(b) provide the regulatory officials with the necessary information to change the recommendations concerning the use of that traditional medicine;
(c) improve communication between health professionals and the public;
(d) 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 health centres, 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:

(a) consultation with all health authorities, traditional health practitioners, professional associations and all other entities involved in the process;

(b) preparation and provision of reporting forms;

(c) sensitization of all health professionals on the definitions, objectives and methods used in phytovigilance;

(d) creation of the phytovigilance centre (recruitment of staff and purchase of the necessary materials and equipment);

(e) staff training;

(f) creation and maintenance of a database;

(g) promotion of the importance of reporting adverse effects of medicines through medical journals and other professional publications;

(h) 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 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 plant products in order to guarantee their safe use.

Article 3: Phytovigilance comprises:

(a) the detection of adverse effects;
(b) the collection of information and reporting of adverse effects, in accordance with the reporting system defined by the ministry of health;
(c) the collation and assessment of the information;
(d) recommendation of the conduct of studies or the safe use or banning of products.

Article 4: The operating costs of the centres shall be borne by the State budget.

Phytovigilance technical committee

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

(a) medicine;
(b) pharmaceutical sciences;
(c) clinical pharmacology;
(d) epidemiology;
(e) pathology;
(f) phytotherapy;
(g) traditional medicine.

The committee shall be responsible for:

(a) preparing the meetings of the national phytovigilance technical committee;
(b) proposing investigations to the national pharmacovigilance committee in the event of an alert;
(c) documenting and assessing the information collected through reports, surveys and related studies;
(d) proposing a management plan for risks related to the use of plant medicines.

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 regulation have been formulated hereunder in the form of articles.

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

Article 2: Adverse effects likely to result from a plant product shall be reported to the phytovigilance centre or the 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:

(a) collecting information provided by reporters;
(b) supporting and advising reporters to complete the reporting forms;
(c) investigations, where necessary;
(d) archiving documents;
(e) providing feedback to reporters;
(f) contributing to the training and raising the awareness of reporters;
(g) forwarding the reporting forms to the national phytovigilance centre.

Article 4: The national centre shall be responsible for:

(a) receiving reports of serious adverse effects directly from any reporter;
(b) 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;
(c) conveying data to the national phytovigilance committee.

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:

(a) readily available reporting forms;
(b) toll free hotline;
(c) acknowledgement of receipt of reports ;
(d) providing feedback to reporter;
(e) providing necessary training to the staff of the centres;
(f) collaborating with local drug committees;
(g) collaborating with professional associations.

Conclusion

Countries need to cooperate with each other in sharing knowledge and practices of TM and exchanging training programmes on TM, consistent with national legislation and relevant international obligations. Countries also need to strengthen regulation of traditional medicine practitioners, practices and products, including advertising, and protect the public against quack practitioners and illicit products.