

In many developing countries traditional medicine is still the main source of health care for about 80% of the population, because of its cultural acceptability, affordability and accessibility. In the last few years, there has also been an upsurge of interest in the use of traditional medicine in developed countries, where it is usually referred to as complementary and alternative medicine. Owing to countries' efforts to institutionalize traditional medicine in health systems and calls made by the WHO Regional Office for Africa over the last two decades, more than half of the countries in the African Region have developed national policies on traditional medicine and regulation is one of the components of such policies. Eighteen countries have developed national codes of ethics to ensure the safety, efficacy and quality of traditional medicines. However, less than half of the countries are yet to implement these policies and therefore, only a few countries have developed regulations for traditional medicine. Twenty-one countries have developed legal frameworks that provide for accreditation, registration of traditional health practitioners (THPs) and the establishment of a THP Council for regulation of traditional medicine practice and products. Non-regulation of traditional and herbal medicines poses a health risk to the populations. This paper discusses the regulation of traditional medicine practices and products, and highlights the challenges posed by attempts to regulate the sector. It also outlines quality, safety and efficacy assessment; product registration; marketing, distribution and post-marketing surveillance.

## RÉSUMÉ

Dans de nombreux pays en voie de développement, pour 80% de la population, la médecine traditionnelle représente encore la principale source de soins médicaux. Elle est culturellement bien acceptée, abordable et accessible. Au cours de ces dernières années, il y a également eu un regain d'intérêt pour la médecine traditionnelle dans les pays développés, où on fait habituellement recours à la médecine complémentaire et à la médecine alternative. Grâce aux efforts des pays pour institutionnaliser la médecine traditionnelle dans les systèmes de santé et les appels faits par le Bureau régional de l'OMS pour l'Afrique au cours des deux dernières décennies, plus de la moitié des pays de la Région africaine ont élaboré des politiques nationales sur la médecine traditionnelle. La réglementation est l'un des composants de ces politiques. Dix-huit pays ont élaboré des codes nationaux de déontologie pour assurer la sécurité, l'efficacité et la qualité des

médicaments traditionnels. Cependant, moins de la moitié des pays doivent encore mettre en œuvre ces politiques. Par conséquent, seuls quelques pays ont élaboré une réglementation pour la médecine traditionnelle. Vingt-et-un pays ont élaboré des cadres juridiques qui prévoient l'accréditation, l'enregistrement des tradipraticiens et la création d'un Conseil des tradipraticiens pour la réglementation de la pratique de la médecine traditionnelle et des produits. L'absence de réglementation des médicaments traditionnels et des médicaments à base de plantes constitue un risque pour la santé des populations. Ce document traite de la réglementation des pratiques de la médecine traditionnelle et des produits. Il souligne les défis posés par les tentatives de réglementer ce secteur. Il expose également l'évaluation de la qualité, de la sécurité et de l'efficacité; l'enregistrement des produits, le marketing, la distribution et la surveillance post-commercialisation.

## SUMÁRIO

Em muitos países em desenvolvimento, a medicina tradicional ainda constitui a principal fonte de cuidados de saúde para cerca de 80% da população, devido à sua aceitabilidade cultural, disponibilidade e acessibilidade. Nos últimos anos, ocorreu também um interesse súbito na utilização da medicina tradicional em países desenvolvidos, onde é normalmente referida como medicina alternativa e complementar. Devido aos esforços dos países no sentido de institucionalizar a medicina tradicional nos sistemas de saúde e às solicitações realizadas pelo Gabinete Regional da OMS para África durante as últimas duas décadas, mais de metade dos países na Região Africana desenvolveram políticas nacionais relativas à medicina tradicional e a sua regulamentação constitui um dos componentes de tais políticas. Dezoito países desenvolveram códigos de ética para assegurar a segurança, eficácia e a qualidade

das medicinas tradicionais. Contudo, menos de metade dos países estão já a implementar estas políticas e, portanto, apenas alguns países desenvolveram regulamentações para a medicina tradicional. Vinte e um países desenvolveram estruturas legais que permitem a acreditação, o registo de praticantes de saúde tradicional (THP) e o estabelecimento de um Conselho de THP para a regulação da prática e dos produtos de medicina tradicional. A ausência de regulamentação dos medicamentos tradicionais e à base de plantas constitui um risco de saúde para as populações. Este documento discute a regulação das práticas e produtos da medicina tradicional, destacando os desafios colocados pelas tentativas de regular o sector. Assinala também a avaliação de qualidade, segurança e eficácia; registo de produtos; comercialização, distribuição e vigilância pós-comercialização.

# REGULATION OF TRADITIONAL MEDICINE IN THE WHO AFRICAN REGION

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**Most of the populations in developing countries use traditional medicines for their primary health care needs because they are accessible, available and affordable. The use of traditional and herbal medicines continues to expand rapidly in developed countries too, where they are referred to as complementary and alternative medicine (CAM). The problems related to the safety and quality of traditional medicines therefore exist in both developing and developed countries. Indeed, the long-term use of traditional medicine is not a guarantee of its safety as any medicine, whether traditional or conventional, can cause health risk.**

It has been observed that a lot of the problems associated with the use of traditional medicines arise mainly from the classification of many traditional medicine products as foods, dietary supplements or herbal medicines in some countries. In these countries, evidence of quality, efficacy and safety of traditional medicines is not required before marketing. Quality tests and production standards tend to be less rigorous or controlled and in some cases, traditional health practitioners (THPs) may not be certified or licensed. Some of the problems may also be due to lack of expertise of THPs or inappropriate preparation or production of traditional medicines. The safety of traditional and herbal medicines has therefore become a major concern to both national health authorities and the general public.

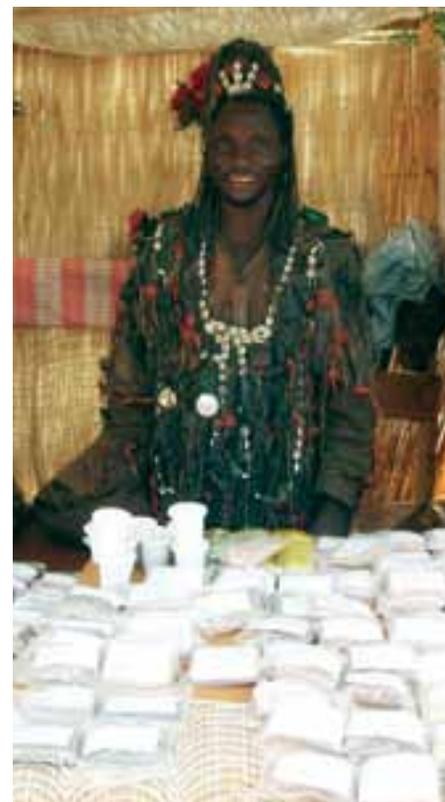
Owing to the complexity of herbs in particular, it is essential that they are subjected to rigorous scientific evaluations like conventional medicines in order

to guarantee their safety; quality and efficacy.

In considering the role of regulating traditional medicine in countries of WHO African Region, three areas need to be addressed within the context of a policy framework. These areas are the regulation of THPs; the regulation of the practice of traditional medicine; and the regulation of traditional medicines.

## THE POLICY CONTEXT OF REGULATION

In recognition of the value of the world's resources of medicinal plants and the need for their rational use, the World Health Assembly has adopted resolutions relating to the cultivation and conservation of medicinal plants; quality control of medicines derived from traditional herbal medicines; compilation of an inventory



and an assessment of medicinal plants; regulation and control of medicinal plant products, and their inclusion in the national formulary of pharmacopoeia of remedies that are safe, effective and of good quality.

The relevant recommendations of WHO and WHO AFRO governing bodies and the orientations of the Regional Health-for-All Policy for the 21<sup>st</sup> century (1,2,3) have underscored the importance of traditional medicine and its practitioners in primary health care (PHC) and have also addressed the strategic options that are available to help achieve health for all. These have been described in other papers contained in this issue.

## REGULATION OF TRADITIONAL HEALTH PRACTITIONERS AND TRADITIONAL MEDICINE PRACTICE

A THP is defined by the WHO as a person recognized by the community in which he or she lives as competent to carry out diagnoses with local sociocultural methods, and contributes to the physical, mental, social, and spiritual well being of the members of their communities. THPs have various specializations such as traditional therapy, traditional midwifery, herbalism, psychiatry, paediatrics and spiritualism. They far outnumber conventional medical practitioners in many African countries and provide health care to about 80% of the population in the Region.

However, despite their valuable contribution to health care delivery, traditional medicine has not been integrated into national health systems for several reasons. Notable among these is denial of the immense potential of traditional medicine to improve the health of the people by policy makers and conventional health

practitioners (CHPs), resulting in a lack of political recognition.

For the full potential of traditional medicine to be realized therefore, there is the need to officially recognize its role in health systems through the development of national policies as has been done in more than half of the countries in the Region. THPs need to be empowered with the requisite regulatory and legal framework (4). The framework should include a code of practice and minimum requirements for the practice of traditional medicine so that only registered THPs would be granted licenses for practice. In addition, such a legal and regulatory framework could assist THPs to organize themselves into functional associations or federations and councils for effective policy implementation. Membership of such associations or federations should be based on accreditation, registration and licensing of qualified practitioners to help eliminate quackery. Although such policy orientations could radically enhance traditional medicine development in the African region, to date just over half of the countries in the Region have established associations of THPs, less than half have federations or umbrella national associations of practitioners and importantly, only twenty

one countries have put in place a legal framework for the practice of traditional medicine.

WHO and other development partners could support this process. WHO Model Legal Framework for the Practice of Traditional Medicine (4) and Guidelines for Minimum Standards for Traditional Medicine practice and Code of Practice (5) and the West African Health Organisation's (WAHO) harmonized regulatory framework (6), could be adapted by Member States to their own specific situations in order to effectively control the conduct of THPs with their patients, the public and with other practitioners.

Moreover, the skills and knowledge of THPs need to be upgraded through proper training and continuing education. This will ensure good communication between THPs and CHPs on the one hand, and between them and their patients on the other. It will also enable THPs to provide proper information and guidance to consumers and the general public on treatment with traditional medicines. To facilitate this, WHO has developed training tools in traditional medicine for health science students and continuing education of CHPs and in PHC for THPs (7-8).

## REGULATION OF TRADITIONAL OR HERBAL MEDICINES

A 2005 WHO global survey found that 84–90 of WHO's Member States (around 60%) had no national policy, laws or regulations for traditional medicine, although more than half of these countries proposed developing them (9). Interestingly, approaches to licensing, dispensing, manufacturing and trading of traditional remedies differ greatly even among those countries with national policies and legal and regulatory frameworks. The lack of regulation in many countries means there are just as many fake remedies and false practitioners as there are genuine treatments—a situation, which can have fatal consequences.

The survey also found that around 110 countries regulate herbal medicines in response to a dramatically increased use globally and demand for more vigorous requirements to ensure quality, safety and efficacy. A number of countries also review and strengthen existing regulations for herbal medicines in a continued effort to improve their use and efficacy. A global network of regulatory agencies responsible for

regulation of herbal medicines, the “International regulatory cooperation for herbal medicines (IRCH)” was established in 2006 under the coordination of WHO and currently has 19 members.

Generally, the use of herbal medicines in the Region is based on oral tradition within a family or a community. As a result, most herbal medicines claimed to provide “effective cures” for various diseases lack scientific evidence for safety, efficacy or quality-essential requirements for evaluating traditional medicines. Yet, they are openly sold in markets, stores, homes and even in pharmacies as over-the-counter medicines and dietary supplements, with little, if any, advice offered on their use. Consumers may often be unaware of how and when herbal medicines may be safely taken, or of their potential side effects. Despite this, most countries in the Region have not established safety-monitoring mechanisms for imported and locally produced traditional medicines, as demonstrated by a survey conducted by WHO in 2002, which showed that only 8 out of the 34 countries covered had regulations on traditional medicines (9). This would seem to reflect the inadequacy of facilities for researchers in the Region for assessing the quality, safety and efficacy of traditional medicines whose composition is usually complex.

Some major challenges facing the development and use of traditional medicines in the Region therefore include inadequate data on scientific and clinical validation of many traditional medicines; poor modes of prescription and marketing of those traditional medicines for which evidence of safety, efficacy and quality exist, and lack of mechanisms for the registration of traditional medicines. Moreover, there is an absence of, or weak, intellectual property rights regimes on traditional medical knowledge (TMK) as well as deficient biodiversity laws on medicinal plants.

In order to promote the registration and marketing of safe, effective and good quality traditional medicines, the WHO African Region has developed Guidelines for Registration of Traditional Medicines (10). The guidelines contain a classification of traditional medicines, and minimum regulatory requirements for their registration vis-à-vis determination of quality, safety and efficacy by national drug regulatory authorities. Similar guidelines, protocols or regulatory frameworks have also been developed for assessing the safety, efficacy and quality of traditional medicines, and for accelerating the protection of TMK and intellectual property rights.

### ASSESSMENT OF QUALITY, SAFETY AND EFFICACY

The establishment of quality is an indispensable process in the production of any therapeutic agent. Proper identification of a medicinal plant material is fundamental to the quality control process; it must be established unequivocally that the source of the plant material is authentic. Ethnobotany and pharmacognosy are effective tools for achieving this. Following this, microbial contamination (fungal and bacterial) must be checked during the stages of processing of the material. Chemical, pharmacological and toxicological evaluations, conducted according to the principles of Good Laboratory Practices (GLPs), will certify the bioactive properties of the material undergoing processing (11). These tests also are often the predictors of safety of the products manufactured. Clinical safety and efficacy will need to be established through exhaustive and usually lengthy trials during the early stages of the development of a therapeutic agent. After that, so long as the standard operating procedures are adhered to, then the unit dosage forms produced will be considered safe. Notwithstanding this, quality assurance procedures must be instituted so that the products coming from the factory are of good quality, safety and efficacy.

### PRODUCT REGISTRATION

National medicines regulatory authorities (NMRAs) in some countries have reported to have granted marketing authorizations for well researched traditional medicinal products. For instance Ghana and Nigeria have granted over 1,000 marketing authorizations respectively for medicines used for various diseases including for malaria, diabetes, sickle cell diseases and hypertension. Other countries which have granted marketing authorizations and reported in the article on local production include Burkina Faso, Democratic Republic of Congo, Guinea Conakry, Madagascar and Mali.

The products manufactured according to the correct procedures should qualify for registration as therapeutic agents in the country of production. WHO Regional Office for Africa has developed guidelines which can assist Member States to classify traditional medicines for registration in the respective countries (10). The guidelines currently range from raw plant materials, through processed, packaged remedies, to imported herbal products. The guidelines can be used to determine the kind of product to be made even before the product is manufactured. In this way, if there is the appropriate regulatory framework in the country, it should be possible to register the product and market

it within and beyond the country of origin in accordance with applicable regulations.

### MARKETING, DISTRIBUTION AND POST-MARKETING SURVEILLANCE

A manufacturing facility should develop a marketing and distribution framework right from the time when the factory is being established. A marketing survey should provide information on the outlets and consumers. In this respect, the products that are manufactured according to the WHO guidelines on the production and classification of traditional medicines will be much easier to market. Once the product is registered in a particular category of traditional medicines, the ethics governing its marketing should conform to national regulations. WHO has provided basic guidelines for post-marketing surveillance and safety monitoring of traditional medicines in the documents on the registration of traditional medicines (10). The WHO Regional Office for Africa's guidelines on documentation of ethnomedical data, describe the steps to be taken to establish the safety and efficacy of a well known traditional medicine preparation. This document is useful in determining whether a traditional preparation could be produced as a therapeutic agent and not as a nutraceutical or an adaptogen (12).

## CHALLENGES IN THE DEVELOPMENT AND IMPLEMENTATION OF REGULATION OF TRADITIONAL MEDICINE/CAM AND HERBAL MEDICINES

**There are many challenges in the development and implementation of regulation of TM/CAM and herbal medicines as explained below.**

- (a) *Challenges related to the regulatory status of herbal medicines:* There are great differences between countries in the definition and categorization of herbal medicines. A single medicinal product may be defined as a food, a functional food, a dietary supplement or herbal medicine in different countries, depending on the regulations applying to foods and medicines in each country. This makes it difficult to define the concept of herbal medicines for the purposes of national medicine regulation, and confuses patients and consumers.
- (b) *Challenges related to the assessment of safety and efficacy:* Requirements and methods for research and evaluation of the safety and efficacy of herbal medicines are more complex than those for conventional pharmaceuticals. A single medicinal plant may contain hundreds of natural constituents, and a mixed herbal medicinal product may contain several times that number. If every active ingredient were to be isolated from every herb, the time and resources required would be tremendous. Such analysis may be impossible in practice, particularly in the case of mixed herbal medicines.
- (c) *Challenges related to the quality control of herbal medicines:* The safety and efficacy of herbal medicines is closely related to the quality of the source raw materials, which in turn is determined by intrinsic factors (genetic) and extrinsic factors (environmental conditions, cultivation and harvesting, field collection and post-harvest/collection, transport and storage). Therefore, it is very difficult to perform quality controls on the raw materials of herbal medicines. Good Manufacturing Practice (13) specifies many requirements for quality control of starting materials, including correct identification of species of medicinal plants, special storage and special sanitation and cleaning methods for various materials. In the quality control of finished products, particularly mixed herbal products, it is more difficult to determine whether all the plants or starting materials have been included.
- (d) *Challenges related to the safety monitoring of herbal medicines:* Adverse events arising from consumption of herbal medicines may be due to a number of factors. These factors include misidentification, adulteration, wrong labelling, contamination with toxic or hazardous substances, over dosage, misuse of herbal medicines by either health-care providers or consumers and use of herbal medicines concomitantly with other medicines. Analysis of adverse events

related to the use of herbal medicines is therefore more complicated than in the case of conventional pharmaceuticals. Furthermore, herbal medicines are used for self-care, and most consumers believe that herbal medicines carry no risk because they are natural. With this belief they tend to take larger quantities than that recommended by a licensed THP. This situation can be prevented if consumers and the public are educated in the proper use of traditional medicines/herbal medicines.

(e) *Challenges related to the lack of knowledge about herbal medicines within national*

*medicine regulatory authorities (NMRAs):* There is generally lack of knowledge about herbal medicines within NMRAs and lack of appropriate evaluation methods. These are factors that delay the development/ updating of national policies, laws and regulations for traditional medicine/CAM and herbal medicines in the Region. Adequate knowledge on herbal medicines would go a long way to solving this problem.

## CONCLUSION

Traditional Medicine still plays an important role in healthcare

delivery in African countries. However, there are many challenges that need to be overcome for its full potential to be realized. A lot more countries need to develop national tools for regulating the practitioners and their practice as well as the traditional and herbal medicines. Various tools and guidelines developed by WHO and other partners can be adopted and adapted by countries to their unique circumstances. For its part, WHO will continue to provide technical and financial support to meet the gaps and challenges for promotion, development of African Traditional Medicine as well as the regulation of the practitioners and their products. 📌

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## REFERENCES

- 1 World Health Organization (1984). Prepare specific legislation governing the practice of traditional medicine within the framework of national health legislation and ensure budget appropriation to allow the effective launching or development of a programme on traditional medicine: In: (Resolution, AFR/RC34/R8) on Report of the Standing Committee on Technical Cooperation among Developing Countries (TCDC). WHO Regional Committee for Africa, Regional Office for Africa, Brazzaville.
- 2 World Health Organization (2000) Essential Drugs in the WHO African Region: Situation and Trend Analysis. Final Report of the WHO Regional Committee for Africa, Windhoek, Namibia, 1999. (Resolution, AFR/RC49/R5).
- 3 World Health Organization (2001) Promoting the Role of Traditional Medicine in Health Systems: A Strategy for the African Region. WHO Regional Office for Africa, Temporary location, Harare, Zimbabwe (Document AFR/RC50/9 and Resolution AFR/RC50/R3).
- 4 World Health Organization (2004) WHO Model Legal Framework for the practice of TM: A Bill for traditional health practitioners in the WHO African Region. In: Tools for institutionalizing traditional medicine in health systems of countries in the WHO African Region. WHO Regional Office for Africa, (AFRO/TRM/2004.4).
- 5 World Health Organization (2004) WHO Model Code of Ethics for traditional health practitioners in the WHO African Region. In: Tools for institutionalizing traditional medicine in health systems of countries in the WHO African Region. WHO Regional Office for Africa, (AFRO/TRM/2004.4).
- 6 West African Health Organization (2008) Traditional Medicine Workshop Report. Situational analysis of the level of development of traditional medicine in the ECOWAS Member States.
- 7 World Health Organization. Guidelines for Training Health Sciences Students and Continuing Education of Western-Trained Conventional Health Practitioners in Traditional Medicine. WHO Regional Office for Africa, Brazzaville (in Press)
- 8 World Health Organization. A guide for Training Traditional Health Practitioners in Primary Health Care. WHO Regional Office for Africa, Brazzaville (in Press)
- 9 World Health Organization (2005). National policy on traditional medicine and regulations of herbal medicines. Report of a WHO Global Survey. WHO, Geneva.
- 10 World Health Organization (2004). Guidelines for the Registration of Traditional Medicines in the WHO African Region. WHO Regional Office for Africa, Brazzaville (AFR/TRM/04.01).
- 11 World Health Organization (2009). Handbook of Good Laboratory Practices (GLP) Quality Practices for Regulated Non-clinical Research and Development. Special Programme for Research and Training for Tropical Diseases, Geneva, 2009.
- 12 World Health Organization (2004). Guidelines for documenting data on ethnomedical evidence. In: Guidelines for Clinical Study of Traditional Medicines in the WHO African Region. WHO Regional Office for Africa, Brazzaville (AFR/TRM/04.04).
- 13 World Health Organization (2007). Good guidelines on good manufacturing practices (GMP) for herbal medicines. WHO, Geneva.