

# TOWARDS SUSTAINABLE LOCAL PRODUCTION OF TRADITIONAL MEDICINES IN THE AFRICAN REGION

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The majority of the population in the WHO African Region and other developing countries, particularly rural dwellers use plant-based traditional medicines for health care. Most developing countries are endowed with vast resources of medicinal and aromatic plants, which have been used over centuries for the treatment of diseases. The global resurgence of interest in herbal medicines has created a large market for plant derived remedies that developing countries could exploit to their advantage, provided they could be produced with acceptable quality and safety specifications. This article highlights the current limitations of traditional medicinal products in the Member States, the essential requirements for the local production of traditional medicines; the status of local production in WHO African Region, approaches to sourcing plant raw materials as well as challenges. Methods for value addition, processing and product improvement for the commercial utilization of medicinal plants are indicated.

## RÉSUMÉ

La majorité de la population vivant dans la Région africaine de l'OMS et dans d'autres pays en voie de développement, en particulier en milieu rural, utilisent des médicaments traditionnels à base de plantes pour se soigner. La plupart des pays en voie de développement disposent de vastes ressources de plantes médicinales et aromatiques, qui ont été utilisées pendant des siècles pour le traitement des maladies. La réapparition dans le monde entier de l'intérêt pour les médicaments à base de plantes a créé un grand marché pour les remèdes dérivés des plantes que les pays en voie de développement pourraient exploiter à leur avantage, pour autant qu'ils puissent

être produits avec une qualité acceptable et des normes de sécurité. Cet article met en évidence les limites actuelles des médicaments traditionnels dans les États membres, les exigences essentielles pour la production locale de médicaments traditionnels, le statut de la production locale dans la Région africaine de l'OMS, les propositions d'approvisionnement de plantes comme matières premières ainsi que les défis à relever. De plus, des méthodes de valeur ajoutée, de transformation et d'amélioration des produits pour l'utilisation commerciale des plantes médicinales sont indiquées.

## SUMÁRIO

A maioria da população na Região Africana da OMS e noutros países em desenvolvimento, particularmente as populações rurais, utilizam medicinas tradicionais à base de plantas para os cuidados de saúde. A maioria dos países em desenvolvimento está dotada de vastos recursos de plantas medicinais e aromáticas, que têm sido utilizadas há séculos no tratamento de doenças. O ressurgimento global do interesse em medicamentos à base de ervas criou um grande mercado de remédios derivados de plantas, que os países em desenvolvimento poderiam explorar em

seu proveito, desde que possam ser produzidos com especificações aceitáveis de qualidade e segurança. Este artigo destaca as limitações atuais dos produtos de medicina tradicional nos Estados-Membros, os requisitos essenciais para a produção local dos medicamentos tradicionais; o estado da produção local na Região Africana da OMS, as abordagens à exploração de matérias-primas à base de plantas e os respectivos desafios. São indicados métodos de adição de valor, processamento e melhoria de produtos para a utilização comercial de plantas medicinais.

**The basis for promoting the local production of traditional herbal remedies is to provide cost-effective medicines to populations who cannot afford but need it most, particularly those with limited access to quality healthcare. However, to ensure sustainability and wide availability of these medicines, a standardized mode of production, which meets modern pharmaceutical manufacturing standards, must be developed. It will then be possible to make these medicines available through direct sale or by prescription, depending on the registration category assigned to the product by a Member State's National Medicines Regulatory Authority.**

The Strategy on Promoting the Role of Traditional Medicine in Health Systems as defined by the WHO Regional Committee for Africa in Ouagadougou in 2000 includes the development of local production and conservation of medicinal plants and the need for regulation of the practice of traditional medicine and its integration into conventional health services (1).

Consequently, a number of institutions in the Member States have, in recent years, embarked on the local production of traditional medicines. While some of the traditional medicinal products meet the standards of quality, efficacy and safety as defined in the WHO guidelines, the quality and safety of many others have been a matter of public health concern. In attempts to address these concerns, the WHO Regional Office for Africa has developed guidelines that will enable institutions and companies in the Member States to manufacture products that are acceptable in all countries of the Region (2). The Regional Office has

also initiated the development of prototypes of medicines that will set the standards of acceptability across the region. The prototypes currently being supported include medicines for the five main diseases: HIV/AIDS, malaria, diabetes, sickle-cell anaemia and hypertension.

A major factor hampering the development of medicinal plant based industries in the African region has been the lack of information on their socio-economic benefits. Except for the medicinal uses of these plants, very little information exists on their commercial value and trading possibilities. Consequently, governments or entrepreneurs have failed to exploit the real potential of these plants.

#### CURRENT LIMITATIONS OF TRADITIONAL MEDICINAL PRODUCTS IN THE MEMBER STATES

It has been noted that a very large number of traditional medicinal products, variously described as nutritional supplements, phytonutrients or

nutraceuticals, are available on the African market. As the names imply, these products are usually sold as functional foods and not as therapeutic agents. They are produced with commercial intent to be used in health promotion, or as agents which can be taken by even healthy individuals as a means of protection against ill health or as tonics to invigorate the body to provide a sense of well being. Since these products are not presented as medicines, they are often exempted from some of the rigorous regulatory requirements that "proper" medicines would normally have to meet before being granted marketing authorisation. This situation therefore poses potential health risks to humans especially for those products that actually possess potent medicinal properties and for which quality and safety may have been compromised in their production. The clinical application of such products would be untenable, because there would be no evidence of their clinical efficacy and no information of any potential adverse effects during use.

In view of the above, the WHO has been supporting the scientific and clinical evaluation of traditional medicines in some research and training institutions for treatment of some priority diseases within the Region (3). The objective here is to support the local production of these medicines using the principles of Good Manufacturing Practices (GMP) (4) and applicable national regulations.

## ESSENTIAL REQUIREMENTS FOR THE LOCAL PRODUCTION OF TRADITIONAL MEDICINES

The fundamental elements that should be considered in the production of traditional medicines include the existence of institutional and legal frameworks, availability and source of raw materials, as well as availability of human and infrastructural capacity.

### INSTITUTIONAL AND LEGAL FRAMEWORK

The production of any therapeutic agent, including traditional medicines, requires approval by the government of the respective Member State. The government needs to provide the political,

economic, legal and regulatory environment for the production of traditional medicines and therefore should have in place the institutional and legal framework for such production. In many African countries, existing laws are sufficient, in that the legal framework will be the same as that required for the establishment of a pharmaceutical production facility. However, there are other aspects of the production, distribution and sale, which are usually not adequately covered by the existing legal frameworks. This situation needs to be rectified by having appropriate and enforceable legal frameworks that will ensure that standards are not compromised at any stage in the production and supply chain.

### AVAILABILITY AND SOURCE OF RAW MATERIALS

The raw materials for the production of traditional medicines are almost invariably medicinal plants, although in some cases, animal, minerals or insect parts may be used as complete entities or added to plant parts. Therefore, in order to make the production sustainable, steps must be taken to ensure that the necessary raw materials are readily available. This will involve the application of the principles of Good Sourcing Practices (GSPs) for Medicinal

Plants (5) as well as Good Agricultural Practices and Good Collection Practices (6) as part of an overall conservation strategy. Besides ensuring sustainable supply of raw materials, this approach will also ensure that endangered or threatened medicinal plants species brought on by the pressure to cultivate land, a high demand for the plants, and destructive methods of harvesting are protected. In addition, local populations should be encouraged to get actively involved in all aspects of conserving and propagating medicinal plants by setting aside land for the creation of medicinal plant gardens both nationally and within communities Box 1 illustrates examples of some approaches adopted by some countries in the African Region to source plant raw materials.

An important aspect of pharmaceutical production of herbal remedies involves the extraction of plants' active ingredients, which are then formulated into the required product. A plant extract usually contains hundreds of compounds, and in some cases the bioactive compound is not usually known. A process known as bioactivity-guided separation is then used to identify the active constituents, which may be several. In order to use this activity-guided separation, a model for activity

**Box 1: Examples of approaches used to source plant raw materials in some Member States****Burkina Faso**

At the Centre Medical St Camille, Ouagadougou, spirulina (green algae) is cultivated in limited quantities within the premises, while an NGO based in Koudougou is engaged in cultivation of the plant. It has been demonstrated at the Centre that spirulina delays the progression of HIV/AIDS in patients. The spirulina farm at Koudougou is also engaged in the processing of the raw plant materials into finished products and has the potential to expand its facilities to meet increased demand. Phytofla Laboratories, Banfora is the largest pharmaceutical industry involved in the local production of traditional medicines in Burkina Faso for treatment of malaria, HIV/AIDS and other important diseases. The Association of Traditional Health Practitioners is engaged in the cultivation and collection of plant raw materials for Phytofla (7).

**South Africa**

*Suntherlandia* product is used as a nutritional supplement against HIV/AIDS, anaemia and cancer. The cultivation, collection and supply of the desired quantities of the plant raw material have been contracted to commercial farmers who engage local women and men on the plantations (8).

**United Republic of Tanzania**

*Artemisia annua* is the plant from which artemisinin, currently the most effective antimalarial medicine, is derived. The plant is native to China, Myanmar, Vietnam and Thailand. Catholic missionaries in Kenya introduced it to the United Republic of Tanzania. The initial cultivation of *A. annua* was at Uwemba Missionary area and then later distributed to secondary schools owned by Njombe District Development Trust. The secondary schools cultivate large quantities of the plant under the guidance of agriculture teachers. The Uwemba Group buys undried *A. annua* leaves for export to Europe, where they are processed and formulated into anti-malarial medicine (e.g. Arinate, Artesunate). Such antimalarial products are subsequently exported from Europe to the United Republic of Tanzania and other parts of the world for sale at generally unaffordable prices. In addition, *A. annua* is grown by individual families in their homes, as it is believed that the plant repels mosquitoes and other insects (9).

outside the human body has to be developed for *in vitro* and/or *in vivo* testing. There are many disease conditions for which such biological models are not easily available, or if even available, would be beyond the means of many institutions or manufacturers in the African region. It has therefore been suggested that perhaps a more prudent and economical approach would be to use total extracts of time-tested medicinal plants for which abundant ethnomedical evidence exists. The mode of preparation can then be based on the traditional methods used to prepare that remedy, taking steps to establish

safety through *in vivo* and *in vitro* studies followed by appropriate pilot clinical trials.

**THE PHYSICAL INFRASTRUCTURE**

Sustainable local production of traditional medicines will also require the acquisition of a production facility, which has specifications that meet the requirements of GMPs (4) of traditional medicines. This facility need not be the same as those for modern (synthetic) pharmaceuticals because of some unique requirements for raw plant materials. For example, the warehouse and storage facilities must be designed to

eliminate fungal growth and other forms of deterioration during storage. There should be an abundant supply of water which can be readily purified into potable water. Furthermore, secondary raw materials (plant extracts) should be painstakingly standardized to guarantee the quality of the finished products. All other requirements of a GMP facility should apply.

In addition, in order to reduce waste, appropriate manufacturing equipments should be acquired according to need. The basic equipment required for making dosage forms such as capsules, tablets,

ointments and emulsions, should be acquired first. Ingredients such as adjuvants, excipients and binding agents may then be acquired according to need.

### HUMAN RESOURCES

The selection of staff for the production of traditional medicines is very critical for ensuring the quality of the final products. At the minimum, they should be trained personnel with an appropriate background in the pharmaceutical sciences. The production manager should by necessity be a pharmacist or a medical herbalist with expertise in pharmaceutical formulations. It is also desirable that the general manager of the factory is a pharmacist or a medical herbalist, but this is not mandatory. There should be personnel to undertake appropriate quality control activities in chemistry, pharmacology and toxicology, pharmacognosy and microbiology. In the less-endowed African countries, departments from local universities or similar institutions can carry out some of the quality control activities by mutually acceptable arrangements. This will reduce the personnel costs, but there must always be one suitably qualified person in the factory to interpret the quality control results appropriate to the manufacturing process.

### PRODUCTION PROCESS

A new pharmaceutical manufacturing unit should begin with the production of only a few products, which can gradually be expanded over time. This will allow production staff to adjust to the production processes and avoid labeling mix-ups. Quality control procedures should be developed in the Standard Operating Procedures (SOPs) for each product, and this includes in-process controls and quality control of the finished product and availability of logistics for the constant supply of quality water and electricity. In view of the fact that the plant extracts used are invariably complex mixtures, it is essential to develop accelerated stability tests as well as on-shelf stability tests which will contribute to the quality assurance of each product. Moreover, the principles of GMPs should be adhered to in the production of traditional medicines, just as with conventional medicines.

### STORAGE

There should be adequate storage space such as warehouses for the raw plant materials, and the finished products should also be stored appropriately to eliminate or reduce microbial contamination. Furthermore, appropriate considerations should be given to temperature and humidity *vis-à-vis* the physicochemical properties of

the formulation and its stability. A newly manufactured product should be quarantined until it has been certified as satisfactory by the quality control processes.

### ASSESSMENT OF QUALITY, SAFETY AND EFFICACY

The establishment of quality control is an indispensable process in the production of any therapeutic agent. Quality assurance procedures must be instituted so that the products coming from the manufacturing unit are of good quality, safe and efficacious. Proper identification of medicinal plant materials 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 (10) and 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.

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 for determining whether a traditional preparation could be produced as a therapeutic agent and not as a nutraceutical or an adaptogen (11). A number of countries are assessing the safety, efficacy and quality of traditional medicines used for priority diseases using these guidelines and other WHO Guidelines (2,12) with some promising results (15–19).

### PRODUCT REGISTRATION

The products manufactured according to the above 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, currently ranging from raw plant materials, through processed, packaged remedies, to imported herbal products, for registration in the respective countries (13). 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. Some countries such as Burkina Faso, Cameroon, Democratic Republic of Congo, Ghana, Madagascar, Mali, Nigeria and Zambia have made some progress in this regard as they have reported to have a registration system for herbal medicines. For instance, the National Medicines Regulatory Authorities (NMRAs) in Democratic Congo have reported to have issued marketing authorizations for 15 traditional herbal medicinal products six of which are included in the national essential medicines list (NEML) (14). One such product, Meyamycin, registered in 1990, is used for the control of acute or chronic infectious diarrhoea and which had been patented in 1988. Dissotis syrup, registered as an expectorant in 1995 in

Guinea Conakry, and FACA used for sickle-cell anaemia in Burkina Faso and registered in 2010 (15).

The Institute of Traditional Medicine in Tanzania has patented Morizella (Juice product) used as a nutritional supplement and Revo cream used for herpes type 8 lesions, fungal infections. Mali reported to have included in her national essential medicines list seven traditional medicinal products used for various diseases including for malaria (16). Others include MADEGLUCYL used for the treatment of diabetes type II reported by Madagascar (17), which had been patented by the national authorities in 2005 and also by the French authorities in 1984; and Saye (18) and N'Dribala (19) used for malaria as reported by Burkina Faso, which obtained marketing authorizations in 2006. During



the same year, the national health authorities in Burkina Faso included these two antimalarials in the national essential medicine list.

### MARKETING, DISTRIBUTION AND FINANCIAL RESOURCES

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 (13) 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.

Funding has always been the greatest challenge that herbal manufacturers in the African Region tend to face. Many entrepreneurs do not see the commercial viability of herbal medicine production and are therefore reluctant to invest in it. However, in order to minimise the potential risks such businesses entail, it is essential that a comprehensive business plan, containing detailed financial analysis with a carefully thought through cash flow, is prepared for the proposed production unit. Such investments should only be made if it is found that the production will be financially viable. If funds are not readily available, then it is necessary to seek help from development partners and other financial institutions.

### INTELLECTUAL PROPERTY RIGHTS (IPRs) AND LICENSING AGREEMENTS

It is crucial that IPR issues are considered right from the point of ethnomedical documentation of the traditional medical knowledge, taking cognizance of ownership and economic implications of the eventual commercial production of the standardized traditional medicines. Currently, IPR laws

on traditional medicine are either non-existent or very weak in Member States. The WHO documents entitled *Guidelines on Policy and Regulatory Framework for the protection of traditional medical knowledge and access to biological resources in the WHO African Region (20,21)* are valuable tools, which can be adopted and adapted by Member States as appropriate.

### POST-MARKETING SURVEILLANCE AND SAFETY MONITORING

Drug safety monitoring is a relatively new area, and even at the global level only 68 Member States have established their own national drug safety monitoring systems, which generally do not include herbal medicines. Genuine adverse reactions of herbal medicines are difficult to distinguish from those attributable to poor quality of medicinal products or due to inappropriate use of the wrong species of medicinal plants, or unsafe, irrational and improper use of herbal products. There is a general lack of knowledge of herbal medicines by conventional health care and traditional and complementary alternative medicine (TM/CAM) providers and consumers. Consumers believe in their safety as they are natural and they have been used for a long time. Therefore, awareness will need to be created through appropriate strategies



including information, education and communication so that all providers and consumers are well-informed about potential adverse events. WHO has developed guidelines on safety monitoring of herbal medicines in pharmacovigilance systems to assist Member States address this gap and will contribute to the promotion of safe use of herbal medicines (22). Marketing and post-marketing surveillance should be planned in accordance with national regulations and applicable international provisions should be made to facilitate inter-country trade of the new medicines.

## CHALLENGES

Some of the challenges relating to the development of traditional medicine can be summarized as follows:

- (a) Lack of institutional and financial support for production and dissemination of key species for cultivation;
- (b) Limited human resources knowledgeable on process technology and development of industries;
- (c) The low prices paid for traditional medicinal plants by herbal medicine traders and urban herbalists;
- (d) Lack of appropriate technology for post-harvest

and pre-processing purposes adapted productively and effectively;

- (e) Insufficient documentation and scientific experimentation for verification of the traditional health practitioner's claims on quality, safety and efficacy;
- (f) Lack of preservation of medicinal extracts for extended shelf life.

## CONCLUSION

Sustainable local production of traditional medicines requires an enabling environment: a strong political will; appropriate legislation and regulations; functional institutions for research and development of traditional medicines; and effective partnerships between traditional health practitioners, researchers and the private sector (23).

Partnership arrangements should be further promoted between the traditional health practitioners and researchers as well as with the pharmaceutical industry. Considerable efforts are needed at both regional and national levels in order to inspire both the private and public sectors to take up the challenge of establishing traditional medicine production units through, for example, South-South and South-North

collaborations. It is expected that such partnerships will be based on fair play, honesty, equality, mutual respect and equitable sharing of benefits.

An important limiting factor in the local production of traditional medicine is the availability of adequate plant resources. Concerted efforts should therefore be made towards the conservation and cultivation of medicinal plants, while the harvesting and collection methodologies of the desired plant parts should be carried out according to Good Collection Practices. Special efforts should be made to engage farmers in the conservation, cultivation, harvesting and post-harvest processing of medicinal plants. It is anticipated that the economic viability of the plants will encourage investors to continue to cultivate them so that the activity becomes sustainable. The fact that the raw plant materials are renewable resources offers an important comparative advantage with in-built commercial gains which need to be carefully controlled by the government so that the products are not only available and accessible, but also affordable to the poor.

Furthermore, special attention should be paid to intellectual property rights and issues related to equitable benefit sharing



emanating from the commercial exploitation of traditional medicines.

In addition, the use of the WHO *Guidelines for the Clinical Study of Traditional Medicines* (2,12) will facilitate the generation of acceptable clinical data *vis-à-vis* the safety and efficacy of standardized traditional medicines. Although WHO is supporting clinical trials of some traditional medicines used against malaria, HIV/AIDS, sickle-cell disorder, diabetes and hypertension at some research institutions, governments are expected to commit themselves to the

continuation and sustainability of these activities.

It is encouraging that limited production of traditional medicines is already in progress in some countries within the region. It is even more significant that some of the standardized African traditional medicines being produced locally in these limited quantities are used for the management of some priority diseases mentioned above. This trend must be accelerated through the commitment of resources by all the stakeholders, creation of a conducive environment for investment and fostering of appropriate

partnerships. However, despite the progress made in locally producing traditional medicines of acceptable standards, the quantities are often inadequate to meet public health demand and the medicines are still generally unacceptable to national regulatory authorities due to lack of convincing data on quality, safety and efficacy. It is hoped that efforts will be enhanced through effective implementation of the *Strategic plan for local production of traditional medicines*(24) to address these drawbacks to ensure that traditional medicines of acceptable quality are made available to the people of the African Region. 📌

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