

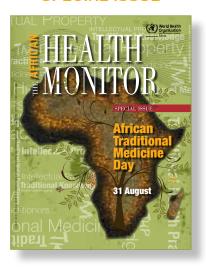


REGIONAL OFFICE FOR Africa

HEALTH MONITOR

AFRICAN TRADITIONAL MEDICINE DAY, 31 AUGUST

SPECIAL ISSUE



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EDITORIAL

THE DECADE OF AFRICAN TRADITIONAL MEDICINE: PROGRESS SO FAR



he 50^{th} Session of the WHO Regional Committee for Africa recognized the importance and potential of traditional medicine for the achievement of health for all. Participants urged accelerating the development of local production of traditional medicines in order to improve access to health care for the African Region. In 2000, the Regional Committee adopted the Regional Strategy on Promoting the Role of Traditional Medicine in Health Systems.

Thus, the year 2010 marks a Decade since the Regional Strategy was adopted. It also marks the end of the Decade on African Traditional Medicine (2001-2010) declared by the Summit of Heads of State and Government in Lusaka in July 2001. The year 2010 also marks a Decade since the institution of African Traditional Medicine Day on 31 August of every year as part of a strategy to boost the role of traditional medicine in national health systems. The decision to observe such a Traditional

The World Health Organization estimates that 80% of the populations of Asia, Africa and Latin America use traditional medicine to meet their primary health care needs. For many people in these countries, particularly those living in rural areas, this is the only available, accessible and affordable source of health care.

Medicine Day was endorsed by the Summit of Heads of State and Government in Maputo in July 2003. Therefore, the theme chosen to mark the "double anniversary" is: A Decade of African Traditional Medicine: Progress so Far.

During the Decade, more than half of the 46 Member States of the Region have formulated national traditional medicine policies and regulatory frameworks to ensure the efficacy, safety and quality of traditional medicines and the regulation of the practice of Traditional Health Practitioners. Member States have established structures, programmes and offices in their Ministries of Health to institutionalize traditional medicine in health care systems. Currently there are 36 countries with such policies

and 39 countries with offices in Ministries of Health to support the development of traditional medicine. In addition, a few training institutions such as the Kwame Nkrumah University of Science and Technology in Ghana, have established a Department of Herbal Medicine under the College of Health Sciences for the training of herbal medicine specialists and to provide continuing education for Traditional Health Practitioners.

The Southern African Development Community has developed a Strategy on traditional medicine, while the Economic Community of West African States has established a traditional medicine programme under the umbrella of the West African Health Organization.

In 2008 WHO and its Member States, celebrated 30 years of the Alma-Ata Declaration and Member States adopted the Ouagadougou and Algiers Declarations which, among other things, underscored the role of traditional medicine in health systems and the need to produce scientific research findings in support of traditional medicine.

In response to all these resolutions and declarations, some countries have promoted research through the establishment of national institutes. These institutes and centres have intensified their efforts to produce scientific evidence on safety, efficacy and quality of traditional medicines, which may have public health importance particularly in the treatment of malaria, opportunistic infections of people living with HIV/AIDS, diabetes, hypertension and sickle-cell disease. Preliminary results from these evidence-based studies are promising.

A number of countries have developed national herbal pharmacopoeias to document medicinal plants that have been found to be effective and to further ensure their safety, efficacy and quality. The West African Health Organization in collaboration with WHO Regional Office for Africa is developing a West African Pharmacopoeia, which will contain monographs

covering some of the medicinal plants common to all the countries of the sub-Region.

Some other countries produce small-scale traditional medicines from wild crafted or cultivated medicinal plants. These traditional medicines are registered with national medicines regulatory authorities and some of these medicines are included in national essential medicines lists. However, there is need for building capacity of countries in order to ensure sustainability, Good Agricultural, Collection and Conservation

Practices of medicinal plants and Good Manufacturing and quality control practices of traditional medicines.

Protection of traditional medicine knowledge is a very important area and Member States therefore need to develop mechanisms within the framework of the global strategy and plan of action on public health, innovation and intellectual property adopted by the 61st World Health Assembly in 2008. Effective implementation of the plan, which charts a roadmap for research and protection of traditional medical knowledge,





among others, will enable Member States to document, preserve, protect and further exploit the social benefits and potential of African traditional medicine.

This special issue of The African Health Monitor aims to present a contemporary picture of traditional medicine in the African Region from distinct perspectives. The first is an overview of traditional medicine situation in the African Region. Then we offer a focus on clinical practices in African traditional medicine and collaboration between practitioners of traditional medicine and

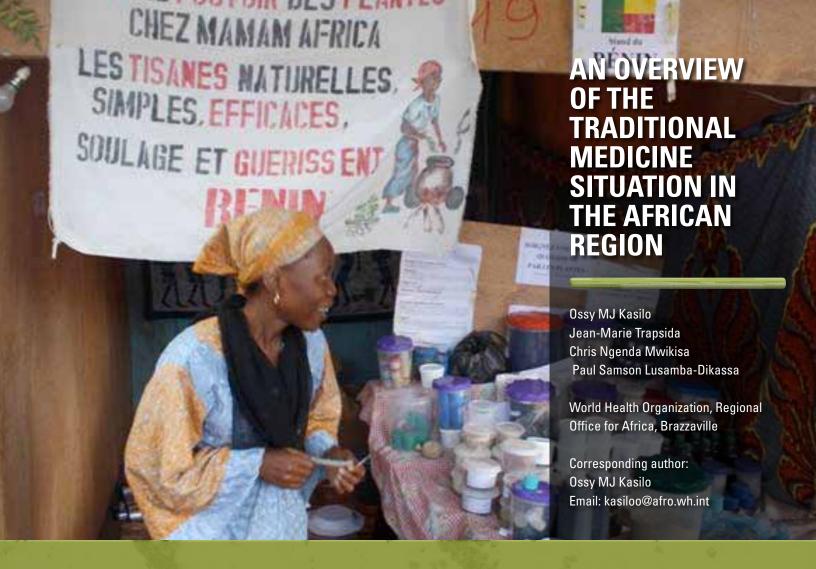
conventional medicine. The next section is on research and development of medicinal plants. A section on local production of traditional medicines is followed by a focus on the protection of traditional medical knowledge.

Despite the achievements of this decade, much still needs to be done if traditional medicine is to occupy its rightful place in national health systems. Member States need to develop and implement policies and regulatory frameworks to allocate and mobilize additional resources for conducting basic research and to undertake more clinical trials in order to

generate scientific evidence on the effectiveness of traditional medicines. Emphasis should be placed on the need to further exploit the rich and diverse African natural resources, which can contribute to discovery and development of new traditional and orthodox medicines. Member States also need to enforce regulations to ensure safety, quality and efficacy of traditional medicinal products, practices and to regulate practitioners. In addition, Member States need to enhance efforts to train health professionals, health science students and traditional health practitioners in traditional medicine and to foster greater collaboration between practitioners of the two systems of medicine as a key strategy for institutionalization of traditional medicine into national health systems.

WHO remains committed to providing support to Member States in the Region and the promotion of the development of African traditional medicine.

Luis Gomes Sambo Regional Director



WHO estimates that about 80% of the population in developing countries depends on traditional medicine for their Primary Health Care (PHC) needs. Traditional medicine and its practitioners were officially recognized by the Alma Ata Declaration in 1978 as important resources for achieving Health for All. Since then, member states and WHO governing bodies have adopted a number of resolutions and declarations on traditional medicine. Notable among these are resolution on "Promoting the role of traditional medicine in health systems: A Strategy for the African Region" adopted by the WHO Regional Committee for Africa in Ouagadougou, Burkina Faso, in 2000 and the declaration on the Decade of African Traditional Medicine (2001–2010) by the Heads of State and government in Lusaka in 2001. This article will focus on the achievements of countries in the implementation of the priority interventions of the Regional strategy since its adoption in 2000. The article will also cover the challenges countries are facing in implementing the Regional strategy and propose the way forward.

RÉSUMÉ

L'OMS estime qu'environ 80% de la population des pays en voie de développement compte sur la médecine traditionnelle pour ses besoins en soins de santé primaires (SMP). En 1978, la Déclaration d'Alma Ata a officiellement reconnu que la médecine traditionnelle et ses praticiens sont des ressources importantes pour atteindre l'objectif de la Santé pour Tous. Dès lors, les États membres et les instances de l'OMS ont adopté un certain nombre de résolutions et de déclarations sur la médecine traditionnelle. Parmi celles-ci, on peut noter la résolution sur « La promotion du rôle de la médecine traditionnelle dans les systèmes de santé : Une stratégie pour

la Région africaine », qui a été adoptée en 2000 à Ouagadougou, Burkina Faso, par le Comité régional de l'OMS pour l'Afrique. En 2001, à Lusaka, les chefs d'Etat et de gouvernements ont adopté la déclaration sur la Décennie de la médecine traditionnelle africaine (2001–2010). Cet article se concentrera sur les réalisations des pays dans la mise en œuvre des interventions prioritaires de la stratégie régionale depuis son adoption en 2000. L'article couvrira également les défis auxquels les pays sont confrontés dans la mise en œuvre de la stratégie régionale et il proposera la voie à suivre.

SUMÁRIC

A OMS estima que cerca de 80% da população dos países em desenvolvimento depende da medicina tradicional para as suas necessidades de Cuidados Primários de Saúde (CPS). A medicina tradicional e os seus praticantes foram reconhecidos oficialmente pela Declaração de Alma Ata em 1978 como importantes recursos para alcançar os objectivos da iniciativa Saúde para Todos. Desde então, os estados-membros e os órgãos dirigentes da OMS adoptaram um conjunto de resoluções e declarações sobre a medicina tradicional. Entre estas, destaca-se a resolução sobre a "Promoção do papel da medicina tradicional nos sistemas de saúde: uma estratégia

para a região africana", adoptada pelo Comité Regional da OMS para África em Ouagadougou, Burquina Faso, em 2000 e a declaração sobre a Década de Medicina Tradicional Africana (2001–2010) dos Chefes de Estado e de Governo, em Lusaka em 2001. Este artigo centrar-se-á no sucesso de alguns países relativamente à implementação de intervenções prioritárias da estratégia Regional, desde a sua adopção em 2000. O artigo abrangerá também os desafios que os países estão a enfrentar na implementação da estratégia Regional e propõe uma via futura.

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 as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness (1-2). Traditional systems in general have had to meet the needs of the local communities for many centuries. China and India, for example, have developed very sophisticated systems such as acupuncture and ayurvedic medicine. Traditional medicine is generally available, affordable, and commonly used in large parts of Africa, Asia, and Latin America. WHO estimates that about 80% of the population in developing countries still depend on traditional medicine for their PHC needs (3). However, this percentage may vary from country to country.

raditional medicine has demonstrated great potential of therapeutic benefits in its contribution to modern medicine. More than 30% of modern medicines are derived directly or indirectly from medicinal plants. Examples of these medicines are analgesics (aspirin, belladonna); anticancer medicines (vincristine and vinblastine), antihypertensive agents (reserpine); antimalarials (quinine, artemisinin); and decongestants (ephedrine). In the African Region, traditional health practitioners (THPs) generally far outnumber medical doctors. In Ghana and Swaziland for example, there are 25,000 and 10,000 patients for every medical doctor whereas there are 200 and 100 patients respectively, for every THP. Given the shortage of medical doctors in the African Region, THPs contribute immensely to health care coverage. Despite the contribution of traditional medicine and its practitioners to health care delivery, they were only officially recognized in 1978

by the Alma-Ata Declaration on PHC as important resources in achieving health for all by the year 2000 (4). Since then, a number of resolutions and declarations have been adopted by WHO governing bodies at regional (5) and global levels (6). In particular, Resolution AFR/RC49/R5 on Essential Drugs in the WHO African Region requested WHO to support Member States to carry out research on medicinal plants and to promote their use in health care delivery systems (7). The Regional Committee that adopted resolution AFR/RC49/R5 also called on WHO to develop a comprehensive strategy on African traditional medicine.

The fiftieth session of the WHO Regional Committee for Africa, held in Ouagadougou in 2000, adopted the regional strategy by its resolution AFR/RC50/R3 on promoting the role of traditional medicine in health systems (1). The aim of the Regional Strategy is to contribute to the achievement of health for all in the Region by optimizing the

use of traditional medicine. The Regional Strategy promotes the integration into health systems of TM practices and medicines for which evidence on safety, efficacy and quality is available and the generation of such evidence when it is lacking. The priority interventions of the Regional strategy are policy formulation; capacity building; research promotion; development of local production, including cultivation of medicinal plants; protection of intellectual property rights and indigenous knowledge.

This year's eighth African Traditional Medicine Day will coincide with the Decade since the adoption of the Regional Strategy in Ouagadougou on 31 August 2000 as well as the Decade of African Traditional Medicine declared by Heads of State and Government in Lusaka in July 2001 and will be commemorated with the theme: A Decade of African Traditional Medicine: Progress so far. This article gives an overview of activities that countries have

undertaken in implementing the priority interventions of the Regional strategy. The article summarizes the achievements made in the past ten years; the challenges faced and proposes the way forward.

ACHIEVEMENTS MADE IN THE PAST TEN YEARS

1 POLICY FORMULATION

Formulation of national policies and regulatory frameworks

The adoption of the Regional strategy and its resolution AFR/ RC50/R3 (1) was followed by the Abuja Declaration of April 2001, which identified traditional medicine as a research priority (8), and the designation, by the Organization of African Unity in 2001, of the period 2001–2010 as the Decade for African Traditional Medicine (9). The adoption of this declaration by African leaders was a strong political commitment that has heightened the profile of traditional medicine in countries of the WHO African Region. The African Summit of Heads of State and Government held in July 2003 in Maputo endorsed the plan of action for implementation of the Decade of African Traditional Medicine and the institution of the African

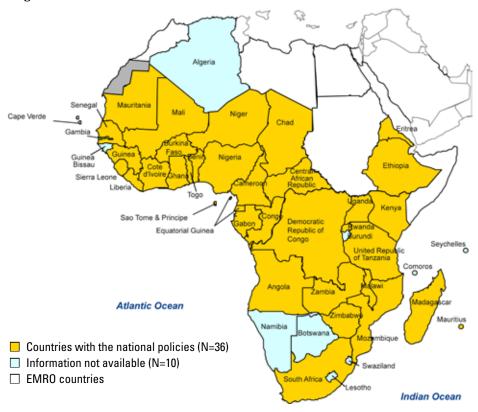
Traditional Medicine Day in Member States (10) to be celebrated every year on 31 August with effect from 2003. In May 2002, the WHA launched the first ever WHO Strategy on Traditional Medicine 2002–2005 (2).

Since the adoption of the Regional strategy, 28 countries have formulated national policies making a total of 36 out of 46 countries in the Region with such policies (Figure 1). In an effort to regulate, promote, develop and standardize the practice of African traditional medicine, 21 countries have developed legal frameworks for traditional medicine practice (e.g. the National Traditional Health

Practitioners (THPs) Act, 2004 of South Africa (11)); while 18 have National Codes of Ethics for THPs to enhance the safety, efficacy and quality of services provided to patients (e.g. the National Code of Ethics for THPs of Ghana of 2004 (12)). However, only 15 countries have developed national strategic plans for implementation of their policies, (e.g., the Congolese National Development Plan for Traditional Medicine (2008-2012) (13)).

National traditional medicine offices have been established in 39 of the 46 countries and 24 countries have traditional medicine programmes in their Ministries of health, of which

Figure 1. Countries with the national policies on traditional medicine in the African Region



12 traditional medicine offices and 14 TM programmes were established during the Decade. A total of 24 countries have established national expert committees as multidisciplinary and multisectoral mechanisms to support the development and implementation of policies, strategies and plans. Eight of these committees were established during the Decade.

The African Traditional Medicine Day

The inaugural African Traditional Medicine Day was commemorated in South Africa in 2003 in conjunction with the Fifty-Third Session of the WHO Regional Committee for Africa with the theme "African TM, Our Culture, Our Future". Some countries, such as Benin, Burkina Faso, Ghana, Mali and Uganda, have instituted a National Traditional Medicine Week. These events have created enabling environments for training, collaboration between practitioners of traditional medicine and conventional medicine, for networking and information exchange.

2 RESEARCH PROMOTION

Production of scientific evidence on safety, efficacy and quality of Traditional Medicines

A number of countries are conducting research on traditional medicines used for the

treatment of malaria, HIV/AIDS, diabetes, sickle-cell anaemia and hypertension in order to produce evidence on safety, efficacy and quality of TMs, and some have reported promising results. For example, the National Institute for Pharmaceutical R&D (NIPRD) in Nigeria has reported to have developed a traditional medicinal product from medicinal and food plants (16). Other herbal medicines for the treatment of sickle-cell disease have been developed by Esoma Herbal Research Institute and Neimeth, based in Abuja, Nigeria. Published data indicate significant clinical efficacy in that a majority of patients were protected from crises, while the frequency and severity of crises were significantly reduced resulting in reduction of hospital visits and increased school and work attendance (16). Published work (17-18) and country reports (19-20) on tests carried out after administration of the traditional medicines in people living with HIV/AIDS for the management of opportunistic infections, showed a decrease in viral load, increase in CD4 and CD8 counts, weight gain, a regain in energy and appetite, improvement of overall clinical conditions and quality of life.

Development of inventories and monographs on medicinal plants and herbal pharmacopoeias

Benin, Cameroon, Chad, Cote d'ivoire, Gabon and Mali reported

to have carried out inventories of medicinal plants while Benin, Burkina Faso, Cameroon, Cote d'Ivoire, Guinea, Madagascar, Mali, Senegal and South Africa have developed monographs on medicinal and aromatic plants. However, only Ghana has published the Second Edition of its National Herbal Pharmacopoeia (21) while Nigeria printed a First Edition (22). **Experts from ECOWAS Member** States are developing the West African Herbal Pharmacopoeia with support from the West African Health Organization (WAHO) in collaboration with the WHO Regional Office for Africa.

3 CAPACITY BUILDING

Inclusion of traditional medicine in training curricula of health professionals

The Kwame Nkrumah University of Science and Technology in Kumasi, Ghana, established a Bachelor of Science Degree in Herbal Medicine in 2001 to train Medical Herbalists. In Nigeria, some courses in TM in certain universities are being taught to undergraduate and graduate pharmacy students within the context of ethnopharmacology and history of pharmacy. However, the country has recently established a college to offer a degree in complementary and alternative medicine. In 2009, Guinea, Sierra Leone and United Republic of Tanzania indicated

that a Masters Degree programme in traditional medicine for pharmacists and in Burkina Faso a Diploma course were in progress while short courses on traditional medicine have been introduced in the curricula of pharmacy students by some universities in South Africa. During 2006–2007, Ghana, Kenya, Mali and the United Republic of Tanzania field-tested WHO training tools for health sciences students in traditional medicine (23) for university pharmacy students whereas Cameroon, Congo, Democratic Congo, and South Africa did so for medical students.

Continuing education and skills development programs for Traditional Health Practitioners for PHC

Burkina Faso, Ghana, Mali, (PROMETRA Senegal International), Uganda (THETA-Traditional and Modern Health Practitioners Together against AIDS) and the United Republic of Tanzania (TAWG-Tanga AIDS Working Group) have reported to have institutionalised training programmes for THPs. Congo, Ghana, Senegal, the United Republic of Tanzania and Uganda field-tested WHO training tools for THPs in PHC (24) for upgrading of their skills.

Effective implementation of WHO training tools will go a long way towards building the capacities of health science students and of

THPs, and fostering collaboration between practitioners of TM and those of conventional medicine. The Ministries of Health in collaboration with THPs Councils or associations of THPs need to intensify their efforts in embarking on continuing education for THPs in PHC.

4 DEVELOPMENT OF LOCAL PRODUCTION AND CULTIVATION OF MEDICINAL PLANTS

Cultivation of medicinal plants

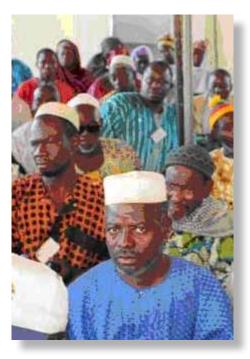
The Republic of Congo and Mali are cultivating medicinal plants while Cameroon, Ethiopia, Ghana, Kenya, Malawi, Mali, Mozambique, Senegal, the United Republic of Tanzania, Uganda, Zambia and Zimbabwe are involved in the cultivation of Artemisia annua for malaria treatment. Ghana(2000), Senegal (2002), Zimbabwe (2007) reported to have established policies related to conservation medicinal plants whereas Cameroon and Mali developed guidelines related to the collection and conservation of medicinal plants (2007).

Local production and commercialization of traditional medicines

Burkina Faso, Cameroon, Democratic Congo, Guinea, Ghana, Madagascar, Mali, Nigeria, Rwanda, South Africa and Togo have reported to be locally producing traditional medicines for the treatment of various diseases. For instance, in 2006, the national medicines regulatory authority (NMRA) in Burkina Faso issued marketing authorizations (MAs) for eleven locally produced traditional medicines including two for malaria (25-26) which have been included in the national essential medicine list (NEML). In 2010 the authority issued another MA for a locally produced plant-based product used for sickle-cell disease. Ghana and Nigeria informed to have issued over 1,000 and 1,500 MAs for locally produced traditional medicines respectively, used for the treatment of various diseases including malaria, HIV/ AIDS, diabetes, hypertension and sickle-cell anaemia. Mali reported to have included seven traditional medicines in the NEML including one for malaria (27) whereas in 2005 MAs were renewed in Madagascar for some medicines including for diabetes (28). Rwanda has reported to have produced antispasmodic and antirheumatic medicines whereas Togo has produced medicines for sicklecell anaemia and hepatitis. However, despite these efforts, governments need to play a key role in scaling up the creation of an enabling policy; economic and regulatory environments for local production of traditional medicines and for development of national regulations.

O INTELLECTUAL PROPERTY RIGHTS (IPRS) AND TRADITIONAL MEDICAL KNOWLEDGE

This is a relatively new subject area and, as a result, only a few countries such as Eritrea, South Africa, Uganda and Zimbabwe, have developed or reviewed their legislation to include the safeguards provided for in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. In addition, Cameroon and Ghana have developed a national framework for IPRs in 2007 and 2008 respectively (29) whereas Nigeria and South Africa have developed a Traditional Knowledge Bill (29). Between 2005 and 2007 Mali held a series of training workshops on IPRs and published two books on indigenous veterinary medicine and on African traditional



medicine (30-31) whereas the United Republic of Tanzania held sensitization workshops on IPRs in 2007.

WHO Support to countries for effective implementation of the priority interventions of the Regional Traditional Medicine Strategy

WHO established a Regional **Expert Committee on traditional** medicine in 2001 to put in place a Regional mechanism for supporting countries to effectively monitor and evaluate progress made in the implementation of the traditional medicine strategy (32). To facilitate development of national traditional medicine policies, regulatory frameworks for the practice of traditional medicine and implementation plans and to enhance research data on the safety, efficacy and quality, WHO published tools for institutionalizing traditional medicine in health systems (33) and guidelines for clinical evaluation of traditional medicines (34). WHO facilitated the exchange of country experiences, dissemination and utilization of research results (35-38) and assessed the Centre for Scientific Research into Plant Medicine in Ghana (2007) and the Department of TM of the National Institute for Research in Public Health in Mali (2008) in view of their proposed designation as WHO Collaborating Centres (WCCs) in traditional medicine research. In 2008, the sixty-first World Health Assembly adopted a global strategy on public health, innovation and intellectual property which sets research priorities in traditional medicine whose effective implementation of this research agenda will go a long way to improving access to medicines for the people of the African Region.

Regarding capacity building, WHO promoted the acquisition of knowledge and skills and facilitated the exchange of country experiences on integration and strengthening collaboration between THPs (39), institutionalization of traditional medicine in health systems (40), regulation of traditional medicines for NMRAs (41-42) and hands on training of officials from NMRAs in Ethiopia (2005) and Uganda (2006) at the National Food and Drugs Board of Ghana. WHO developed training tools on traditional medicine and on PHC (23-24) which were field-tested in the countries mentioned above to facilitate the development of training programmes and materials.

WHO in collaboration with the African Initiative and the Centre for Development of Enterprise and Industry of the European Union, carried out joint missions to Benin and Mali in 2001 to provide technical support for local production of traditional

medicines used for sickle-cell anaemia and malaria. Between 2001 and 2005, WHO supported feasibility studies in Benin, Burkina Faso, Democratic Congo, Mali, Nigeria and the United Republic of Tanzania and needs assessment on local production of traditional medicines in collaboration with the African Union's Scientific and Technical Research Commission in Benin, Burkina Faso, Côte d'Ivoire, Democratic Congo, Ghana, Kenya, Madagascar, Nigeria, South Africa, United Republic of Tanzania and Egypt (2004 and 2006). To support countries in these areas WHO developed a strategic plan for strengthening capacities for local production of traditional medicines (43).

In order to establish mechanisms for the protection of cultural rights and IPRs intended for countries to adapt to their specific situation, WHO developed guidelines (44) and a regulatory framework for the protection of traditional medical knowledge (45), which are complementary to the OAU Model Law (46). WHO will continue to work in close collaboration with organizations dealing with IPR issues particularly the African Union, the African Regional Intellectual Property Organization (ARIPO) and the African Organization for Intellectual Property Rights (OAPI).

CHALLENGES

Although progress has been made in implementing the regional strategy on promoting the role of traditional medicine in health systems (1), countries have faced some challenges that hamper the "institutionalization" of traditional medicine into national health systems. These challenges include:

- (a) Limited national organizational arrangements for institutionaliztion of traditional medicine such as the allocation of adequate financial resources for implementation of traditional medicine activities; the establishment of mechanisms for the official recognition of traditional health practitioners; lack of national policies in some countries and limited national strategic plans for policy implementation; and lack of mechanisms of collaboration between practitioners of conventional and traditional medicine:
- (b) Limited research data on the safety, efficacy and quality of traditional medicines; and limited resources for conduct of phase III clinical trials as golden standards for confirmation of safety, efficacy and quality of medicines; and

- documentation of traditional medicine practices;
- (c) The majority of countries have not included some aspects of traditional medicine in the curricula of health sciences students and other higher learning institutions; and continuing education training programs for THPs are not structured;
- (d) Inadequate regimes for adequate protection of traditional medicine knowledge and intellectual property rights;
- (e) The majority of countries have not developed national policies on conservation of medicinal plants and engaged in large-scale cultivation of medicinal plants of botanical gardens. Governments have not played their key roles in scaling up the creation of an enabling policy, economic and regulatory environments for small and large-scale manufacturing of traditional medicines.

THE WAY FORWARD

(a) Strengthen national multidisciplinary and multisectoral mechanisms to support the implementation of policies and regulatory frameworks and actively collaborate with all partners

in the implementation and evaluation of the national strategic plans; facilitate effective collaboration between traditional and conventional health practitioners. Countries can adapt WHO tools for institutionalizing traditional medicine in health systems to develop national policies, national regulatory frameworks for TM practice and national strategic plans for implementation of policies.

- (b) Include traditional medicine research and development in the national health research agenda as requested by the Algiers Declaration on health research and produce scientific evidence on the safety, efficacy and quality of traditional medicines and link with health services and policy-makers to facilitate the utilization of research results. Countries should continue to produce scientific evidence on the safety, efficacy and quality of traditional medicines using WHO and other relevant research protocols and guidelines.
- (c) Intensify the integration of aspects of traditional medicine into training programmes by relevant institutions involved in education and training. Countries can adapt WHO training tools in traditional medicine and PHC to their

- training programmes, syllabi and curricula.
- (d) Develop mechanisms for the protection of intellectual property rights and indigenous knowledge taking into account fair and equitable sharing of benefits of relevant holders, in collaboration with relevant partners. Countries can adapt WHO guidelines and regulatory frameworks for the protection of traditional medical knowledge and access to biological resources to their specific situations.
- (e) Actively promote, in collaboration with all other partners, the scaling-up of cultivation and conservation of medicinal plants for ensuring sustainability of raw materials for research and local production of traditional medicines. Play a key role in scaling up the creation of an enabling policy, economic and regulatory environments for small and large-scale manufacturing of traditional medicines.
- (f) Foster strong Regional and sub-Regional collaboration in information exchange; play a key role in allocating and mobilizing adequate resources and strengthen capacity-building, equipment and other laboratory facilities in collaboration with the private sector.

CONCLUSION

The traditional medicine situation in the African Region shows important differences between the countries in the degree of organization and integration of traditional medicine into mainstream health systems. It can be concluded that while some countries have no structures in place, others have considerable organization and integration is being achieved. However, countries need to implement the above-mentioned recommendations to mitigate some of the challenges. On its part, WHO will, among other things, continue to advocate for and stimulate the development and implementation of tools for institutionalizing traditional medicine in health systems; advocate and mobilize additional resources for supporting countries to conduct and share research results; and to develop local production of standardized traditional medicines for inclusion in national essential medicines lists; and promote the acquisition of knowledge and skills by facilitating the exchange of experiences; and the development of training programmes and training materials; and work with relevant partners in supporting countries to document and protect traditional medicine knowledge.

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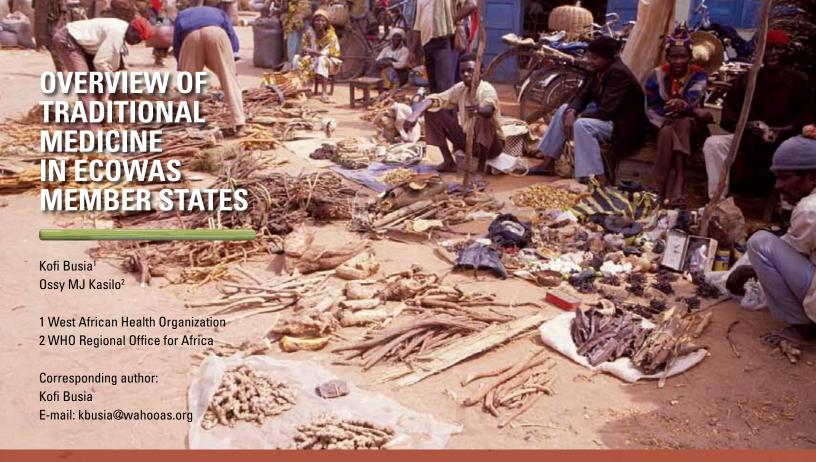
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Traditional medicine has been the main source of healthcare for the vast majority of people in the Economic Community of West African States (ECOWAS). It is currently estimated that between 70–80% of West Africans use traditional medicine for the management of both communicable and non-communicable diseases. In 2007, the West African Health Organization (WAHO) conducted a situational analysis to assess the level of development of traditional medicine in its member states. The findings showed that although there was strong political will from West African governments for the development of traditional medicine, the disparities in the level of development among the countries were very huge. For instance, it was observed that whist some countries had advanced to the stage where they had established training institutions and had herbal medicines on their essential medicines lists, others had not even developed national traditional medicine policies and legal frameworks, codes of ethics and strategic plans for implementation of national policies. Although all countries have made very good progress in the area of sensitization and popularization of traditional medicine, some others have made good progress in the development of national traditional medicine policies (11 out of 15). However, no country has a health insurance coverage for TM, alternative and complementary medicine. Intellectual property is still a relatively new area and this situation delays the development of frameworks for the protection of traditional knowledge and access to biodiversity in majority of Member States.

RÉSUMÉ

La médecine traditionnelle a été la principale source de soins médicaux pour la grande majorité des personnes de la Communauté économique des États de l'Afrique de l'Ouest (CEDEAO). Actuellement, on estime qu'entre 70 et 80% des Africains de l'Ouest ont recours à la médecine traditionnelle pour le traitement des maladies transmissibles et non transmissibles. En 2007, l'Organisation Ouest-Africaine de la Santé (OOAS) a effectué une analyse de la situation pour évaluer le niveau de développement de la médecine traditionnelle dans ses Etats membres. Les résultats ont montré que, même s'il y avait une forte volonté politique des gouvernements ouest-africains pour le développement de la médecine traditionnelle, les disparités au niveau du développement entre les pays étaient considérables. Par exemple, on a observé que pendant que certains pays avaient progressé en créant des institutions de formation et en incluant des plantes médicinales sur leurs

listes de médicaments essentiels, d'autres n'avaient même pas mis au point des politiques nationales de médecine traditionnelle, des cadres juridiques, des codes d'éthique et des plans stratégiques pour la mise en œuvre des politiques nationales. Bien que tous les pays aient fait de grands progrès dans le domaine de la sensibilisation et de la vulgarisation de la médecine traditionnelle, d'autres ont bien progressé dans l'élaboration des politiques nationales de médecine traditionnelle (11 sur 15). Cependant, aucun pays n'a un système de couverture d'assurance maladie pour la médecine traditionnelle, les médecines alternatives et complémentaires. Dans la majorité des Etats membres, la propriété intellectuelle est un domaine encore relativement nouveau. Cette situation retarde l'élaboration de cadres juridiques pour la protection des connaissances traditionnelles et l'accès à la biodiversité.

SUMÁRI

A medicina tradicional tem sido a principal fonte de cuidados de saúde para a vasta maioria de pessoas da Comunidade Económica dos Estados da África Ocidental (ECOWAS). Estima-se actualmente que entre 70-80% dos habitantes da África Ocidental usem a medicina tradicional na gestão de doenças comunicáveis e não comunicáveis. Em 2007, a Organização Oeste-Africana de Saúde (WAHO) conduziu uma análise situacional para avaliar o nível de desenvolvimento da medicina tradicional nos seus estados-membros. Os resultados mostraram que apesar da forte vontade política dos governos Oeste-Africanos no sentido do desenvolvimento da medicina tradicional, as disparidades no nível de desenvolvimento entre os países eram imensas. Por exemplo, observou-se que enquanto alguns países haviam avançado para a fase em que haviam estabelecido instituições de formação e possuíam

medicamentos à base de plantas nas suas listas de medicamentos essenciais, outros ainda nem haviam desenvolvido políticas nacionais e estruturas legais de medicina tradicional, códigos de ética e planos estratégicos para a implementação de políticas nacionais. Embora todos os países tenham operado um progresso muito positivo na área da sensibilização e popularização da medicina tradicional, outros lograram um bom progresso no desenvolvimento de políticas nacionais de medicina tradicional (11 de 15). Contudo, nenhum país dispõe de uma cobertura de seguros de saúde para a MT, e medicinas alternativas e complementares. A propriedade intelectual é uma área ainda relativamente nova e esta situação atrasa o desenvolvimento de estruturas para a protecção do conhecimento tradicional e do acesso à biodiversidade na maioria dos Estados-Membros.

Globally, there is now a general recognition that traditional medicines, the medicines once described as primitive, could be mankind's saving grace — and, therefore, within the past three decades, the changing view of herbs in particular, as medicines moved from that of "witches brew" to major medicine (1). It is estimated that out of a global population of approximately 6.3 billion, about 4 billion utilize plants to meet their primary health care (PHC) needs, It is also now recognized that about half the people in industrialized countries regularly use what is described as complementary and alternative medicine (CAM). However, this growth in consumer demand and availability of services for complementary medicine has outpaced the development of policy by governments and health professions.

raditional medicine has been the main source of healthcare for the vast majority of people in the Economic Community of West African States (ECOWAS). It is currently estimated that between 70 and 80% of West Africans use traditional medicine for the management of both communicable and noncommunicable diseases such as cancer, malaria, HIV/AIDS, diabetes, hypertension, and tuberculosis. Available records show that a high percentage of rural populations utilize traditional midwifery for their maternal and neonatal health problems. In several African countries, traditional birth attendants (TBAs) assist in the majority of births. A study

carried out by WHO showed that in Ghana, Mali and Nigeria, the first line of treatment for 60% of children with high fever resulting from malaria is the use of herbal medicines (2). As part of the global effort to institutionalize traditional medicine in the health systems of Member States of the WHO, several countries including those of the ECOWAS Region have signed up to various traditional medicine-related declarations and resolutions.

In response to the growing recognition of the potential of traditional medicine, the West African Health Organisation (WAHO), a specialised agency of ECOWAS, at the behest of the Region's Heads of State,

established its traditional medicine programme in 2007, with the objective of supporting the ECOWAS countries to institutionalize traditional medicine in their health systems. This decision was epoch-making in the sense that it marked ECOWAS as the first Regional economic community to take concrete steps towards the attainment of the Alma-Ata Declaration of 1978 (3). At the 2009 African Traditional Medicine Day held in Lagos, the State Governor Babatunde Fashola reiterated the pivotal role of traditional medicine in healthcare delivery in Africa and its potential to contribute to the attainment of the health-related provisions of the Millennium Development Goals (MDGs), stressing that reduction of child mortality, improving maternal health and combating HIV/AIDS, malaria, tuberculosis, leprosy, malnutrition, among others, are all linked to how far we are able to harness the hidden potential of our traditional medicine (6).

ECOWAS Member States

Benin Burkina Faso Cape Verde Côte d'Ivoire The Gambia Ghana Guinea Bissau Guinea Conakry Liberia Mali

Niger Nigeria Senegal Sierra Leone Togo In addition, the sub-Region identified key priority areas for interventions, taking into account the available resources and challenges faced: establishment of sub-regional associations of traditional medicine practitioners (TMPs) for efficient policy and program implementation; development of guidelines and standards of registration modalities for TMPs; development of an integrated

programme for training of TMPs and health personnel; protection of intellectual property rights and traditional medical knowledge; promotion of dialogue between TMPs and orthodox health personnel to enhance mutual trust and respect; promotion of research into traditional medicine, particularly herbal medicines, as well as well promotion of conservation, local production and cultivation of

medicinal plants. It worth noting that the choice of all these priority interventions was informed by the WHO Regional Strategy (3). This article will highlight and discuss the findings of the situation analysis of traditional medicine development in ECOWAS Member States, challenges and propose the way forward with a view to creating awareness to policy makers and stakeholders.

SITUATIONAL ANALYSIS OF TRADITIONAL MEDICINE DEVELOPMENT IN THE ECOWAS MEMBER STATES

As a critical first step, WAHO conducted a situational analysis in 2007 to assess the level of development of traditional medicine in the member states; and some of the findings are reflected in Table 1 and are discussed in the following sections.

• ORGANIZATIONAL STRUCTURES, NATIONAL POLICIES, AND REGULATORY FRAMEWORKS FOR TRADITIONAL MEDICINE PRACTICE

It was observed was that nearly all the countries had established either a National traditional medicine office or a traditional medicine programme in the Ministry of Health (MOH), although with the exception of a few, notably Benin, Burkina, Côte d'Ivoire, Ghana, Mali and Nigeria, many did not have a budget line for traditional medicine activities in their national health budgets.

Eleven out of the 15 countries in the sub-Region had a national traditional medicine policy whereas 9 countries had a law and regulation of traditional medicine (Table 1); with only 7 countries having a regulatory framework for traditional medicine practice (7). Even countries such as Guinea, which was the first to develop a national policy in 1994, well before the declaration of the Decade of African Traditional Medicine in July 2001 and the adoption of the WHO Resolution on traditional medicine in August 2000 (3), does not have a legal framework and code of ethics and practice to date, but has a strategic plan which was developed in 2005. Cape Verde, Guinea Bissau and Liberia need to join the other countries to develop their traditional medicine sector.

It was therefore acknowledged that a sub-Region-specific harmonized policy and regulatory framework suitable for use by member states would help to address some of the problems confronting the traditional medicine sector. Using the WHO Tools for the institutionalization of traditional medicine in health systems (8) and the national policies from countries which

Table 1. Situational analysis of the level of Development of Traditional Medicine in ECOWAS Member States (2007, 2008) (6)

Country	National Policy on TM	Law and regulation on TM	Guidelines on Registration & Evaluation of TM	Register of TMPs	Expert Committee on TM	National Research Institute on TM	National Herbal Pharmacopoeia	Registration of Herbal Medicine	Health Insurance Coverage for TM/CAM	Higher Education	National Programme (P) Office (PO) on TM
Benin	Yes-2007	Yes-2001	Yes-2001	Yes-1999	No	No	No	No	No	No	P 1999 Yes – 1996
Burkina Faso	Yes-2004	Yes-1994	Yes-2004	Yes-2006/2007	2000 Yes-2005	Yes-1978	Monographs	Yes-2005	No	In progress— Diploma	P0-2007
Cape Verde	No	No	No	No	No	No	No	No	No	No	No
Cote d'Ivoire	Yes-2007	In progress	In progress	Yes-2007	2002	No	Monographs	No	No	No	Yes-2001
The Gambia	Yes-2005	No	No	Yes (2001)	Yes-2002	No	No	No	No	No	Yes-2001
Ghana	Yes-2000	Yes-2000 (1999)	In progress	In progress	No	Yes	Yes-1992; 2007	Yes	No	Yes BSc—PhD	2000 Directorate
Guinea Bissau	No	No	No	In progress	No	No	No	No	No	No	In progress
Guinea Conakry	Yes-1994	In progress (1997)	Yes-1996	Yes-1996	Yes-1996	In progress	No (national monographs— 2007)	No	No	In progress— Masters	No
Liberia	No	No	No	No	No	No	No	No	No	No	No
Mali	Yes-2005	Yes-1994	Yes-1994	Yes-1991	No	Yes-1968	No	Yes-1991	No	No	Yes-2005
Niger	Yes-2002	Yes-1997	Yes-1999	Yes-2001	No	No	No	Yes-1999	No	No	2000 in progress
Nigeria	Yes-2004	Yes-2007	Yes	No	No	Yes-1994	Yes-2007	Yes	No	No	Yes-2000
Senegal	In progress	In progress	In progress	Yes-2003	No	No	No	In progress	No	No	In progress
Sierra Leone	Yes-2007	In progress	No	No	No	In progress	No	In progress	No	In progress— Masters	No
Togo	Yes-1996	Yes-2001	No	In progress	No	No	No	No	No	No	In progress
Total	11	7	5	7	5	3	2	5+2 in progress	0	1+3 in progress	7

 $TM = Traditional\ Medicine; TMP = Traditional\ Medicine\ Practitioner; CAM = Complementary\ and\ Alternative\ Medicine$

already had them, a harmonized document was developed in Accra and validated by all the member states in Lomé in August 2008. It is reassuring to note that since the development of this document, in June 2010, Togo revised its national policy of 1996 and financial support has been given to Guinea Bissau and other countries to develop national policies.

2 RESEARCH AND DEVELOPMENT OF IMPROVED TRADITIONAL MEDICINES

Some research institutions in the region have made giant strides in conducting R&D for validating the safety, efficacy and

quality of traditional medicines used for priority diseases such as malaria, HIV/AIDS, diabetes, sickle-cell anaemia and hypertension. For example, researchers from countries such as Burkina Faso, Ghana, Mali and Nigeria, have reported that clinical trials on traditional medicines used for malaria compared favourably with the recommended national standard treatment (9). Furthermore, Benin, Burkina Faso, Cote d'Ivoire, Ghana, Mali, Nigeria, Senegal and Togo among others showed that administration of some traditional remedies led to increased CD4/CD8 counts, decreased viral load, increase in weight gain in some patients,

improvements in the quality of life and clinical conditions of people living with HIV/AIDS (PLWA) (9).

In yet other scientific investigations conducted in Benin, Ghana, Mali and Nigeria, subjects suffering from Type II diabetes treated exclusively with traditional medicines were reported to have decreased blood glucose level and the low-density lipoproteins; but increased insulin release from the tissues as well as glucose uptake by the tissue (11). Other countries are conducting research on other medicinal plants in addition to the five priority diseases such those used for hepatitis,

ulcers, hypertrophy of the prostate, reproductive health and as immune boosters (9). The most frequent reason given by physicians for not accepting the use of traditional medicine is that they perceive such therapies as lacking rigorous scientific support. As the global and regional strategies (2,4) and the Beijing Declaration notes (10), for integration of traditional medicine in national health systems to be achieved, it is important that traditional medicine research be vigorously promoted.

3 EDUCATION AND TRAINING

Education and training are among the key ingredients required for the institutionalisation of traditional medicine in national health systems. Some countries within the Region have already begun training programmes in traditional medicine. For example, the Kwame Nkrumah University of Science and Technology, Ghana, established a Bachelor of Science Degree in Herbal Medicine in 2001 to train medical herbalists. At the time of its inception, it was thought to be the first of its kind on the African continent, but now countries such as Burkina Faso have also established a Diploma course in Traditional Medicine, while efforts are being made in Guinea and Sierra Leone to develop a Masters Degree (7,9). In Nigeria, which boasts of some

internationally renowned plant medicine research scientists, emphasis is being placed on the training of CAM practitioners as they have established a college to offer degree programmes in CAM.

Training materials for THPs have been developed by in Burkina Faso, Ghana, Mali, Senegal etc. (9) while Ghana reported that a training manual for THP's developed in 2005 will be reviewed in 2010 in line with WHO training tools (12,13). In collaboration with the nongovernmental organization (NGO), Africa First Ltd., in 2006, the Ministry of Health in Ghana, organized a Global Summit on HIV/AIDS, traditional medicine and traditional medical knowledge in Accra (14). Such activities have since been organized in 2008 in Accra, 2009 in Kumasi and 2010 in Cape Coast. Burkina Faso and REJOUMETRA (a network of journalists for promotion of traditional medicine) have trained over 200 THPs and 200 conventional medicine practitioners (CHPs) good manufacturing practices and on ethnomedical evidence, respectively. Mali organized training workshops on intellectual property rights (IPRs) for THPs and CHPs and researchers in Bamako in 2006 and 2007 (9).

Research, education and training are key strategic objectives of

WAHO. In pursuit of its objective of strengthening the capacities of both TMPs and CHPs on traditional medicine research, a team of experts from the ECOWAS countries met in 2009 to develop training modules on the six priority diseases (HIV/AIDS, TB, sickle-cell anaemia, malaria, diabetes and hypertension) for TMPs and CHPs. The project will soon be piloted in three countries to assess its strengths and weaknesses to inform future review and validation. At the same time, ongoing training programmes will be supported while efforts are made to support other countries to establish their own. WAHO recognizes the importance of traditional medicine research for the promotion and integration of traditional medicine and will therefore collaborate with the WHO/AFRO to provide both technical and financial support to research institutions to intensify their traditional medicine research activities, particularly on plant medicines for the treatment of priority diseases.

◆ COLLABORATION BETWEEN PRACTITIONERS OF TRADITIONAL MEDICINE AND CONVENTIONAL MEDICINE

The regional strategy on traditional medicine (4) and plan of action on implementation of the Decade of African traditional

medicine (7), call on countries to establish mechanisms of collaboration between CHPs and TMPs in areas such as referral of patients and information exchange at local level to facilitate the institutionalization of traditional medicine in their health systems. Despite these policy orientations, the situation analysis indicated that although there was an informal integration, in the form of crossreferrals, research, training, and prevention of HIV infection, etc., the majority of CHPs still remained uninterested or against integration. However, prescription of herbal medicines by doctors was taking place in Mali, Ghana, Côte d'Ivoire, Senegal and Nigeria. The situational analysis also showed that decades of disregard from governments had created mistrust between THPs and CHPs. Even in countries where serious efforts are being made to promote traditional medicine, co-operation with TMPs existed primarily with TBAs, who are perceived to have much affinity with the practical approach of Western medicine (15). There are several examples of such useful collaboration around the world which could serve as a basis for the promotion of such collaboration in the Region. For example, health care for the multicultural community of Otavalo, Ecuador, which has been provided by the Jambi Huasi

clinic established in 1984 (16) for over 20 years.

In order to foster collaboration between the two sectors, WAHO has taken steps to engage the custodians of TM, research scientists and clinicians in respective countries in fruitful dialogue. For example, integrated training programmes, which emphasize the therapeutic benefits of a sensible fusion of conventional medical best practices with herbal therapeutics in treating diseases are being developed. In addition, an annual scientific congress between TMPs and CHPs has been institutionalized and has been running for the last two vears.

© CULTIVATION AND CONSERVATION OF MEDICINAL PLANTS

In 2002, some countries in the Region, such as Liberia, Mali and Sierra Leone, reported being engaged in cultivation of medicinal plants. Burkina Faso had indicated that botanical gardens would be established in all regions in 2008, but is already cultivating Artemisia annua. Ghana also reported that associations for the planting and collection of commercially important medicinal plants e.g. Moringa oleifera, Voacanga africana, Artemisia annua have been formed and are being strengthened. Mali established

botanical gardens for THPs in Siby, Kolokani, Badiangara and Bamako, in 2002 and 2005-2007 (9). Ghana developed a Manual on Cultivation and Harvesting of Medicinal Plants in 2003 by adapting WHO guidelines on Good Agricultural and Collection Practices (GACP) (17) of Medicinal Plants. However, only Burkina Faso, Ghana and Mali have developed policy documents related to conservation of medicinal plants and other countries efforts need to be made in this regards.

6 LOCAL MEDICINES FORMULATION AND PRODUCTION FROM AFRICAN PLANTS

It was found that manufacturing activities for local production of African traditional medicines were carried out in Benin, Burkina Faso, Ghana, Mali, Nigeria and Senegal. Ghana's Centre for Scientific Research into Plant Medicine established since 1973, produces on a small scale herbal preparations for utilization in a clinical setting. In Mali, several herbal products derived from Euphorbia hirta (for dysentery) (Fig 1), Cassia italica and Combretum micranthum (both for constipation), have been formulated as tea bags by private herbal industries for clinical application (10). The Department of Pharmacognosy of Obafemi Awolowo University, Ile-Ife, Nigeria, has embarked

Figure 1. Euphorbia hirta



on the manufacture of many standardized herbal preparations, specifically for use in the management of different opportunistic infections in people living with HIV/AIDS. These include antithrush, febrifuge, antidiarrhoeal, antidysentery, anticough, and anti-infective preparations (18). In 2003, researchers found scientific evidence supporting the efficacy of traditional Ghanaian plants for the treatment of wounds (19,20).

Burkina Faso, Ghana, Mali and Nigeria have issued marketing authorization for traditional medicines (10) whereas Burkina Faso, Mali and Niger have reported to have included traditional medicines in their national essential medicines list (10). Ghana has established a national register of essential traditional medicines and monographs on the plants,

which constitute the essential traditional medicines have been compiled (21).

Despite some progress made, ECOWAS member states need to enhance the creating of an enabling policy and regulatory environment to ensure that largescale manufacturing is carried out in line with the African Union Decade of African Traditional Medicine (5), the Pharmaceutical Manufacturing Plan for Africa (22) and the Regional Strategy on Traditional Medicine (4). WAHO in collaboration with the WHO will continue to support countries to document traditional medicines for scientific evidence on safety, efficacy and quality; and to identify herbal medicines of proven safety and efficacy for their large-scale local production through a Public-Private Partnership approach.

• THE WEST AFRICAN HERBAL PHARMACOPOEIA

To date, many countries in the ECOWAS do not have national herbal pharmacopoeias. Although, countries such as Burkina Faso, Cote d'Ivoire, Guinea, Mali and Senegal, have some documented evidence of proper use of their medicinal plants through R&D of national monographs, only Ghana (23,24) and Nigeria (25), have national herbal pharmacopoeias. Since their publication, these pharmacopoeias have helped

to promote the responsible use of herbal medicines, both in terms of safety and efficacy and formulated standards of identity, purity and analysis in these countries. However, these documents have clearly shown that whereas sufficient laboratory research has been undertaken to

Figure 2 (a). Cassia occidentalis L.



Figure 2 (b). Argemone mexicana L.



substantiate the ethnomedical uses of many African medicinal plants, information on properly controlled clinical trials is almost non-existent. In all a total of 57 medicinal plants (e.g. Fig. 2(a) and 2(b), common to the countries of ECOWAS, have been chosen to feature in the Pharmacopoeia (details are given elsewhere in this special issue).

3 BIODIVERSITY, SUSTAINABILITY AND INTELLECTUAL PROPERTY RIGHTS

One of the objectives of the Regional Strategy on Traditional Medicine is to establish mechanisms for the protection of cultural and intellectual property rights (4). In the sub-Region, Cote d'Ivoire carried out a survey among TMPs that has recorded more than 2,000 traditionally used plants. In 2007, Ghana developed a national policy on protection of IPRs which was reviewed in 2008. In 2006 and 2007 Nigeria developed national legislation and Bill on IPRs whereas Mali organized a series of national and sub-Regional workshops for the protection of traditional medical knowledge (TMK). Ghana developed a database on Ethnobotanical Floristic Studies and Traditional Medicine Pharmacopoeia in 2000 and Senegal developed a database of THPs in 2003. Benin and Mali reported to have established in 1999 and 2004

databases related to 7,500 THPs and TMK and access to biological resources respectively. This is an area that WAHO will collaborate with WHO and other relevant partners to support member states develop national policies and regulatory frameworks, carry out national inventories of medicinal plants to ensure that indigenous knowledge is used correctly and continuously over generations, obtain patents protection, establish databases, and Traditional Knowledge Digital Libraries (TKDL) to document formulations used in traditional medicine to prevent misappropriation as it is done in India.

CHALLENGES

Challenges confronting the traditional medicine sector are related to: weak organizational and institutional frameworks for regulating the practice of traditional medicine and for the protection of traditional medical knowledge; limited funding, limited involvement of THPs in the institutionalization process and weak dissemination and information exchange on research results where this is available. There is also limited inventories on medicinal plants and documentation on traditional medicine practice, therefore difficult to know how it functions and poor collaboration between biomedical practitioners and traditional health practitioners.

THE WAY FORWARD

At the 11th Ordinary Session of the Assembly of ECOWAS Health Ministers organised by WAHO in Freetown, Sierra Leone in April 2010, a round-table meeting was held during which a presentation titled "Traditional medicine within ECOWAS Region: achievements, prospects and challenges", was made. The presentation generated stimulating discussions at the end of which experts from the member states called on WAHO and its stakeholders to:

- (a) Give due consideration to pharmacovigilance of traditional medicine use and to ensure compliance with Good Cultivation and Manufacturing Practice (GCMP) by herbal practitioners;
- (b) Redouble efforts to integrate herbal medicine into national health systems;
- (c) Give consideration to the work done by the United Nations and the African Union on intellectual property rights and the preservation of indigenous knowledge;
- (c) Support research and development of traditional

- medicine and involve academia in scientific meetings;
- (d) Conduct a study to assess the cost-effectiveness and toxicity of herbal medicines;
- (e) To include the expenditure of traditional medical care in National Health Accounts;
- (f) Establish training programmes for traditional medicine and conventional health practitioners; and
- (g) Encourage countries to have a budget line for traditional medicine in their national health budget.

It is hoped of all the advocates of good traditional medicine practices attention would be given to these concerns to ensure the realisation of the ideals, which inspired the inception of the WAHO traditional medicine programme.

CONCLUSION

The situation analysis has shown that member states are at different stages of implementing the regional strategy on promoting the role of traditional medicine in health systems (3) and plan of action on the Decade of African Traditional Medicine.

As we enter the second decade of the 21st century, the ECOWAS Member States will have to take total responsibility for the health of their people. Institutions such as the WHO, WAHO and other partners, will obviously provide the needed financial and technical assistance, but in the end the key decisions to drive the traditional medicine sector will have to come from the countries. Additional financial resources for conducting clinical trials and for local production of traditional medicines need to be increased if traditional medicine is to occupy its rightful place and mainstreamed in health systems and services.

We tend to agree with Prof Honolu Konotey, the renowned Ghanaian sickle-cell physician who said: "Unless Africans can find alternative sources of therapeutic measures in traditional medicine. the future is bleak indeed. because even with improvement in public health measures, people will still require drug treatment. We therefore need to collect and record all anecdotes, including the embarrassing and most primitive ones. By sifting through them carefully we can use our scientific knowledge not only to discard harmful practices, but also discover hidden treasures (26). @

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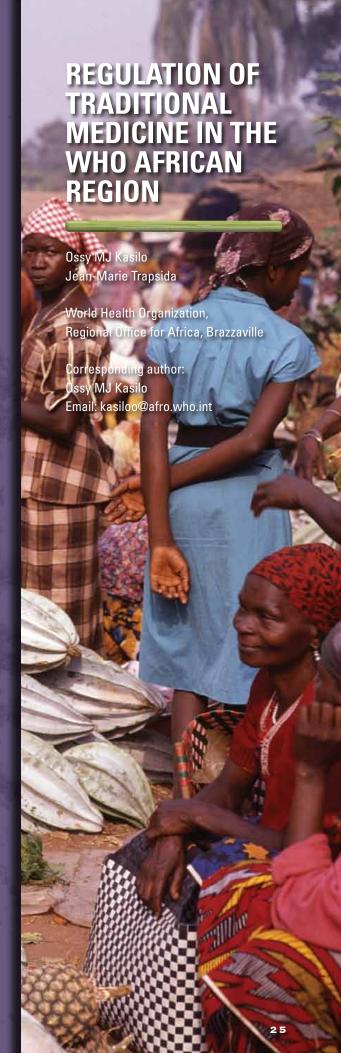
In many developing countries traditional medicine is still the main source of health care for about 80% of the population, because of its cultural acceptability, affordability and accessibility. In the last few years, there has also been an upsurge of interest in the use of traditional medicine in developed 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.

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 tradipracticiens et la création d'un Conseil des tradipracticiens 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.

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 Concelho 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.



ost 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 21st 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 overthe-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 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 (11). 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 (11). 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. herbal Furthermore, medicines are used for selfcare, 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, here 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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CLINICAL PRACTICES OF AFRICAN TRADITIONAL MEDICINE

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In African traditional medicine, the curative, training, promotive and rehabilitative services are referred to as clinical practices. These traditional health care services are provided through tradition and culture prescribed under a particular philosophy, e.g. *ubuntu* or *unhu*. Norms, taboos, tradition and culture, which are the cornerstones of clinical practice of traditional medicine, are the major reason for the acceptability of traditional health practitioners in the community they serve. The philosophical clinical care embedded in these traditions, culture and taboos have contributed to making traditional medicine practices acceptable and hence highly demanded by the population. This paper discusses the different traditional health care services, such as curative services, general traditional healthcare, mental healthcare, midwifery, bone setting, rehabilitative and promotional services that increases health awareness and developing positive attitudes and behaviour towards healthier living).



Dans la médecine traditionnelle africaine, les services de traitement, de formation, de promotion et de réhabilitation sont considérés comme des pratiques cliniques. Ces services traditionnels de soins médicaux sont dispensées en tenant compte de la tradition et de la culture qui sont préconisées en vertu d'une philosophie particulière, par exemple, « *Ubuntu* ». Les normes, les tabous, la tradition et la culture, qui sont les pierres angulaires de la pratique clinique de la médecine traditionnelle, sont les principales raisons de l'acceptabilité des praticiens de santé traditionnels dans la communauté qu'ils servent. La philosophie

des soins cliniques étant intégrée dans ces traditions, la culture et les tabous ont contribué à rendre les pratiques de la médecine traditionnelle acceptables et donc très demandées par la population. Cet article examine les différents services traditionnels de soins médicaux, tels que les services de traitement, les soins généraux traditionnels, les soins de santé mentale, de sage-femme, de rebouteux, les services de rééducation et de promotion qui sensibilisent sur les problèmes de santé et développent des attitudes et des comportements positifs envers une vie plus saine.

Na medicina tradicional africana, os serviços curativos, de formação, promotores e de reabilitação são referidos como práticas clínicas. Estes serviços tradicionais de cuidados de saúde são prestados por tradição e cultura e prescritos ao abrigo de uma filosofia particular, por exemplo *ubuntu* ou *unhu*. Normas, tabus, tradição e cultura, que são as pedras basilares da prática clínica da medicina tradicional, constituem a principal razão para a aceitabilidade de praticantes de saúde tradicional na comunidade que servem. Os cuidados clínicos filosóficos embebidos

nestas tradições, cultura e tabus contribuíram para tornar as práticas de medicina tradicional aceitáveis e, assim, procuradas pela população. Este documento discute os diferentes serviços tradicionais de cuidados de saúde, tais como serviços curativos, cuidados de saúde tradicionais gerais, cuidados de saúde mental, obstetrícia, endireita, serviços de reabilitação e promocionais que aumentam a sensibilização para a saúde e o desenvolvimento de atitudes e comportamentos positivos no sentido de uma vida mais saudável

ealth is a level of functional and/or metabolic efficiency of an organism, often implicitly human.

Awofeso (1) defines health as "a dynamic state of well-being characterized by a physical and mental potential, which satisfies the demands of life commensurate with age, culture, and personal responsibility", while Saracchi defines health as "a condition of well being, free of disease or infirmity, and a basic and universal human right" (1). For the Australian Aboriginal people "...health does not just mean the physical wellbeing of the individual but refers to the social, emotional, spiritual and cultural well-being of the whole community". This is a holistic view of life and includes the cyclical concept of life-death-life (1).

However, the most commonly quoted definition of health is that given by the World Health Organization (WHO) over half a century ago. It defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (2,3). The WHO Constitution states that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being". Overall health is achieved through a combination of physical, mental, emotional, and social well-being, which, together is commonly referred to as the health triangle.

Clinical practice is the process of evaluating conditions of ill health of an individual and its management. The treatment guide used by traditional health practitioners (THPs) in general and diviners in particular, varies greatly and depends on the THP's own knowledge and skills, as well as the nature of the patient's illness. Satisfactory healing involves not merely recovery from physical symptoms, but also the social and psychological re-integration of the patient into his/her community.

In African traditional medicine clinical practice, THPs personally assess patients in order to diagnose, treat, and prevent disease using their clinical judgement. The THP - patient relationship typically begins with interrogations through case-history taking and recourse to basic diagnostic procedures such as divination to determine the cause of the patient's complaint. Once the primary causes of the ailment are determined, the THP then prepares medicines, which may be derived from medicinal plants, animal parts or minerals (4,5).

The THP's own experience, added to the accumulated knowledge handed down by their ancestors, allow the THPs to offer cheap, but effective remedies for treating the main ailments that afflict the populations of the African THE ENJOYMENT OF THE HIGHEST ATTAINABLE STANDARD OF HEALTH IS ONE OF THE FUNDAMENTAL RIGHTS OF EVERY HUMAN BEING.

Region, such as malaria, stomach infections, respiratory problems, rheumatism, arthritis, sexual dysfunction, anaemia, parasitic infections, mental problems, bone fractures and conditions requiring midwifery services (5).

TRADITIONAL MEDICINE AND HEALTH CARE SERVICES

In African TM, health care delivery includes curative, apprenticeship (training), promotional and rehabilitation services. These services are being provided through tradition and cultural philosophy for example ubuntu philosophy. The philosophy requires a THP to provide health services under a "humanityfirst" consideration and not for material gain. There are many philosophical terminologies in African culture, used to describe a THP as a person of high standing in a community, open and available to serve others, when they need health care services.

Traditional health care services are practiced in accordance with *ubuntu* philosophy (an African ethical or humanist philosophy

focusing on people's allegiances and relations with each other). It is believed that THPs, who uphold this principle throughout their lives will, in death, be united with the living.

Ubuntu philosophy requires THPs not to provide services for material gain. THPs are therefore obliged to provide health care services to their patients without demanding any charges. This taboo imposes on the practitioners a strong code of ethics in the provision of health care services to which they should always abide. This places a huge responsibility on the THP/ individual to demonstrate a high sense of "professionalism" and integrity in the discharge of their work. A THP, who believes in ubuntu strives to provide health care services according to the tenets of the taboo.

There are several types of African traditional medicine practices in the Region, however, and not all of them are recognized by communities and governments. According to the Regional Strategy on Promoting the Role of Traditional Medicine in Health Systems, which was adopted by the Fiftieth Session of WHO Regional Committee for Africa in Ouagadougou in 2000 (7), recognition of traditional health services, by communities and governments is a prerequisite for integrating traditional systems

of medicine into national health care services.

Examples of African traditional medicine practices that are recognized by almost all communities in the African Region include general traditional health services, traditional midwifery, bone setting and mental healthcare. Traditional health services that are not often recognized by all communities and governments include divination and circumcision.

Diagnosis is a key part of African traditional medicine. This entails a systematic quest for answers to the origins (immediate cause) of a particular disease to determine, who or what caused it (efficient cause), and why it has affected a particular person at a particular time (ultimate cause). In situations where divination is utilised, diagnosis may comprise of a combination of observation, where the patient's physical symptoms are noted, and patient self diagnosis, where the patient reports their problem to the THP. Where necessary, the impressions of other family members regarding the patient's illness may also be obtained. The process of divination will then involve such techniques and beliefs as the casting of divination objects, extra-sensory perception or ability (clairvoyance/ telepathy) or interpretation of dreams and visions.

In African traditional medicine, practitioners treat all age groups and all health problems, using and administering medicines that are readily available and affordable. The treatment guide used by THPs in general and diviners in particular, may vary greatly and depends on the THP's own knowledge and skills, as well as the nature of the patient's illness. Satisfactory healing involves not merely the recovery from physical symptoms, but also the social and psychological reintegration of the patient into his/her community. Treatment is comprehensive and has curative, protective and preventive elements. Moreover, treatment can be either natural or ritual or both, depending on the cause of the disease. The mode of administration of medications includes, among others, oral ingestion, steaming, sniffing of substances, cuts (the African traditional medicine form of injection) and/or body piercing (the African traditional medicine form of acupuncture).

Another aspect of clinical practice of African traditional medicine are norms and taboos. These belief systems account for the widespread acceptability of THPs in the communities they serve.

In the African context and traditional medicine practices in particular, food taboos are a set of rules developed to control the dietary habits of humans. They ensure that people abstain from consuming certain foods and drinks for reasons, which may be religious, cultural or hygienic. They also give directions as to how certain foods may be prepared. The origin of these prohibitions or restrictions varies from one community to another.

Food taboos include abstention from the consumption of meat of certain animals. These may be mammals, rodents, reptiles, amphibians, bony fish, or crustaceans. Some taboos are specific to a particular part or excretion of an animal, while other taboos restrict the consumption of certain plants, fungi, or insects.

To date, many antenatal and postnatal cases are still handled by traditional healers and midwives in many parts of Africa. In Tanzania, for example, 97% of all pregnant mothers attend antenatal clinics, but only 47% attend modern health facilities during delivery, and 53% of all deliveries occur at home with the assistance of either traditional midwives or relatives. As a result, some taboos have evolved to control maternal health. For example, intake of some foods is prohibited during gestation as a way of controlling abnormal weight gain of unborn babies, which could cause harm to mothers during labour (7).

CURATIVE SERVICES

In countries of WHO African Region, 60-80% of people rely on African traditional medicine for their primary health care. Traditional medicines are used to treat most non-acute illnesses that do not need emergency intervention. Even today, because of the limited access to antiretrovirals (ARVs) many people living with HIV/ AIDS (PLWAs) rely totally on African traditional medicines for treatment. Also, several cases of bone fractures and psychiatric disorders are treated by THPs using traditional medicines. In respect of curative services, the efficacy and potency of herbs are very real in traditional health services provisions.

THPs also provide preventive health care. The experiences they accumulate, are transferred to their successors from one generation to another through apprenticeship.

Some African countries are locally producing traditional medicines used for various diseases such as chronic diarrhoea, liver disorders, amoebic dysentery, constipation, cough, eczema, ulcers, hypertension, diabetes, malaria, mental health and HIV/AIDS in order to improve people's access to medicines. This will enhance the process of integrating traditional systems of medicine into the healthcare services (6).



TYPES OF PRACTICES/ SERVICES

Traditional health services cover many areas including general traditional health services; bone setting; traditional midwifery and traditional mental health services.

GENERAL TRADITIONAL HEALTH SERVICES

General clinical practices are services provided to clients by non-specialised healthcare providers. The general THP manages conditions such as malaria, stomach infections, respiratory problems, rheumatism, arthritis, sexual dysfunction, anaemia and parasitic infections.

MENTAL HEALTH SERVICES

The African concept of disease and medicine is the foundation of traditional medicine treatment. Unlike the situation elsewhere, in countries of the African Region, medicines have a personality and potent living force. For example, the management of neurosis is markedly different in

Africa than elsewhere. African THPs make use of divination to unravel the mental and psychological problems of their patients. Divination therefore plays a significant role in the treatment of neurosis and helps re-trace a patient's life from its metaphysical past to how it interplays with the present and future.

The THP provides for a link between a patient and the patient's own social, cultural and intellectual environmental background.

Studies have shown that the number of common mental disorders recorded among patients consulting THPs is twice as great as that recorded for those attending a primary health care clinic. The most common symptoms presented in both settings, were fatigue, obsessions, worries about physical health and depression. However, people who seek traditional medicine treatment are more likely to have chronic complaints and to have seen several doctors. These results suggest that THPs are a last resort for patients with longterm health problems, who may be unhappy with the outcome of biomedical treatment. In general, primary health care consultations are free, but very short, with little time to discuss symptoms or their causes (8).



MIDWIFERY SERVICES

Midwifery is a health care profession in which providers give prenatal care to expecting mothers, attend the birth of the infant, and provide postpartum care to the mother and her infant.

Midwives are autonomous practitioners who are specialists in a low-risk pregnancy, childbirth, and the postpartum stage. They generally strive to help women have a healthy pregnancy and natural birth experience. Midwives are trained to recognize and deal with deviations from the norm (9).

A midwife may practice in any setting including in the home, the community, hospitals, clinics or health units. Many traditional midwives live in rural, and often isolated communities. They may work at considerable distance from health facilities and are often older mothers; many are post-menopausal. Many midwives are also herbalists, or specialize in other traditional healing practices.

In the past 30 years, several efforts have been made in Africa to improve the skills and practices of traditional midwives, often referred to as Traditional Birth Attendants (TBAs). However, most of these

training programmes failed to give attention to the working environment of the TBAs. For traditional midwives to be able to provide optimal care, an enabling environment has to be provided and their collaboration with nurses and doctors in health facilities strengthened. Moreover, they must have access to basic medical equipments, such as gloves, scissors, etc. They must also have a reliable means of transportation to be able to have timely access to their patients (10).

In the United Republic of Tanzania, in the Kilombero and Hai districts (Morogoro and Kilimanjaro regions respectively), TBAs have become partners in a programme for the prevention of mother-to-child transmission of HIV/AIDS (PMTCT). This programme is being implemented by the district health authorities with technical assistance of Axios and funding from the Elizabeth Glaser Paediatric AIDS Foundation, UK. About 400 TBAs have been mobilized and trained in the provision of HIV/AIDS education to clients, in the mobilization of women for voluntary counselling and treatment (VCT), in the provision of directly observed treatment (DOT) to HIV+ mothers who are on Nevirapine treatment who deliver at home, and postnatal referral of these mothers to health facilities to allow their

infants to receive Nevirapine syrup (11,12).

This initiative is in line with the Regional Strategy on Promoting the Role of traditional medicine in health systems that calls for integration into health systems of traditional medicine practices and medicines for which evidence on safety, efficacy and quality is available and the generation of such evidence when it is lacking. In this context, "integration" means increase of health care coverage through collaboration, communication, harmonization, partnership-building between conventional and traditional systems of medicine, while ensuring intellectual property rights and protection indigenous knowledge (4).

BONE SETTING

A bonesetter is a practitioner of joint manipulation. Before the advent of chiropractors, osteopaths and physical therapists, bonesetters were the main providers of this type of treatment. Bonesetters would also reduce joint dislocations and re-set bone fractures.

Another aspect of bone setting is spinal adjustment, which is a variation of a procedure known today as spinal manipulation. Records show that this form of treatment has been in existence since the time of Hippocrates and ancient Egypt and was passed down through the ages by families of bonesetters. The modern form of spinal manipulation techniques have characteristic biomechanical features, and are usually associated with an audible "popping" sound. In countries of WHO African Region, traditional bonesetting (TBS) has been practised for centuries (14).

TRAINING AND PROMOTIONAL SERVICES

Apprenticeship is a system of training a new generation of practitioners to acquire some skill. Most of this training is done on the job while working for an employer, who helps the apprentices learn their trade, in exchange for their continuing labour for an agreed period of time after they become skilled. Theoretical education may also be informally involved, via the workplace (14).

Although years of colonial rule repressed African traditions, culture, norms and taboos, African traditional medicine has survived to date. Traditional medicine practices have since been passed from one generation to another through training and apprenticeship. Grooming trainees to understand diseases, diagnostic procedures, medicinal resources and preparation of the required prescription and

administration of the medications, requires appropriate theoretical and practical training methods.

The training and promotional aspects of African traditional medicine prepare practitioners to be responsible, accommodating, hardworking, good listeners, as well as having a sense of pride of themselves and their tradition and culture – the *ubuntu* philosophy.

REHABILITATIVE SERVICES

In the African context and *ubuntu* philosophy, rehabilitation is carried out as a family or community duty. Traditionally and culturally there is no system of skills development for disabled people leading to employment. Instead, the family and the community are responsible for the rehabilitation of the disabled person. This situation gives the disabled a sense of belonging, creating an accommodating way of living through tradition, culture, norms and taboos. Every disabled person is regarded as part of the family or community and is supported to lead a functional life.

FUTURE PERSPECTIVES

Future perspectives in this area include:

(a) Traditional medicine and

its practitioners should be formally and explicitly recognized by all countries in the Region through policy and regulatory framework development and implementation. This will ensure the establishment of systems for the qualification, accreditation or licensing of THPs that respect their traditions and customs, and to assist them to upgrade their knowledge and skill in collaboration with relevant health providers. Effective implementation of the policy and regulatory frameworks will also provide for the protection of traditional medical knowledge and access to biological resources.

- (b) Available structures should be strengthened and an enabling environment provided for addressing the traditional health services in the context of policy formulation, capacity building, research and development, local production of traditional medicines, and capacity building in African traditional medicine;
- (c) Collaboration between THPs and conventional health practitioners (CHPs) should be strengthened, particularly in the case of traditional medicine research into priority diseases such as malaria, Tuberculosis, HIV/AIDS; sickle cell anaemia,

hypertension and diabetes
(d) A forum is needed for sharing country experience, service development, policy and regulatory frameworks.

CONCLUSION

The African philosophical clinical healthcare practice is the bridge between people's well-being and life. It is the practice that is embedded in the tradition, culture and taboos that are still relevant to the way of life of Africans. In order to maximize health care coverage there is a need for formalization of traditional health services through the integration of traditional medicine into health systems. This calls for enhanced collaboration between practitioners of conventional medicine and traditional medicine for the benefit of the people in the WHO African Region. This realization is in line with the principles of the Regional Strategy. The aim of the Strategy is to contribute to the achievement of health for all in the Region by optimizing the use of traditional medicine and one of its principles is institutionalization of traditional medicine. This includes the

development of mechanisms for collaboration between CHPs and THPs in areas such as patient referrals and information exchange at local level.

The future of African traditional medicine is bright if viewed in the context of service provision and increase of health care coverage, economic potential and poverty reduction. The increase of health care coverage will be achieved through collaboration and partnerships between THPs and CHPs which is already happening, particularly in the area of traditional medicine research. When a large number of scientifically evaluated traditional medicines become available, local production will be scaled up and this will improve access to medicines for the population. This in turn would reduce the cost of imported medicines, increase countries' revenue and employment opportunities in both industry and practice. In addition, the African Region will be able to grow medicinal plants on a large scale as resources for research and local production. Industrial processing of locally produced medicines will require packaging and marketing thus contributing to poverty reduction.

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Since the early 1970s, the WHO has repeatedly advocated for the recognition of Traditional Health Practitioners (THPs) as Primary Healthcare (PHC) providers and for the integration of traditional medicine in national health systems. Several calls have been made on governments to take responsibility for the health of their people and to formulate national policies, regulations and standards, as part of comprehensive national health programmes to ensure appropriate, safe and effective use of traditional medicine. One of the priorities of the African Regional Strategy on Promoting the Role of TM in Health Systems is promotion of collaboration between practitioners of traditional and conventional medicine. However, despite the health benefits such collaboration could bring to the populations, decades of disregard of traditional medicine practices and products has created mistrust between the two sectors hampering all the efforts being made to promote this potentially useful partnership. This article outlines the strategies that have been adopted by the WHO to ensure the integration of traditional medicine into national health systems, examples of ongoing collaboration between research institutions and THPs based on research and management of patients; and between THPs and conventional health practitioners in HIV/ AIDS prevention and care and HIV/AIDS/STI/tuberculosis programmes; factors that have contributed to sustaining these partnerships as well as mechanisms for strengthening such collaborations.

RÉSUME

Depuis le début des années 1970, l'OMS a maintes fois plaidé en faveur de la reconnaissance des tradipracticiens en tant que pourvoyeurs de soins de santé primaires (SSP). Elle a également plaidé pour l'intégration de la médecine traditionnelle dans les systèmes de santé nationaux. Les gouvernements ont été sollicités plusieurs fois. On leur a demandé de prendre sous leur responsabilité la santé de leurs populations et, dans le cadre de vastes programmes nationaux de santé, d'élaborer des politiques nationales, des règlements et des normes afin d'assurer une utilisation appropriée, sûre et efficace de la médecine traditionnelle. L'une des priorités de la stratégie régionale africaine pour la promotion du rôle de la médecine traditionnelle dans les systèmes de santé est la promotion de la collaboration entre les praticiens de la médecine traditionnelle et ceux de la médecine conventionnelle. Cependant, malgré les avantages qu'une telle collaboration pourrait

apporter à la population, des décennies de nonrespect des pratiques de la médecine traditionnelle et des produits ont créé une méfiance entre les deux secteurs, entravant ainsi tous les efforts faits pour promouvoir ce partenariat potentiellement utile. Cet article décrit les stratégies qui ont été adoptées par l'OMS pour assurer l'intégration de la médecine traditionnelle dans les systèmes de santé nationaux. Il donne des exemples de collaboration en cours entre les institutions de recherche et les tradipracticiens, basée sur la recherche et la gestion des patients, et également entre les tradipracticiens et les praticiens conventionnels de la santé en matière de prévention et de soins du VIH/SIDA et des programmes de VIH/SIDA/MST / tuberculose. Enfin, cet article traite des facteurs qui ont contribué au maintien de ces partenariats ainsi que des mécanismes de renforcement de ces collaborations.

SUMÁRIO

Desde o início da década de 1970, a OMS tem advogado repetidamente o reconhecimento dos Praticantes de Saúde Tradicional (THP) como prestadores de Cuidados de Saúde Primários (CPS) e a integração da medicina tradicional nos sistemas de saúde nacionais. Foram levadas a cabo junto dos governos várias solicitações no sentido de assumirem a responsabilidade pela saúde das suas populações e de formularem políticas nacionais, regulamentações e normas, como parte de programas completos de saúde nacional para assegurar a utilização apropriada, segura e eficaz da medicina tradicional. Uma das prioridades da Estratégia Regional para a Promoção do Papel da MT nos Sistemas de Saúde Africanos é a promoção da colaboração entre os praticantes de medicina tradicional e convencional. Contudo, apesar dos benefícios para a saúde que tal

colaboração poderia proporcionar às populações, décadas de desrespeito nas práticas e produtos da medicina tradicional criaram desconfiança entre os dois sectores, dificultando todos os esforços que estão a ser feitos no sentido promover esta parceria potencialmente útil. Este artigo sublinha as estratégias que foram adoptadas pela OMS no sentido de assegurar a integração da medicina tradicional nos sistemas de saúde nacionais, exemplos de colaboração contínua entre as instituições de pesquisa e os THP com base na pesquisa e gestão de doentes; e entre os THP e os praticantes de saúde convencional na prevenção do VIH/SIDA/DST/tuberculose; factores que contribuíram para a sustentabilidade destas parcerias, assim como os mecanismos de fortalecimento de tais colaborações.

About 80% of the population in developing countries and the African Region use traditional medicine for their PHC needs (1). Despite this high patronage, traditional medicine is often stigmatized by the practitioners of modern medicine so much so that in some countries it is even illegal to practice it. However, with the global resurgence of interest in traditional medicine and increasing need for expanded health care in the past 30 years, the governing bodies of WHO have adopted a series of resolutions aimed at institutionalizing traditional medicine in the health systems of Member States.

number of key resolutions were adopted (2,3,4,6) culminating in the development of the landmark document, "Promoting the Role of Traditional Medicine in Health Systems: A Strategy for the African Region" (5), which seeks to promote "integration" of traditional medicine practices and medicines for which evidence on safety, efficacy and quality is available, and the generation of such evidence when it is lacking, into health systems. In this context "integration" means increase of health care coverage through collaboration,

communication, harmonization and partnership-building between conventional and traditional systems of medicine, while ensuring the protection of intellectual property rights and indigenous knowledge.

The Regional strategy also calls for institutionalization of TM through the development of mechanisms for official recognition of TM and promotion of effective collaboration between conventional health practitioners (CHPs) and traditional health practitioners (THPs). In addition, the World Health Report 2006,

"Working together for health", highlights the importance of human resources for health (7). The shortage of trained health professionals is among the main obstacles to strengthening low-income countries' health systems and to scaling up HIV/ AIDS control efforts. THPs have been identified as a vital resource for scaling up comprehensive HIV/AIDS care and prevention strategies in sub-Saharan Africa (8-11). An appropriate and effective response to the HIV/AIDS crisis therefore requires reconsideration of the collaboration between THPs and

Box 1. Proposed mechanisms for strengthening of collaboration between traditional health and conventional medicine practitioners

- Political leadership that defines the social goals of the system: this involves ensuring strategic policy frameworks exist and are combined with effective oversight, coalition-building, regulation, attention to system-design and accountability.
- A range of interventions for health promotion, prevention, and rehabilitation as well as for treatment. Good health services are those
 which deliver effective, safe, quality personal and non-personal health interventions to those that need them, when and where needed,
 with minimum waste of resources.
- The right number and mix of health workers with the appropriate skills. A well-performing health workforce is one that works in
 ways that are responsive, fair and efficient to achieve the best health outcomes possible, given available resources and circumstances.
- The required medicines, technologies, and facilities. A well-functioning health system ensures equitable access to essential medical
 products, vaccines and technologies of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and costeffective use.
- Timely and reliable information, research evidence and capabilities in knowledge management. The acquisition, generation, sharing
 and use of information, research evidence and knowledge is critical so that the system can be adapted to changing circumstances,
 improve and develop.
- Robust and equitable mechanisms and institutions for long-term financing. A good health financing system raises adequate funds
 for health, in ways that ensure people can use needed services, and are protected from financial catastrophe or impoverishment
 associated with having to pay for them. It provides incentives for providers and users to be efficient.

CHPs as already documented (8-11). However, there needs to be more communities' views on prerequisites for collaboration between modern and traditional health sectors in relation to STI/HIV/AIDS care (12).

Consequently, over the last decade, there has been renewed interest in fostering effective collaboration between practitioners of the two systems of medicine as part of attempts to strengthen control of the AIDS epidemic, which has placed a heavy burden on already weakened health systems in sub-Saharan Africa. In pursuit of this objective, the fourth African Traditional Medicine Day in 2006 was also commemorated with the theme, "Scaling up Collaboration between THPs and CHPs in the Prevention of HIV/AIDS". This was in line with the launch by the African Union and the United

Nations system of 2006 as the "Year for Acceleration of HIV Prevention".

However, as a result of the level of mistrust that exists between the two health sectors, innovative strategies that would promote mutually-beneficial collaboration (some of which are summarised in Box 1) (13) would be required.

COLLABORATION BETWEEN RESEARCH INSTITUTIONS, CONVENTIONAL HEALTH PRACTITIONERS AND TRADITIONAL HEALTH PRACTITIONERS

Given the increasing popularity of traditional medicine globally, it is imperative that medical and other healthcare personnel collaborate with THPs to understand traditional medicine practices and products. There

are two main reasons why such collaboration is important. First it is important for health personnel to have an understanding of all the health services their patients may be accessing. Secondly, health personnel (especially general practitioners, nurses and pharmacists) are often used by patients as an information source for all health and health-related issues. An understanding of traditional medicine will therefore enable them to advise their patients appropriately.

Functional collaboration between THPs and biomedical researchers is also required for validation of the claims of THPs. Such collaborations will facilitate the assessment of the quality, safety and efficacy of the plant raw materials and the finished medicinal products. In addition, with the increasing burden of various communicable diseases. particularly HIV/AIDs and malaria on the health systems of Member States, it is imperative that any primary health care (PHC) delivery plans draw on the skills and knowledge of THPs especially because of their close proximity to the community.

Collaboration between THPs and biomedical practitioners is now being encouraged in many African countries. In East Africa, such collaborative links have been utilized in the management of HIV/AIDS. The Entry Point



of this collaboration involved consultative meetings with recognized THPs associations and health personnel. Several examples of similar collaborations also exist in some countries on the African continent. Notable among these are the ongoing collaborations in the Ministry of Health's Public Health Research Institute in Mali (14), which is research-based; management of patients in Senegal (15); HIVAIDS prevention and care in Uganda (16); HIV/AIDS/STI/tuberculosis programs in South Africa (17).

TOWARDS IMPROVED HEALTH CARE AND HEALTH PROMOTION IN PARTNERSHIP WITH TRADITIONAL HEALING SYSTEMS, BIOMEDICINE AND THE LARGER COMMUNITY

MALIAN EXAMPLE

In Mali a very effective collaboration between THPs and CHPs has been developed. The principles which underpin this collaboration include mutual respect and awareness of limits of competence and voluntarism. THPs and CHPs agree to collaborate without receiving remuneration for services rendered.

Research is a major component of the collaboration, while patient

referrals are routinely made. Determination of the limits of practice is undertaken by the Department of Traditional Medicine in the Ministry of Health's Public Health Research Institute following a prescribed evaluation process. The success of this partnership is illustrated by the situation in Bandiagara, near Timbuktu, Mali, where collaboration between THPs and CHPs resulted in the decline of the rate of mortality caused by serious malaria, from 5% in 1997 to 2% in 1998. In 2008 collaboration between THPs and CHPs in the treatment of severe malaria resulted in reduction of mortality from 38% to less than 10%. Similarly, in 2007 such collaboration resulted in 18% of referral of tuberculosis patients to health centers by trained THPs (14).

SENEGALESE EXAMPLE

PROMETRA (Promotion of Traditional Medicine), based in Senegal, has for many years been promoting collaboration between modern and traditional systems of medicine. At the PROMETRA International's Experimental Centre for Traditional Medicine (CEMETRA) in Fatick, which consists of 450 member associations of THPs of Sine, known as MALANGO, officially recognized by the government of Senegal, THPs collaborate with western-trained medical doctors. An important characteristic of CEMETRA is that only THPs are authorized to treat patients within the centre. The medical doctor measures the patient's vital signs such as blood pressure, pulse, respiratory cycle, temperature, weight, etc., and makes a diagnosis after analysis of laboratory tests, but the CHP cannot take part in treatment. The role of the medical doctor here is to make an initial diagnosis and send the patient to the qualified THPs (15).

After treatment, the THP sends the patient back to the modern medical unit in order to measure the impact of the traditional medicine treatment. Physical examinations and laboratory tests are carried out before and after the treatment, and the impact and outcome of treatment are determined by comparison of preand post-treatment laboratory results, vital signs and physical examination findings. This collaboration helped to reduce health workers' scepticism and strengthened mutual appreciation, understanding and respect between practitioners of the two health systems of medicine.

UGANDAN EXAMPLE

In Uganda, the Traditional and Modern Health Practitioners against HIV/AIDS (THETA) have demonstrated the positive impact THPs can make on health care delivery. Initiated in 1992 through a partnership

between The AIDS Support Organization (TASO) Uganda Ltd and Medicines Sans Frontières (Doctors without Borders), an international humanitarian organization, THETA is a mutually respectful partnership between THPs and Biomedical Health Practitioners in the fight against AIDS and other diseases. It began as a collaborative clinical study with THPs evaluating the effectiveness of local herbal treatments for selected AIDSrelated diseases. The success of this initiative transformed the project into an organization working with THPs in HIV/ AIDS education, counselling and improved patient care. One of the key projects of THETA is supporting children orphaned by HIV/AIDS. However, despite its importance, it operates with very little resources and under very harsh conditions, although the number of children that are cared for keep increasing (16).

A case study on building partnerships between conventional medicine and traditional African Knowledge and medicines in Kirumba in Rakai District in Uganda also illustrates opportunities for the delivery of improved and affordable primary health care to rural communities. The results of the case study clearly demonstrate that improved and affordable primary health services can be provided through

such THP-CHP partnerships. The study was initiated by a community-based crisis management group in Kirumba Sub-County, Rakai District in Uganda, with the main objective of providing home-based health care for the local community, which had been devastated by AIDS and other diseases.

The Kirumba Crisis-Management Group decided to develop a herbal medicine, a first aid kit that could be utilized by the local community to treat common disease symptoms of patients who were bedridden. Through a partnership involving the local community called the Munno mu Kabi (literally translated as "your friend in bad times+), a nongovernmental organization and a government research institute, the Group was able to:

- (a) Identify a number of locally available plant species (corresponding to 147 local names) that could be used to treat 29 local disease symptoms;
- (b) Identify and prioritize plants with toxic effects and associated side effects by screening 184 samples of medicinal plants, thereby improving the quality and safety of the herbal medicines extracted from those plant species;
- (c) Supply improved herbal medicines to more than 600 patients;

- (d) Improve public awareness in sanitation and hygiene, thereby reducing the spread of disease and preventing new infections; and
- (e) Generate income for the local community through the growing of the plant species, distillation of herbs, use of local preservation methods and the sale of the herbal medicines.

The success of the project has major national policy implications for Uganda. It demonstrates that health-related projects initiated by local communities and which utilize traditional African knowledge and herbal medicines are more likely to succeed if they are based upon partnerships involving conventional medicine. An institutional and legal framework as well as the development of a national herbal medicine policy is critical for Uganda's public health system to benefit from the lessons and success recorded by this case study.

As a result of the success of this approach, other rural communities in Rakai District as well as other districts in Uganda have expressed interest in emulating it.

SOUTH AFRICAN EXPERIENCE

Collaborative HIV/AIDS, STI, and tuberculosis (TB) programmes involving THPs have been initiated in a number of sub-Saharan African

countries (17-22) with varying success. A controlled study of an HIV/AIDS/STI/TB intervention with traditional healers in two rural and two urban areas in KwaZulu-Natal, South Africa, was conducted to determine whether training traditional healers can reduce the risks of their practices and encourage them to provide appropriate information and referral for STI/ HIV and TB care. All traditional healers residing in the identified study areas were eligible; 233 (out of 234) participated, 160 in the intervention group and 73 in the control arm. There were some differences between groups: there were more female healers in the intervention group (81% vs. 62% in the control) and from urban areas (41% vs. 23% in the control). Healers were classified as herbalists, diviners, or herbalist-diviners. This later study's findings (23) are similar to those that have previously reported significant improvement of HIV/AIDS knowledge among healers after training.

The largest group of traditional healers in the study was female diviners. Given the gendered nature of the HIV epidemic in South Africa and the need for strategies to enhance the ability of women to protect themselves, it is important to devise interventions that will enable these women to provide more support to other women in their communities.



The possibility of involving traditional healers in areas where they are well respected by the community and attend to clients at risk of HIV, STIs, and TB still needs to be explored. It appears that education programs can improve the healers' general knowledge and ability to counsel clients. However, better interventions need to be developed to change actual risk practices and encourage traditional healers to work with biomedical personnel.

FACTORS CONTRIBUTING TO COLLABORATION BETWEEN THPS AND CHPS

A critical review of all these collaborative initiatives will show that they have all been instigated by certain key factors. These include:

· The universal presence of

- THPs in most developing countries (1 THP per 150 people in Uganda)
- Inadequate or nonexistent modern health facilities
- The unique knowledge of THPs and the respect they command in their communities
- Cultural acceptability and cost-effectiveness of many traditional medicine treatments
- Multisectoral collaboration in traditional medicine in research and in the prevention of HIV/AIDS
- Training and provision of adequate information to consumers and THPs
- Political will shown by many governments on the African continent

CONCLUSIONS

In spite of the huge benefits such collaborations and partnerships offer, considerable challenges still remain. For example, there is often a lack of transparency in the process of actualizing collaboration, resulting in a situation where the so-called "collaboration process" is dominated by one group (often CHPs). The lesson therefore is that any successful collaboration must be based on mutual understanding through dialogue for a free exchange of

information on management of illnesses/diseases, materials and technology used in preparation and dispensing. It also involves stressing complementarities of both systems by referral from one health system to another. But most importantly is the selection of genuine THPs, i.e., recognized THPs in the community through competence in managing diseases/ illnesses and trustworthiness.

THPs are generally very knowledgeable with great potential, so that if they are well sensitized, informed and encouraged to work in close collaboration with CHPs, they could make a difference in helping to stem the tide of

many of the disease pandemics that afflict the people of Africa. Countries in the African Region must therefore be encouraged to officially recognize THPs and develop mutually-beneficial collaborative programmes. Such collaboration should make it possible for the work of THPs to be taken into account in the compilation of health statistics in the Region.

The importance of such collaboration, which is a necessary pre-requisite for the ultimate institutionalization of traditional medicine in national health systems, is summed up in a speech delivered by the WHO Director General, Dr Margaret Chan, during the WHO Congress on Traditional

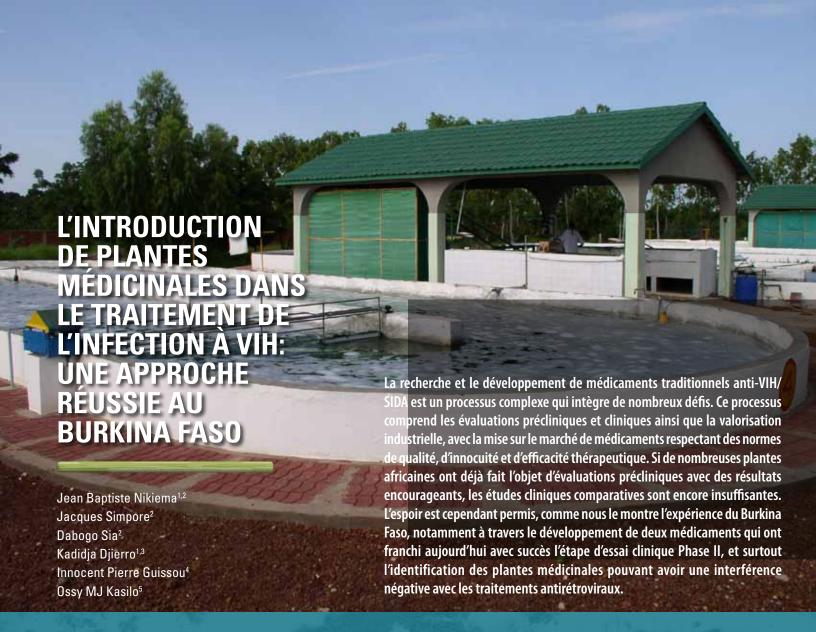
Medicine held in Beijing, in November 2008 (24). She said: "The two systems of traditional and Western medicine need not clash. Within the context of PHC, they can blend together in a beneficial harmony, using the best features of each system, and compensating for certain weaknesses in each. This is not something that will happen all by itself. Deliberate policy decisions have to be made. But it can be done successfully. Many countries have brought the two systems together in highly effective ways. In several countries where health systems are organized around PHC, traditional medicine is well integrated and provides a backbone of much preventive care and treatment of common ailment..."

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ABSTRACT

The research and development of traditional anti HIV/AIDS medications is a complex process, which involves many challenges. This process includes preclinical and clinical trials as well as an industrial evaluation, with the eventual marketing of medicine meeting the established quality, safety and therapeutic efficiency standards. Although numerous African plants have already been through preclinical evaluation/trials with encouraging results, to date there have been

insufficient comparative clinical trials. Nevertheless, there have been encouraging developments, such as those in Burkina Faso, where two medicines have been developed which recently successfully completed Phase II clinical trials, and especially through the identification of medicinal plants that can have a negative reaction with antiretroviral therapies, with the support of the WHO's Regional Office for Africa.

UMÁRIC

A pesquisa e o desenvolvimento de medicamentos tradicionais anti-VIH/SIDA representam um processo complexo que integra numerosos desafios. Este processo compreende as avaliações pré-clínicas e clínicas, assim como a valorização industrial, com a introdução no mercado de medicamentos que respeitem as normas de qualidade, de inocuidade e de eficácia terapêutica. Se é verdade que numerosas plantas africanas foram já objecto de avaliações pré-clínicas com resultados encorajadores, os

estudos clínicos comparativos são ainda insuficientes. Todavia, existe ainda esperança, como nos mostra a experiência do Burquina Faso, nomeadamente através do desenvolvimento de dois medicamentos que ultrapassaram hoje, com sucesso, a etapa do ensaio clínico de Fase II e, sobretudo, a identificação de plantas medicinais que podem vir a ter uma interferência negativa nos tratamentos antiretrovirais, com o apoio do gabinete regional da OMS.

e VIH/SIDA représente aujourd'hui, un problème majeur de santé publique pour l'Afrique (1). La grande majorité des personnes infectées (22,4 millions) vivaient sur ce continent en 2009, avec un faible accès aux médicaments antirétroviraux et aux soins de base (1,2). La forte mortalité liée à cette maladie en Afrique (1,4 millions de décès en 2009), et les multiples souffrances des orphelins (14 millions en 2008), sont autant d'indicateurs des faiblesses des systèmes de santé.

Nul doute que beaucoup d'efforts ont été fournis par les institutions internationales pour améliorer l'accès des malades africains aux médicaments. C'est dans ce sens que les initiatives de l'OMS, de l'ONUSIDA, du Fonds Mondial, d'UNITAID, d'ESTHER, et bien d'autres, méritent d'être saluées. Par exemple, la résolution de l'OMS sur promouvoir le rôle de la médecine traditionnelle dans le système de santé : Stratégie de la Région africaine (3), invite instamment les Etats Membres à établir des inventaires des pratiques efficaces, à apporter la preuve de l'insécurité, de l'efficacité et de la qualité des remèdes traditionnels et à entreprendre des recherches appropriées. La même résolution prie le Directeur régional de conseiller les pays sur la documentation

des remèdes dont l'innocuité, l'efficacité et la qualité sont avérées et de faciliter l'exchange et utilisation de ces informations par les pays (3).

Cependant, il reste beaucoup à faire pour parvenir à l'accès universel des malades du SIDA aux soins de qualité. De même, l'apparition de souches virales résistantes aux traitements antirétroviraux de première ligne, nécessite l'introduction de traitements de deuxième ligne, dont la disponibilité n'est pas toujours garantie dans les pays à faible revenu (2). En résumé, les malades sont dans les pays pauvres et les traitements sont dans les pays développés. C'est dans ce contexte que de nombreux malades africains se tournent vers la médecine traditionnelle, essentiellement pour faire face aux infections opportunistes (4,5,6,7,8). La recherche s'est bien entendu intéressée à cette situation. Il serait très difficile de faire ici, un point exhaustif de toutes les initiatives de recherches et développements, entrepris dans les pays de la région Africaine, sur les médicaments issus de la pharmacopée traditionnelle anti-VIH/SIDA. Nous nous proposons d'aborder les principales étapes du processus de développement, ainsi que quelques succèsstories tirées de l'expérience du Burkina Faso.

LES PRINCIPAUX DEFIS DE LA RECHERCHE

Le premier défi de la recherche sur les plantes anti-VIH/SIDA concerne l'évidence ethnomédicale. Le VIH/SIDA reste une maladie relativement récente pour la médecine traditionnelle. De ce fait, les connaissances, les aptitudes et les pratiques des tradipraticiens de santé, ne sont pas toujours suffisamment documentées. En outre, certains d'entre eux confondent le VIH/SIDA avec les maladies opportunistes.

Le deuxième défi est relatif à la définition de fenêtres de recherche pour les évaluations précliniques et cliniques. Il convient de rappeler que les médicaments issus de la pharmacopée traditionnelle utilisables dans le traitement de l'infection à VIH, doivent, comme tout autre médicament, faire la preuve de la qualité pharmaceutique, de l'innocuité et de l'efficacité thérapeutique. La démarche scientifique pour réunir toutes ces informations passe nécessairement par des essais précliniques et cliniques. C'est dans ce sens que des outils ont été élaborés par le bureau régional de l'OMS pour

l'évaluation des médicaments issus de la pharmacopée traditionnelle anti-VIH/SIDA(9). Il est souhaitable de définir des fenêtres d'application des traitements traditionnels, qui puissent être facilement exploitables dans le cadre des protocoles nationaux de prise en charge des patients souffrant de VIH/SIDA. A titre d'exemple, au Burkina Faso, les échecs immunologiques et certains effets secondaires observés au cours du traitement par les médicaments antirétroviraux, de même que les infections opportunistes sont des fenêtres reconnues pour l'utilisation de traitements traditionnels (4). Ces fenêtres, loin d'être des contraintes, doivent simplement être considérées comme des opportunités de recherche. A l'opposé, la recherche de plantes pouvant masquer la sérologie VIH ou l'inverser, ne peut être considérée comme une fenêtre acceptable.

LE PROCESSUS DE DEVELOPPEMENT

Le processus de développement d'un médicament issu de la pharmacopée traditionnelle anti-VIH/SIDA ne diffère pas fondamentalement de celui des autres médicaments à base de plantes. Les informations scientifiques issues des recherches précliniques et cliniques doivent être protégées par les mécanismes existants de protection des droits de propriété intellectuelle (brevet, marque, dessins et modèles industriels, droit d'auteur, secret d'affaire). Il faut reconnaître que ces mécanismes ne sont pas toujours adaptés à la protection de ce type du savoir traditionnel. C'est pour cette raison que l'Union Africaine (10) et le bureau régional de l'OMS (11,12) ont développé des outils intégrant des mécanismes sui generis de protection du savoir médical traditionnel. Les inventeurs ont besoin du soutien des Etats pour assurer non seulement la protection de leurs inventions mais aussi leur valorisation par la production industrielle. Cette valorisation commence bien entendu par les études de faisabilité, qui prennent en compte la production pilote, l'étude de marché et les démarches pour l'enregistrement. Le médicament, une fois protégé et enregistré, peut maintenant faire l'objet de licence d'exploitation pour une production à grande échelle et une commercialisation dans le circuit officiel. Les étapes suivantes concernent l'inscription dans la liste nationale des médicaments essentiels et l'intégration dans le protocole national de traitement de l'infection à VIH.

LES INTERFERENCES PLANTES/ARV

Les substances naturelles en dépit du bénéfice que certaines d'entre elles apportent aux PvVIH, peuvent avoir une interaction avec les traitements ARV, aux conséquences parfois néfastes pour le patient. Celles qui contiennent des quantités significatives de dérivés (1,8) hydroxyanthracéniques laxatifs, de tanins catéchiques en usage interne peuvent être classées à risque. Il en est de mêmes des plantes hépatotropes et inductrices enzymatiques. Au Burkina Faso, les substances naturelles dites à risque, ont été identifiées, et les professionnels de santé (médecins, pharmaciens et tradipraticiens de santé) sont sensibilisés pour conseiller les patients dans le but de favoriser un usage rationnel de ces produits (4,16,17,18).

LES SUCCESS-STORIES

Les patients souffrants de VIH/SIDA ont recourt à des substances naturelles pour traiter les mycoses rebelles, le zona, les poussées herpétiques et les affections diarrhéiques (4,6). Au Burkina Faso, les sucs issus de l'expression des feuilles fraîches de Mytracarpus scaber et de Cassia alata sont utilisés comme antimycosiques. En ce qui concerne le zona et les poussées herpétiques, les feuilles fraîches de Phyllanthus amarus, la sève de Mangifera indica, le gel de Aloe buettneri et la galle de Guiera senegalensis, sont les drogues végétales les plus utilisées. La propolis, les parties aériennes de Euphorbia hirta et

les affections diarrhéiques. Des substances naturelles sont également recommandées pour la récupération immunologique et nutritionnelle, le traitement précoce de l'infection à VIH et la

réduction des effets secondaires des traitements ARV. Il s'agit respectivement pour les plus importantes d'entre elles, des feuilles de Moringa oleifera, de la pulpe du fruit de Detarium

microcarpum, de la spiruline et du pollen issu de la ruche.

En ce qui concerne les évaluations,

la pulpe du fruit de Adansonia digitata sont indiquées dans

de nombreuses plantes africaines (Ancistrocladus abbreviatus, Fagara xanthoxyloides, Combretum micranthum, Phyllanthus amarus, Guiera senegalensis, Moringa oleifera, etc.) ont déjà fait l'objet d'évaluations précliniques (13,14,15,17,19,20). Malheureusement, très peu d'études cliniques ont été réalisées suivant les normes internationales, pour établir la tolérance et l'efficacité des traitements proposés (essais cliniques randomisés phases I, II et III, en double aveugle, contrôlé par un traitement conventionnel ou un placébo). Cette situation est en partie imputable au caractère très complexe du traitement de l'infection à VIH.

Euphorbia hirta L.



Aloe buettneri A. Berger



Au Burkina Faso, 02 médicaments préparés à partir de plantes fréquemment utilisées par les tradipraticiens de santé pour le traitement de l'infection à VIH, sont en cours de développement avec le concours du bureau régional de l'OMS. Il s'agit du FMG341 et du PMG151. Ces médicaments ont déjà franchi les étapes de l'évidence ethnomédicale et de l'essai clinique comparatif phase II, randomisé en double aveugle (publication en cours).

LES DIFFICULTES

Les difficultés ne manquent pas dans le processus de développement des médicaments issus de la pharmacopée traditionnelle anti-VIH/SIDA. La première difficulté concerne le coût élevé des évaluations précliniques et surtout cliniques. En outre, les plateaux techniques des laboratoires ne sont pas suffisamment complets pour effectuer certaines analyses comme les tests de résistances croisées avec les médicaments antirétroviraux. La deuxième difficulté est d'ordre pharmaceutique. En effet, la fabrication d'un placébo comparable au médicament qui doit être testé, est un obstacle majeur pour l'évaluation clinique des médicaments présentés sous forme de poudres végétales ou d'extraits bruts. Une autre difficulté importante concerne la faiblesse de recrutement des patients asymptomatiques pour les essais cliniques.

CONCLUSION ET PERSPECTIVES

La recherche et le développement des médicaments traditionnels est très active dans les pays de la région africaine. Les résultats déjà obtenus sur les évaluations ethnomédicales et précliniques sont encourageants et méritent d'être approfondis par des essais cliniques standards. Certaines plantes africaines ont montré en études précliniques une activité anti-VIH significative. Les perspectives concernent la poursuite des essais cliniques et la constitution des dossiers d'enregistrement.

REMERCIEMENTS

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Auteur correspondant Jean Baptiste Nikiema, Laboratoire de Pharmacognosie et de Phytothérapie, UFR-SDS, Université de Ouagadougou, 03 BP 7021 Ouagadougou 03, Burkina Faso La recherche et le développement de médicaments antidrépanocytaires est une priorité en Afrique, où vivent la grande majorité des personnes souffrant de drépanocytoses. C'est dans ce sens que le FACA a été développé au Burkina Faso, à partir de la Médecine Traditionnelle et avec le soutien du bureau régional de l'OMS. Les propriétés antifalciformantes, anti-inflammatoires, antipyrétiques et myorelaxantes ont été évaluées. Il en est de même de la toxicité. Les plantes composant le FACA, agissent en synergie contre les principaux symptômes de la crise drépanocytaire. Administré en évaluation clinique, le FACA est bien toléré et réduit de manière significative, la fréquence des crises. Après son autorisation de mise sur le marché, le FACA fait maintenant l'objet d'une production industrielle.

BSTRACT

Research and development of antisickling medicines is a priority in Africa, which has the largest number of people suffering from sickle-cell anaemia (drepanocytosis). The antisickling medicine FACA (a combination of *Fagara xanthoxyloides* and *Calotropis procera*) was developed in Burkina Faso, starting from a traditional medicine, and with the support of the WHO-AFRO. Antisickling, anti-inflammatory,

antipyretic and muscle relaxant properties were tested, as well as toxicity. The plants that make up FACA act in synergy against the principal symptoms of the sickle cell anaemia. Administered in clinical conditions, FACA is tolerated well and significantly reduces the frequency of crises. After gaining approval for commercialization, FACA is now being produced industrially.

SUMÁRIC

A investigação e o desenvolvimento de medicamentos contra a drepanocitose constituem uma prioridade em África, onde vive a grande maioria das pessoas que sofrem de drepanocitose. É nesse sentido que o FACA (a combinação de *Fagara xanthoxyloides* com *Calotropis procera*) foi desenvolvido no Burquina Faso, a partir da Medicina Tradicional e com o apoio do gabinete regional da OMS. As propriedades anti-falciformes, anti-inflamatórias, antipiréticas e

miorrelaxantes foram avaliadas. O mesmo se passa com a toxicidade. As plantas que compõem o FACA actuam em sinergia contra os principais sintomas da crise drepanocitária. Administrado em avaliação clínica, o FACA é bem tolerado e reduz de forma significativa a frequência das crises. Após a sua autorização de introdução no mercado, o FACA é agora objecto de produção industrial.

a drépanocytose est un problème majeur de santé publique dans les pays en développement, mais aussi en Europe et en Amérique du nord, où les populations originaires d'Afrique sont significativement représentées (1,2). La drépanocytose est une des cinq maladies prioritaires avec le paludisme, le HIV/SIDA, le diabète, et l'hypertension artérielle pour lesquelles le bureau régionale de l'OMS soutien la recherche et le développement des médicaments issus de la Pharmacopée Traditionnelle. Elle concerne plus de 4% de la population mondiale, avec essentiellement une anomalie de l'hémoglobine. Sa prévalence sur le continent africain atteint 5 à 7% de la population et sa fréquence est maximale en Afrique sub-saharienne. Dans certains pays comme le Cameroun et la République Démocratique du Congo, cette prévalence atteint 30 à 40% de la population (3,4). Au Burkina Faso, les hémoglobinoses représentaient 37,66% de la population totale avec une fréquence d'environ 16,8% pour la drépanocytose. En 1991, le taux de létalité de la maladie drépanocytaire était de 13% en milieu pédiatrique burkinabé; et en 2001, 29,5% des nouveaux nés étaient porteurs d'une anomalie de l'hémoglobine. Parmi ceuxci, 2,8% étaient porteurs d'une drépanocytose majeure soit 2,03% d'Hb SC et 0,74% d'Hb SS (1,5,6).

Le profil épidémiologique de la drépanocytose qui touche habituellement des populations pauvres, en fait une maladie tropicale négligée. En effet, les laboratoires pharmaceutiques pays développés ne lui accordent pas suffisamment d'attention. De ce fait, les traitements sont rares et les innovations ne peuvent venir principalement que des institutions de recherche des pays africains. C'est dans ce contexte qu'une équipe de recherche du Burkina Faso dirigée par le Professeur Innocent Pierre Guissou, développe depuis 20 ans un médicament issu du savoir médical traditionnel. Il s'agit du FACA, qui vient d'obtenir l'autorisation de mise sur le marché. Nous nous proposons d'aborder ici, le processus de développement de ce médicament, à travers les évaluations précliniques et cliniques, ainsi que la valorisation industrielle.

LES EVALUATIONS PRECLINIQUES

Les enquêtes ethnobotaniques peuvent être considérées comme la première étape des évaluations précliniques. Elles ont permis d'identifier une recette préparée par un tradipraticien de santé à partir de 2 plantes, Fagara xanthoxyloides (Rutaceae) et Calotropis

procera (Asclepiadaceae), et traditionnellement utilisées dans le traitement de la drépanocytose (7). Une convention de partenariat a été ensuite signée entre l'équipe du Professeur Guissou et le tradipraticien de santé, détenteur des connaissances traditionnelles sur la recette.

Les évaluations précliniques ont porté sur les tests pharmacologiques réalisés à partir d'extraits aqueux, hydro-alcooliques et à l'acétate d'éthyle. Les propriétés antifalciformantes, a n ti-inflammatoires, anti-inflammatoires, anti-inflammatoires, anti-inflammatoires, anti-inflammatoires, anti-inflammatoires, anti-inflammatoires, antipyrétiques et myorelaxantes, ont été évaluées non seulement sur la recette, mais également sur chaque plante prise séparément. Les figures 1, 2 et 3, résument les principaux résultats obtenus (8,9,10,11).

PRÉPARATION DES EXTRAITS AOUEUX

Chaque extraction consiste à mélanger 250 g de poudre d'écorces de racines séchées avec 1000 mL d'eau distillée et désionisée. Le mélange est laissé en macération à température ambiante et sous agitation magnétique, puis filtré. La durée de la macération est respectivement de 1 heure 30 minutes pour *Calotropis* et de 12 heures pour *Fagara* et FACA. Le filtrat obtenu est centrifugé à 2000 tours par minute pendant cinq minutes. Le surnageant

Figure 1. Evolution du taux de drépanocytes en fonction du temps de contacts avec les extraits totaux (Fa : Fagara, Ca : Calotropis, FACA : Fa + Ca)

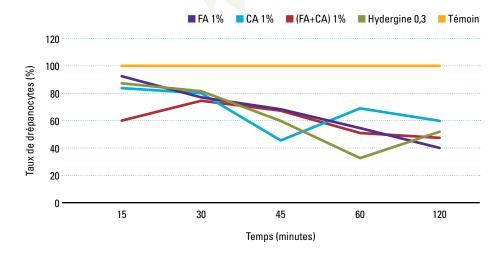
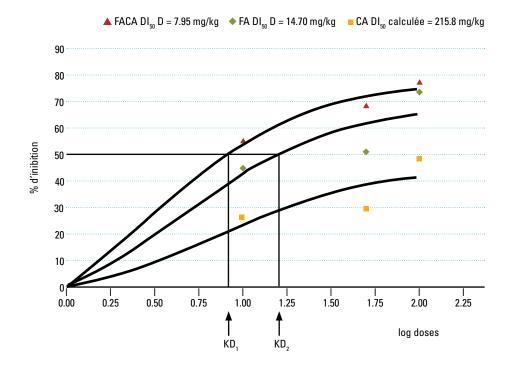


Figure 2. Evolution du % d'inhibition de l'élévation de la température en fonction du logarithme de la dose des extraits totaux (Fa : Fagara, Ca : Calotropis, FACA : Fa + Ca)



(extrait aqueux) est congelé à -5°C puis lyophilisé à -50°C. Les résidus (lyophilisats) ont été conditionnés dans des flacons opaques en verre de couleur brune et conservés dans un dessiccateur tout au long des tests pharmacologiques

EVALUATION DES PROPRIÉTÉS ANTI-FALCIFORMANTES

Les propriétés antifalciformantes ont été évaluées dans un premier temps à partir des extraits totaux qui sont les lyophilisats des macérés aqueux des écorces de racines de Fagara et/ou de Calotropis. Cette évaluation a ensuite servi de test pharmacologique de bioguidage pour l'isolement des principes actifs. C'est ainsi qu'un fractionnement bioguidé de l'extrait aqueux le plus actif, celui du Fagara, a permis d'identifier les Burkinabines comme principes actifs antifalciformantes extractibles par l'acétate d'éthyle.

EVALUATION DES PROPRIÉTÉS ANTIPYRÉTIQUES

Les propriétés antipyrétiques ont été évaluées à partir des extraits totaux qui sont les lyophilisats des macérés aqueux des écorces de racines de Fagara et/ou de Calotropis.

Les résultats des tests pharmacologiques montrent que les plantes composant le

FACA, agissent en synergie, au niveau des différentes propriétés pharmacologiques évaluées. En outre, sa toxicité est faible, avec une dose létal 50 (DL50) de 600 mg/kg (11). Le bioguidage a permis d'isoler et d'élucider les structures de 3 molécules antifalciformantes nouvelles (figures 4, 5 et 6), les burkinabines A, B et C, à partir de Fagara xanthoxyloides (10), Les dérivés de l'acide benzoïque, isolés par l'équipe de Sofowora (14,15), ne sont probablement pas les seuls acides phénols actifs de cette plante.

LES EVALUATIONS CLINIQUES

L'évidence ethnomédicale a été tout d'abord évaluée sur un échantillon de 30 enfants atteints d'hémoglobinoses SS et SC (7,12). Le FACA, administré à la dose de 160 mg /jour, réduit de manière significative le pourcentage de drépanocytes chez l'enfant drépanocytaire. Le suivi des paramètres biologiques relatifs à la tolérance hépatique et rénale, indique que le FACA est bien toléré (13). A la suite de l'évidence ethnomédicale, un essai clinique randomisé Phase II, en double aveugle a été réalisé. Les résultats de cet essai confirment l'efficacité et la tolérance du FACA dans la prévention et le traitement de la crise drépanocytaire.

Figure 3. Evolution de la relaxation du duodénum de rat contracté par l'acétylcholine ou le chlorure de baryum, en fonction de la concentration d'extrait total de Fagara

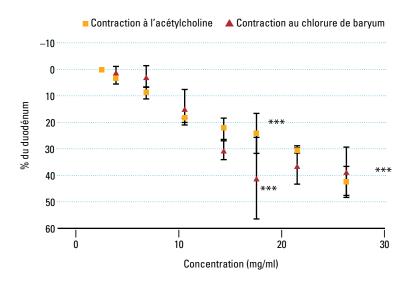


Figure 4. Structure de la burkinabine A

Figure 5. Structure de la burkinabine B

HOOC
$$\frac{H}{4'}$$
 $\frac{H}{5'}$ $\frac{H}{6'}$ $\frac{H}{CH_3O}$ $\frac{4'}{3'}$ $\frac{4'}{CH_3O}$ $\frac{2'}{4'}$ $\frac{1'}{C}$ $\frac{1}{C}$ $\frac{$

LE PROCESSUS DE DEVELOPPEMENT

La recherche sur le FACA a permis de réunir des données scientifiques portant sur la qualité pharmaceutique, l'innocuité et l'efficacité, notamment à travers les évaluations précliniques et cliniques. Cependant, ces données ne suffisent pas pour la valorisation industrielle du médicament. En effet, la sécurisation de l'approvisionnement des matières premières constitue un sérieux défis, plus particulièrement

au Burkina Faso, un pays situé dans la bande sahélienne. Fort heureusement la situation se présente différemment pour les 2 plantes composant le FACA. Calotropis procera, est une plante abondante, très répandue sur l'ensemble du territoire, et sa matière première est suffisamment constante. La récolte de Calotropis procera dans les zones de peuplement naturel, est donc acceptable. En revanche, la situation est différente pour Fagara xanthoxyloides, une plante menacée de disparition au Burkina Faso. En outre, les études réalisées dans le cadre de la faisabilité industrielle montrent une variabilité significative dans

la teneur en principes actifs, en fonction des saisons et des zones de peuplement naturel. Un contrôle systématique de la matière première est donc nécessaire. Pour faire face à cette difficulté, l'équipe du Professeur Guissou, expérimente, dans la région de Bobo-Dioulasso (une ville située à 360 km à l'ouest de Ouagadougou), la culture à grande échelle de Fagara xanthoxyloides.

C'est dans ce contexte caractérisé par le succès des évaluations précliniques et cliniques, et surtout une maîtrise de la chaîne de production, que l'autorité nationale de réglementation pharmaceutique du Burkina Faso a accordé une autorisation de mise sur le marché pour le FACA. Conformément aux outils développés par le bureau régional pour l'Afrique de l'OMS (16-17), le dossier technique du FACA a été examiné au préalable, par un comité d'experts d'homologation des médicaments. Le FACA est maintenant produit de façon industrielle par U-Pharma.

CONCLUSION ET PERSPECTIVES

La recherche et le développement du FACA a non seulement permis de réunir les données scientifiques nécessaires à son enregistrement, mais aussi d'aboutir à une valorisation industrielle de ce médicament. Cette valorisation ne peut se poursuivre sans la sécurisation de l'approvisionnement des matières premières notamment par la culture des plantes médicinales, suivant les bonnes pratiques. La perspective la plus immédiate concerne l'inscription du FACA sur la liste nationale des médicaments essentiels.

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Les institutions de recherche créées pour développer la médecine traditionnelle encouragées dans ce domaine par l'OMS mènent des activités vers des maladies prioritaires comme le paludisme, le VIH/SIDA, la drépanocytose, le diabète et l'hypertension artérielle. La prise en charge de l'hypertension artérielle par les médicaments conventionnels est très élevée amenant plusieurs patients à s'orienter vers la médecine traditionnelle dont les produits ayant l'innocuité, l'efficacité et la qualité prouvées doivent être utilisés. Différents organes des plantes utilisées par les tradipraticiens ont fait l'objet d'études phytochimique diurétique, et antihypertensive au Département de Médecine Traditionnelle à Bamako et à l'Institut de Recherche en Sciences de la Santé de Ouagadougou: Cymbopogon giganteus, Gynandropsis gynandra, Portulaca oleracea, Jatropha gossypiifolia et une recette de tradipraticien. L'infusé de Portulaca oleracea à la dose de 37,5 mg/kg avec une excrétion urinaire de 163,10% a donné une importante activité diurétique. Une élévation de la pression artérielle provoquée par l'adrénaline à la dose de 75µg/kg a été inhibée par le macéré agueux de Jatropha gossipiifolia 94,64% à la dose de 20mg/kg. Ces travaux viennent en complément des tests de toxicité pour permettre l'évaluation de l'évidence ethnomédicale sur des recettes à base de ces plantes suivie d'autres tests biologiques de formulation galénique et des essais cliniques. Peu de phytomédicaments de la médecine traditionnelle africaine ont obtenu l'autorisation de mise sur le marché à l'exception du Guinex-HTA produit en Guinée.

ABSTRACT

The research organizations created for the development of traditional medicine, supported in this area by the WHO, are involved in activities dealing with the main illnesses such as malaria, HIV/AIDS, sickle cell anaemia, diabetes and hypertension. The treatment of hypertension with conventional medicines is too expensive, leading many patients to use traditional medicines. It is essential that these should be safe, efficient and of proven quality. Different plant organs used by traditional practitioners have been the subject of diuretic phytochemical and antihypertensive studies at the Department of Traditional Medicine in Bamako and at the Scientific and Health Research Institute in Ouagadougou: these include *Cymbopogon giganteus*,

Gynandropsis gynandra, Portulaca oleracea, Jatropha gossypiifolia and a traditional practitioners' recipe. The infusion of Portulaca oleracea in a dosage of 37.5 mg/kg with a urinary excretion of 163.10% produced substantial diuretic activity. A rise in tension provoked by a 75µg/kg dose of adrenalin was inhibited by the aqueous maceration of Jatropha gossipiifolia 94.64% to a dose of 20mg/kg. These initiatives support the toxicity tests and enable the evaluation of ethno-medical evidence on recipes from these plants followed by other biological galenic tests and clinical trials. Very few phytomedicines from traditional African medicine have obtained approval for commercialization, with the exception of Guinex-HTA, produced in Guinea.

SUMÁRIO

As instituições de pesquisa criadas para desenvolver a medicina tradicional e encorajadas nesse domínio pela OMS, levam a cabo actividades contra doenças prioritárias como o paludismo, o VIH/SIDA, a drepanocitose, a diabetes e a hipertensão arterial. O preço do tratamento da hipertensão arterial por medicamentos convencionais é bastante elevado, levando muitos doentes a virar-se para a medicina tradicional, cuios produtos que possuam a inocuidade, a eficácia e a qualidade comprovadas deverão ser utilizados. Diferentes órgãos de plantas utilizados pelos praticantes da medicina tradicional foram objecto de estudo fitoquímico diurético e anti-hipertensor pelo Departamento de Medicina Tradicional em Bamako e pelo Instituto de Pesquisa e de Ciências da Saúde de Ouagadougou: Cymbopogon giganteus, Gynandropsis gynandra, Portulaca oleracea,

Jatropha gossypiifolia e uma receita da prática tradicional. A infusão de Portulaca oleracea numa dose de 37,5 mg/kg com uma excreção urinária de 163,10% apresentou uma actividade diurética importante. Uma elevação da pressão arterial provocada pela adrenalina numa dose de 75 µg/ kg foi inibida pelo macerado aquoso de Jatropha gossipiifolia a 94,64% numa dose de 20 mg/kg. Estes trabalhos complementam os testes de toxicidade para permitir a avaliação da evidência etnomédica das receitas à base dessas plantas, seguidos de outros testes biológicos de formulação galénica e de ensaios clínicos. Poucos fitomedicamentos da medicina tradicional africana obtiveram a autorização de introdução no mercado, com excepção do produto Guinex-HTA, produzido na Guiné.

D'après une estimation de l'OMS, environ 80% des populations rurales vivant dans les pays en développement sont tributaires de la médecine traditionnelle pour satisfaire leurs besoins en soins de santé. La faiblesse des ressources économiques des populations dans ces pays limite l'achat des produits pharmaceutiques. L'une des conséquences de cette situation est la désertion ou la fréquentation tardive des formations sanitaires. Pour pallier à ces problèmes, le Burkina Faso et le Mali comme la plupart des pays de la région Afrique de l'OMS sont résolument engagés dans la valorisation du patrimoine médical traditionnel, encouragés en cela par l'OMS (1).

es recherches entreprises ont pour objectifs la valorisation de la médecine traditionnelle, à travers l'implication des tradipraticiens de santé, la découverte de nouvelles molécules, la formulation de médicaments accessibles et utilisables dans le traitement des pathologies prioritaires.

Parmi les pathologies prioritaires, l'hypertension artérielle occupe une place importante en raison des conséquences de cette maladie sur la survie. En l'an 2000 la prévalence globale de l'hypertension dans la population mondiale adulte était estimée à 26,4% (26,6% chez les hommes et 26,1% chez les femmes) 972 millions d'individus dont 639 millions sont dans les pays en voie de développement. La projection indique que le nombre d'hypertendus pourrait être de, 1,56 milliards d'individus en 2025 (2).

En Afrique, elle constitue un problème de santé publique avec une fréquence en population comprise entre 15 et 40%, une fréquence hospitalière comprise entre 30 et 70% (3).

Ouedraogo a montré que le taux de prévalence de l'HTA en milieu urbain dans la ville de Ouagadougou (Burkina Faso) était de 23% (4). Au Mali, Maïga a évalué en zone sahélienne la prévalence de l'hypertension artérielle à 23,7% (5). (Maïga, 1989). En Guinée la prévalence de l'hypertension est de 43,6% en milieu urbain et de 14,9% en milieu rural (6).

L'OMS intègre dans son programme de l'amélioration de la santé, le problème de dépistage et de traitement de l'hypertension artérielle. Malgré les efforts déployés, la lutte contre ce fléau est limitée par le coût élevé du traitement et dont la prise en charge peut durer plusieurs années voire toute la vie (7). La prise en charge utilise plusieurs groupes de médicaments parmi lesquels les diurétiques, les vasodilatateurs, les β bloquants, les inhibiteurs de l'enzyme de conversion. Cette maladie affecte

la productivité d'un pays à cause de sa mortalité, des invalidités et arrêts de travail.

Le faible pouvoir d'achat des populations africaines et le coût élevé du traitement de l'hypertension interpellent à l'intensification des recherches sur les plantes médicinales réputées antihypertensives, utilisées par les tradipraticiens et qui se révèlent efficaces. C'est ainsi que plusieurs plantes médicinales dans le traitement de l'hypertension artérielle ont été identifiées lors d'enquêtes ethnobotaniques. Parmi ces plantes nous pouvons citer Spondias mombin, Ziziphus mauritiana, Catharanthus roseus Cassia occidentalis, Rauwolfia vomitoria, Tamarindus indica, Combretum micranthum, Guiera senegalensis, Euphorbia hirta, Allium sativum, Hibiscus sabdarif, Olea europa Sclerocarya birrea et Vitex doniana (8,9,10,11,12,13).

La recherche en médecine traditionnelle africaine dans le cadre de l'hypertension artérielle vise principalement à identifier les comportements des tradipraticiens de santé face à l'hypertension artérielle; développer la collaboration entre tradipraticiens et agents de santé conventionnelle et à mettre au point des phytomédicaments pouvant intervenir dans la prise en charge des hypertendus.

La mise au point d'un phytomédicament est un processus à plusieurs étapes dont nous présentons ici une étude préclinique de plantes médicinales africaines utilisées traditionnellement dans le traitement de l'hypertension artérielle. Les activités diurétiques des extraits extemporanés et des extraits lyophilisés ont été déterminées et l'effet sur la tension artérielle

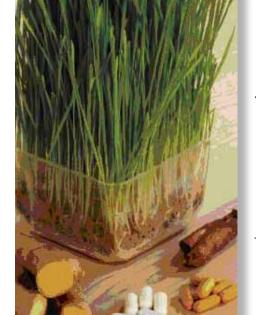
de différents extraits de plantes. Dans le but d'une valorisation de l'usage des produits de ces plantes en phytothérapie, nous avons entrepris ces études in vivo chez l'animal et in vitro sur organe isolé. Les résultats attendus sont la mise en évidence des supports pharmacodynamiques qui interfèrent sur les facteurs de variation de la pression artérielle. Ils contribueront aux pré-réquis nécessaires aux études cliniques du phytomédicament et à la rétro- information en direction des utilisateurs tradipraticiens.

Les produits de cette étude ont été : *Cymbopogon giganteus, Gynandropsis gynandra, Portulaca oleracea, Jatropha gossypiifolia* et la recette Kebufura. 1934 et 135 respectivement pour *Cymbopogon giganteus, Gynandropsis gynandra, Portulaca oleracea* et *Jatropha gossypiifolia.*

Matériel animal: Les tests biologiques in vivo ont été réalisés sur des souris blanches de masse variant entre 22-39g de type CF1 (Carworth Farms Souche 1) qui a été introduite à l'institut Marchoux sous le nom de OF1 (Oncins France Souche 1) et des rats adultes mâles et femelles de poids compris entre 200 et 300g à l' Institut de Recherche en Sciences de la Santé (IRSS) de Ouagadougou.

Analyses phytochimiques: Les différents groupes chimiques ont été caractérisés dans les organes de plantes selon le protocole de Cuilei adapté à Bamako et Ouagadougou (14,15,16).

Activité diurétique : Mesure de l'excrétion urinaire chez la souris mise en surcharge saline selon la méthode de Colot a été réalisée à Bamako (17). Les lyophilisats ont été administrés à des doses en relation avec celles du tradipraticien 12,5mg/ kg, 25mg/kg et 37,5mg/kg pour Portulaca oleracea. Les extraits extemporanés administrés à la dose de 25ml/kg étaient des solutions préparées à 5g/250 ml pour Gynandropsis gynandra, Portulaca oleracea et 10g/500ml pour Cymbopogon giganteus. La surcharge saline a été faite par administration



MÉTHODOLOGIE

Matériel végétal: Il était constitué par les fleurs de Cymbopogon giganteus, les feuilles de Gynandropsis gynandra, la plante entière de Portulaca oleracea récoltées en 2006 à Sotuba Bamako et la recette Kebufura fournie un tradipraticien de santé. Les feuilles de de Jatropha gossypiifolia récoltées en septembre 2003 à Kombisiri (40km) de Ouagadougou. Un spécimen de chaque espèce est déposé à l'herbier du Departement de Médecine Traditionnelle sous les numéros : 2324, 0750,

de 50ml/kg de NaCl à 1,8% dans l'eau distillée.

Etude in vivo de la pression artérielle : Elle a été réalisée à l'IRSS à Ouagadougou. La méthode utilisée dite sanglante est celle du capteur de la pression à l'oscillographe. Elle suit la méthode décrite par Martinez. Le rat est anesthésié par l'éthylcarbamate 50% par voie intrapéritonéale (i.p.) à la dose de 1250 mg/kg de poids corporel (18). L'effet hypotensif des extraits est étudié par l'administration de doses croissantes des extraits et l'effet anti-hypertensif est étudié après avoir provoqué l'élévation de la PA par stimulation du système vasculaire et cardiaque successivement par l'administration de l'adrénaline, et le phényléphrine et en utlisant comme produit de référence (prazocine).

RÉSULTATS

PHYTOCHIMIE

Ces organes de plantes ont été caractérisés par la présence de coumarines, mucilages, flavonoïdes, hétérosides cardiotoniques, des saponosides, des tanins, des leucoanthocyanes, des oses et holosides, par contre les alcaloïdes, les anthracénosides combinés et les anthocyanes ont été absents dans tous ces échantillons. L'eau a été le

Tableau 1. Résultats de l'activité diurétique des extraits lyophilisés

Traitements	Doses mg/kg	Excrétion urinaire volumétrique (%)	Interprétation
Décocté de C. giganteus	60	104,52	Pas d'activité diurétique
Infusé de G. gynandra	56	143,04	Modeste activité diurétique
Infusé de <i>Portulaca oleracea</i>	12,5	140	Modeste activité diurétique
	25	140,76	Modeste activité diurétique
	37,5	163,10	Importante activité diurétique
Macéré de la recette Kebufura	70	138,88	Modeste activité diurétique
	135	152,94	Importante activité diurétique
Eau distillée	25	147,87	Modeste activité diurétique
Furosémide	20	170,51	Importante activité diurétique

L'infusé de *Portulaca oleracea* à la dose de 37,5 mg/kg avec une excrétion urinaire de 163,10% a donné une importante activité diurétique contre 170,51% pour la furosémide à 20mg/Kg.

Effet des extraits sur la pression artérielle (PA) chez le rat anesthésié.

Le macéré aqueux et éthanolique agissent su la pression artérielle du rat de façon dose dépendante. A la concentration de 7,5 mg/kg le macéré aqueux entraîne une baisse la pression artérielle de 59,97 % ±6,97 alors que l'extrait hydroalcoolique à la même dose la diminuait de 28.06 % ±6.02.

Effet des extraits de *Jatropha gosipiifolia* sur l'élévation de la pression artérielle provoquée par l'adrénaline (75µg/kg) et par la phenyléphrine (100µg/kg).

Une élévation de la pression artérielle provoquée par l'adrénaline à la dose de 75µg/kg a été inhibée par le macéré aqueux de *Jatropha gossipiifolia* de 14%±7,77 et 94,64%±3 respectivement aux doses de 7,5 et 20mg/kg alors que le propranolol (substance de référence) inhibait de 98,34%±6,2 à la dose de 10µg/kg.

Le pourcentage d'inhibition de l'élévation de la pression induite par la phenyléphrine (100μg/kg) est de 99,4% ±0,84 pour l'extrait aqueux et 99,25%±1,06 pour l'extrait hydroalcoolique respectivement aux doses de 20mg/kg et 25 mg/kg contre 100% pour la prazocine (10μg/kg).

solvant ayant entraîné le meilleur rendement pour l'extraction de ces organes de plantes à l'exception de *Jatropha. gossipiifolia.*

ACTIVITÉS DIURÉTIQUES

Les solutions extemporanées à la dose de 5g/250ml de Cymbopogon giganteus, G. gynandra et du Kebufura n'ont pas donné une activité diurétique par contre celle de l'infusé de Portulaca oleracea a donné une modeste activité diurétique avec une excrétion urinaire volumétrique de 135,57. Les extraits lyophilisés ont présenté différentes activités diurétiques qui sont résumés dans le tableau 1.

ANALYSES

La recherche en médecine traditionnelle africaine dans le domaine de l'hypertension artérielle comporte différentes étapes dont le but est d'une part de développer le partenariat entre agents de santé conventionnel et tradipraticiens et d'autre part. de mettre à la disposition des patients des médicaments dont l'efficacité, l'innocuité et la qualité sont prouvées D'une enquête ethnobotanique des plantes ont été sélectionnées et vont faire l'objet d'une évaluation de l'évidence ethnomédicale



et d'étude de toxicité, de tests biologiques, de phytochimie, de formulation galénique et d'essai clinique. Dans ce travail de recherche sur les plantes utilisées dans le traitement de l'hypertension artérielle à la suite des tests de toxicité il a été mis en évidence des groupes chimiques comme anthocyanes, coumarines, mucilages, saponosides qui pourraient être bénéfiques dans la prise en charge de l'hypertension. Les coumarines sont douées de propriété vasodilatatrice, les mucilages réduisent le taux de cholestérolémie et de lipidémie, les saponosides sont douées de propriétés diurétique et hypotensive et les polyphénols d'activité antioxydante (19,20).

La mesure de l'excrétion urinaire est une méthode d'étude de

l'activité biologique des plantes utilisées dans le traitement de l'hypertension artérielle et il a été démontré que parmi les 4 échantillons Portulaca oleracea à la dose de 37,5mg/kg a donné une meilleure activité diurétique avec une excrétion urinaire volumétrique de 163,10% presque égale à celle de Nitrokoudang (recette d'un tradipraticien utilisée contre l'hypertension artérielle) qui à la dose de 23,44mg/kg avait donné une excrétion urinaire volumétrique de161,49% (21), Ziziphus mauritiana à 450mg/ kg avait donné une excrétion urinaire volumétrique de164,86% (13). Spondias mombin à la dose de 150mg/kg qui avait donné une excrétion urinaire volumétrique de 186,84% (12). Dans les mêmes

conditions expérimentales la furosémide avait montré une importante activité diurétique à la dose de 20mg/kg une excrétion urinaire volumétrique de 170,51%.

Une autre méthode est l'évaluation de l'activité des extraits sur la pression artérielle du rat. Le travail réalisé avec les extraits aqueux et hydroalcoolique des feuilles de Jatropha gossypiifolia. Le macéré aqueux semble plus actif que l'extrait hydroalcoolique. L'extrait aqueux semble avoir un effet β bloquant similaire à celle du propranolol, β bloquant de référence qui exerce une action inhibitrice sur l'élévation de la pression artérielle provoquée par l'adrénaline (22). La plante aurait une interférence avec le système cardiaque en exerçant une action sur les récepteurs β adrénergiques.

Si ces modèles permettent de définir mêmes les mécanismes d'action des plantes médicinales il est nécessaire de souligner l'importance de l'étude de la toxicité subchronique et chronique pour les plantes utilisées dans le traitement de l'hypertension artérielle. Si les tradipraticiens peuvent facilement cerner certains aspects de la toxicité aigüe par autotest il est nécessaire de développer la collaboration avec les institutions de recherche

pour identifier les éléments de la toxicité chronique car ces phytomédicaments sont administrées pour de longues périodes.

Portulaca oleracea et Jatropha gosipiifolia sont des plantes sur lesquelles les travaux doivent se poursuivre. Ces travaux doivent se poursuivre dans le cadre de réseaux de collaboration entre les institutions de recherche sur la médecine et la pharmacopée traditionnelle comme cela existe entre le Mali et le Burkina Faso, le Togo ou la Guinée. Dans le cadre des recherches sur les plantes utilisée dans le traitement de l'hypertension artérielle le Conseil africain et Malgache a créé un réseau en Afrique centrale.

CONCLUSION

Les recherches en médecine traditionnelle africaine dans le domaine de l'hypertension artérielle sont multiples. Elles sont principalement axées sur les enquêtes ethnobotaniques, l'évaluation de l'évidence ethnomédicale. les screening phytochimique et pharmacologique des plantes comme vient d'être présentés pour Portulaca oleracea et Jatropha gossypiifolia. Peu de formulations galéniques ont été faites. Cependant signalons le cas du GUINEX-HTA phytomédicament de la Guinée contre l'hypertension artérielle qui a l'autorisation de mise sur le marché. La Diurotisane mélange de *Vepris heterophylla* et *Cympopogon giganteus* est utilisée au Mali.

Les plantes ayant fait leur preuve doivent faire l'objet de culture et des dispositions doivent être prive pour faciliter la circulation des phytomédicaments disposant d'autorisation de mise sur le Marché entre les différents pays.

La communication entre tradipraticiens de santé, chercheur et agents de santé conventionnels est indispensable pour établir et maintenir la confiance, développer la collaboration entre les deux systèmes de santé pour une meilleure prise en charge des personnes hypertendues. @

REMERCIEMENTS

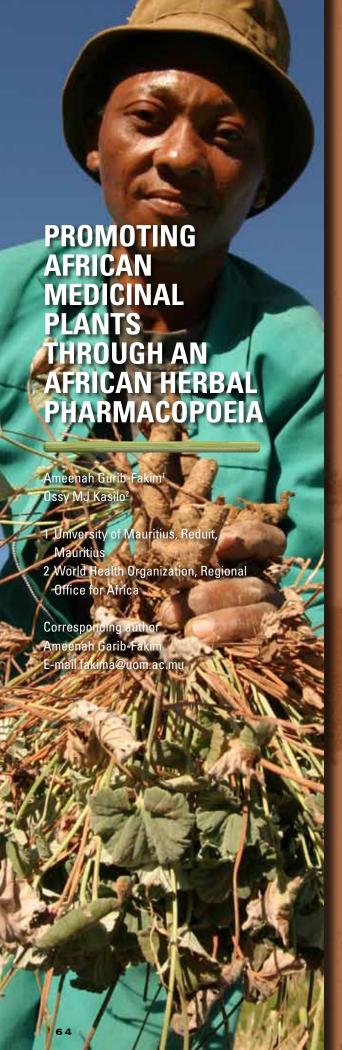
A l'OMS pour son soutien financier aux activités de recherche sur les plantes utilisées dans le traitement de l'hypertension artérielle; aux tradipraticiens pour leur collaboration; aux équipes de recherche du DMT et de l'IRSS.

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Various resolutions adopted by the World Health Assembly and Regional Committee for Africa call upon Member States, among others things, to develop herbal pharmacopoeias and to develop and apply scientific criteria and methods for proof of safety and efficacy of medicinal plant products. However, only few countries have developed national herbal pharmacopoeias; limited plant species that provide medicinal herbs have been scientifically evaluated for their possible medical applications; and the safety and efficacy data are available for even fewer herbs. Without well documented information on the safety, efficacy and phytochemical characteristics of different compounds, it is difficult for external buyers to assess the likely utility or value of some new raw materials and extracts of African origin. In order to address these lacunae, the Association of African Medicinal Plants Standards is developing an African Herbal Pharmacopeia with trading standards which provide information and technical data on some 50 important medicinal plants. The objective of developing the monographs is to ensure that these plants become visible on the world market. The monographs lay emphasis on the quality control issues, dosage, use, efficacy, pharmacology and safety of important African medicinal plants.

RÉSUMÉ

Plusieurs résolutions adoptées par l'Assemblée mondiale de la Santé et le Comité régional pour l'Afrique demandent aux États membres de développer, entre autres, des pharmacopées à base de plantes, d'élaborer et d'appliquer des critères scientifiques et des méthodes pour prouver la sécurité et l'efficacité des produits à base de plantes médicinales. Cependant, seuls quelques pays ont élaboré des pharmacopées nationales à base de plantes. Ils ont limité les espèces végétales fournissant des plantes médicinales scientifiquement testées pour leurs éventuels usages médicaux. Les données relatives à leur sécurité et à leur efficacité sont disponibles pour un nombre de plantes médicinales encore plus faible. Sans informations bien documentées sur la sécurité, l'efficacité et les caractéristiques phyto-chimiques des différents

composés, il est difficile pour les acheteurs externes d'évaluer l'utilité probable ou la valeur de certaines nouvelles matières premières et certains extraits d'origine africaine. Afin de remédier à ces lacunes, l'Association des normes sur les plantes médicinales d'Afrique est en train d'élaborer une pharmacopée africaine à base de plantes comprenant des normes commerciales qui fournissent des informations et des données techniques sur une cinquantaine de plantes médicinales importantes. L'objectif visant à développer des monographies permet de s'assurer que ces plantes deviennent visibles sur le marché mondial. Les monographies mettent l'accent sur les questions de contrôle de qualité, de posologie, d'utilisation, d'efficacité, de pharmacologie et de sécurité des plantes médicinales importantes

SUMÁRIO

Várias resoluções adoptadas pela Assembleia Mundial de Saúde e pelo Comité Regional para África solicitam aos Estados-Membros, entre outras coisas, o desenvolvimento de farmacopeias ervanárias e o desenvolvimento e aplicação de critérios e métodos científicos para garantia da segurança e eficácia dos produtos de plantas medicinais. Contudo, apenas alguns países desenvolveram farmacopeias ervanárias nacionais; um número limitado de espécies de plantas que fornecem ervas medicinais foi avaliado cientificamente relativamente às suas possíveis aplicações médicas; e os dados de segurança e eficácia ainda só estão disponíveis para um número reduzido de ervas. Sem informação bem documentada sobre segurança, eficácia e características fitoquímicas dos diferentes

compostos, é difícil aos compradores externos avaliar a provável utilidade ou valor de algumas das novas matérias-primas e extractos de origem africana. De modo a fazer face a estas lacunas, a Associação de Normalização de Plantas Medicinais Africanas está a desenvolver uma Farmacopeia Ervanária Africana com normas de comercialização que proporcionam informações e dados técnicos sobre cerca de 50 plantas medicinais importantes. O objectivo do desenvolvimento de monografias consiste em assegurar que estas plantas se tornem visíveis no mercado mundial. As monografias colocam ênfase nos aspectos de controlo de qualidade, dosagem, aplicação, eficácia, farmacologia e segurança de plantas medicinais africanas mais importantes.

edicinal plants and plant-derived medicines are widely used in traditional cultures all over the world and they are becoming increasingly popular in modern society as natural alternatives to synthetic chemicals. Many cultures throughout the world still rely on indigenous medicinal plants for their primary health care needs (1). various levels of health workers.

The importance of medicinal plants in the health care systems in many developing countries has been underscored by various resolutions of the World Health Assembly and WHO Regional Committees. For example, Resolution WHA31.33 on Medicinal plants of 1978 (2) requested WHO to coordinate the efforts of Member States to, among other things, develop and apply scientific criteria and methods for proof of safety and efficacy of medicinal plant products, especially galenicals; international standards and specifications for identity, purity and strength of and to develop methods for the safe and effective use of medicinal plant products, especially galenicals, including labelling containing adequate directions for use, and criteria for use or prescription by various levels of health workers.

Resolution WHA41.19 of 1988 on Traditional medicine and

medicinal plants (3) urged Member States to examine the situation with regard to their indigenous medicinal plants; and to take effective measures to ensure their conservation and encourage their sustainable utilization. That resolution requested WHO to promote inter-country meetings for the dissemination of knowledge and the exchange of experience on the subject; and to collaborate with Member States in the design and implementation of programs for the conservation and sustainable utilization of medicinal plants.

Similarly, resolution AFR/RC50/ R5 of 1999 on Essential drugs in the WHO African Region situation and trends analysis (4) requested WHO to support Member States in carrying out research on medicinal plants and promoting their use in the health care delivery systems; while resolution AFR/RC5//R3 of 2000 on Promoting the role of traditional medicine in health systems: A Strategy for the African Region (5) urged Member States to actively promote, in collaboration with all other partners, the conservation of medicinal plants and requested WHO to strengthen WHO Collaborating Centres and other research institutions to carry out research and develop monographs of medicinal plants and disseminate results on safety and efficacy of traditional medicines.

In implementing these policy orientations, some countries, such as Benin, Burkina Faso, Cameroon, Cote d'Ivoire, Ghana, Guinea, Madagascar, Mali, Mauritius, Nigeria, Senegal, Seychelles and South Africa, have developed monographs of medicinal plants. Similarly, Benin, Cameroon, Chad, Cote d'Ivoire have developed inventories of medicinal plants and documented traditional recipes used for the treatment of malaria and hypertension (Chad), opportunistic infections for people living with HIV/AIDS (PLWA), sickle-cell diseases, diabetes and hypertension (Cameroon and Nigeria). WHO has also developed monographs on some medicinal plants commonly used in developed and developing countries to support WHO Member States in their efforts in this regard (6). Apart from Ghana (7), and Nigeria (9), which have published national herbal pharmacopoeias most countries have not published their work, hence cannot be easily accessed. Other countries have been conducting research on traditional medicines used for the treatment of priority diseases and some of the promising results have been reported in the articles on the overviews of traditional medicine in countries of the African Region and ECOWAS Member States published in this issue.

To date 25% of modern medicines are derived from plants that

have been used by traditional medical practitioners (9). Among the most famous ones are: Taxol (anticancer drug derived from the Yew Tree (Taxus sp.) and two anti-leukaemia drugs extracted from the Madagascan Periwinkle (Catharanthus roseus). It is a fact that traditional systems of medicine have become a topic of global importance. Although modern medicine may be available in many developed countries, people are still turning to alternative or complementary therapies including medicinal herbs.

Yet, few plant species that provide medicinal herbs have been scientifically evaluated for their possible medical applications. The safety and efficacy data are available for even fewer herbs, their extracts and active ingredients and the preparation containing them. Furthermore, in many countries, the herbal medicines market is poorly regulated and herbal products are often neither registered nor controlled. Assurance of safety, quality and efficacy of medicinal plants and herbal products has now become a key issue in industrialised and developing countries. Recognising the efficacy of herbal remedies, both the general consumer and health care professionals need up to date, authoritative information on the safety and efficacy of medicinal plants.

Africa contains between 40-45.000 species of plant with a potential for development and out of which 5.000 species are used medicinally. It must be emphasized also that the continent already contributes nearly 25% of the world trade in biodiversity. Still there is a paradox: in spite of this huge potential and diversity, the African continent has only contributed 83 of the 1100 blockbuster drugs globally (10).

This may be explained by addressing the constraints that are hampering this industry. It is now being recognized that one of these constraints is the lack of suitable technical specifications and quality control standards for African medicinal plants and extracts. This makes it extremely difficult for buyers whether local or overseas to compare batches of product from different places or from year to year. Lack of trading standards also implies that Good Agricultural and Collecting Practices (11), traceability, and Good Manufacturing Practices (12) are not adhered to. This is in marked contrast with countries in other WHO regions such as China in the West Pacific Region and India in the South East Asia Region where traditional formulations have not only been recorded but are evaluated both at the local and national level and used in their health

centres. China, for example, is able to provide adequate and constantly improving health care coverage for its vast urban and rural population precisely because it harnesses the precious legacy of traditional medicine (13). Consequently, the inability of most countries in WHO African Region to develop their own legacy of traditional medicine, because it is denied official recognition, is partly responsible for the current health care crisis in the Region specifically and the African continent generally.

The pharmaceutical industry has come to consider traditional medicine as a source for identification of bioactive agents that can be used as leads in the preparation of synthetic medicine. However, they are not looking to study the rare plant species; they want to test the most commonly-used species. The valuable medicinal plants are those with the longest track record in the most locations. Many of the more pharmacologically (commercially) interesting medicinal plant species in use around the world are employed in more than one community, and often in more than one country (e.g., Hoodia found in Namibia and South Africa), for multiple uses.

The natural products industry in Europe and the United States of America is equally interested in traditional medicine. In Europe and in America where the phytomedicine industry is thriving, extracts from medicinal plants are sold in a purified form for the treatment and prevention of all of diseases (13). Countries of WHO African countries are at a stage where traditional medicine is considered more for its capacity to generate other medicine than for its own sake. In many cases research undertakings and the commercial use stemming from that research have always relied on information provided by the local communities and in many instances, have hardly benefited from the research results (13,14).

Furthermore without well documented information on the safety, efficacy and phytochemical characteristics of different compounds, it is difficult for of African origin. Consequently, the level of world trade in Indian and Chinese medicinal plants and extracts is far more extensive than those of the African Region and they occupy a big share of the European and American herbal drugs market.

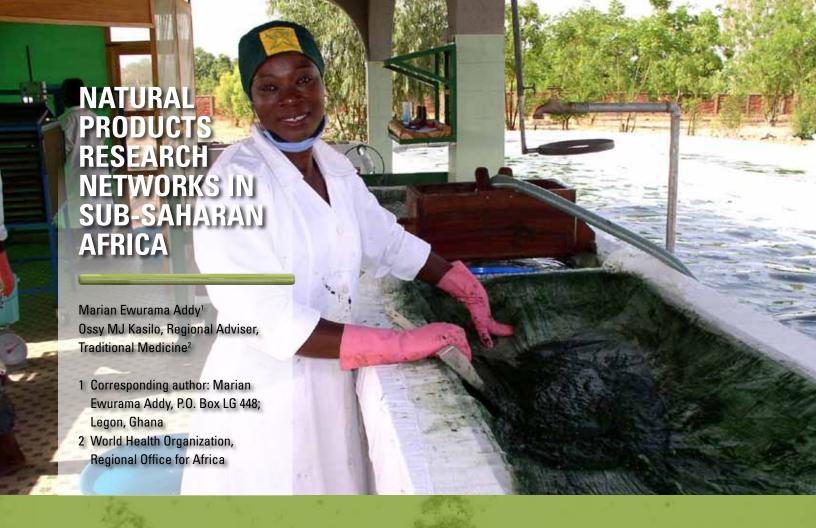
Nonetheless, in recent years there has been an upsurge in research and development in African universities and research centres on new medicinal products and new medicinal crops. This can be shown in the rapid increase in the number of scientific publications and patents.

However, despite the fact that an estimated 10% of the plant species of the world is found in southern Africa, for example, only a few have been commercialized and the basic scientific information is often not available. Yet, this information is needed to guide the rapidly accelerating commercialization process, especially the selection of superior varieties and the standardization of raw materials (15).

In order to address these lacunas. an African Herbal Pharmacopoeia (AfHP) with trading standards is currently being prepared. This will help not only the potential buyer from Europe or the USA but also the farmer and the seller from countries in WHO African Region and beyond. The AfHP is being prepared by the Association of African Medicinal Plants Standards (AAMPS: http://www.aamps.org) (16) and has been funded by the Centre for Development and Enterprise (CDE) of and ProInvest (Brussels). These monographs provide information and technical data on some 50 important medicinal plants including the Madagascan Periwinkle (Catharanthus roseus) to the South African Buchu (Agathosma betulina) and Pelargonium (Pelargonium sidoides), the Namibian Hoodia Cactus (Hoodia gordonii) among others. These monographs (see photo showing Pelargonium sidoides on page 64), whose prime objective is to ensure that these plants become visible on the world market, also lay emphasis on the quality control issues, dosage, use, efficacy, pharmacology and safety of important African medicinal plants. This publication is slated for issuance in August 2010. \odot

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Networking is a means of calibrating the quality of work that a group of people is undertaking; fostering international collaboration, pooling of available resources to provide quality training and research in various scientific disciplines and ensuring rapid worldwide dissemination of research information. Several networks involved in research and development of medicinal plants exist in the various sub-regions of the African Region. However, this paper discusses only six such networks of African researchers which share certain common characteristics. These networks aim to foster research on natural products and their sustainable use in human health, and the dissemination of information on research into natural products among others. They also aim to enhance research training capabilities of institutions through national and Regional activities; promote collaboration and research partnerships and mentoring of young researchers in the advancement of natural products research and support the principles of biodiversity conservation. However, these networks have many challenges, mostly financial. A suggestion has been made for the African Network of Drug and Diagnostics Innovation to consider the involvement of other existing networks in its structure for synergizing the efforts to create health products.

ഗ M

Le réseautage est un moyen de vérifier la qualité du travail qu'un groupe de personnes est en train d'entreprendre, de favoriser la collaboration internationale, de mettre en commun des ressources disponibles pour fournir une formation et une recherche de qualité dans diverses disciplines scientifiques. Il permet aussi d'assurer la diffusion rapide dans le monde entier d'informations issues de la recherche. Plusieurs réseaux impliqués dans la recherche et le développement des plantes médicinales existent dans les différentes sous-régions de la Région africaine. Cependant, cet article ne traite que de six de ces réseaux de chercheurs africains qui partagent certaines caractéristiques humaine communes. Ces réseaux visent à favoriser la recherche sur les produits naturels et leur utilisation durable pour la santé de l'homme ainsi que la diffusion

d'informations, notamment sur la recherche de produits naturels. Ils tendent également à renforcer les capacités de formation pour la recherche des institutions par le biais d'activités nationales et régionales, de promouvoir des partenariats de collaboration, de recherche et de tutorat de jeunes chercheurs dans l'avancement de la recherche sur des produits naturels et de soutenir les principes de la conservation de la biodiversité. Toutefois, ces réseaux ont de nombreux défis à relever, surtout d'ordre financier. Une suggestion a été faite au Réseau africain pour l'innovation dans la domaine de médicaments et des produits diagnostiques (ANDI) d'envisager la participation d'autres réseaux existants $dans\,sa\,structure\,afin\,d'obtenir\,une\,synergie\,d'efforts$ pour créer des produits médicaux.

_ _ U M Á O Networking (criação de redes) constitui um meio de calibrar a qualidade do trabalho que um grupo de pessoas está a realizar, fomentando a colaboração internacional, o agrupamento dos recursos disponíveis para proporcionar formação de qualidade e a pesquisa em várias disciplinas científicas, assegurando a rápida disseminação mundial da informação de investigação. Existem várias redes envolvidas na pesquisa e desenvolvimento de plantas medicinais nas várias sub-regiões da Região Africana. Contudo, este documento discute apenas seis dessas redes de investigadores africanos que partilham certas características comuns. Estas redes visam fomentar a pesquisa de produtos naturais e a sua utilização sustentada em saúde humana, além da disseminação da informação sobre a pesquisa de

produtos naturais, entre outros. Têm também como objectivo melhorar as capacidades das instituições em termos da formação em pesquisa, além das actividades regionais; promover a colaboração e parcerias de investigação e orientação de jovens investigadores no avanço da pesquisa de produtos naturais no apoio de princípios de conservação de biodiversidade. No entanto, estas redes enfrentam muitos desafios, maioritariamente financeiros. Foi apresentada uma sugestão à Rede Africana de Inovação Medicamentosa e de Diagnóstico no sentido de considerar o envolvimento de outras redes existentes na sua estrutura, com o intuito de criar sinergias a partir dos esforços de criação de produtos

Networking may be regarded as a means of calibrating the quality of work that a group of people are undertaking. It is also a means of fostering international collaboration and pooling of available resources to provide quality training and research in various scientific disciplines as well as ensuring rapid worldwide dissemination of research information.

etworking among African researchers, who work under extremely difficult conditions, is no different. When work is done in isolation, irrespective of the brilliance of the personnel involved and the use of state-of-the-art equipment, it may be difficult to evaluate the quality of work done in terms of the extent to which the work done meets the aspirations or objectives of those doing the work (fitness for purpose), as well as the usefulness or relevance of the work being done to the society or community at large (fitness of purpose). Therefore, when networks are formed in spite of the challenges, they ought to be supported to make them sustainable.

The WHO Regional Strategy on promoting the role of traditional medicine in health systems adopted by the fiftieth session of WHO Regional Committee for Africa in Ouagadougou in 2000 (1), underscored the importance of partnerships and networking and called upon the Ministers of Health to promote contact with other ministries, professional associations, consumer groups, non-governmental

organizations, associations of TM practitioners, regional and interregional working groups on TM and training institutions in both private and public sectors to optimise the use of TM. The Ministries of Health were are also urged to facilitate effective collaboration between traditional and conventional health practitioners (1).

Several networks involved in research and development of medicinal plants exist in the various sub-regions of the African Region, but for the purpose of this paper only five which share certain common characteristics, will be discussed. All these networks aim to foster research on natural products and their sustainable use in human health and agriculture, and the dissemination of information on research into natural products. They also aim to enhance research training capabilities of institutions through national and regional activities; promote collaboration and research partnerships and mentoring of young researchers in the advancement of natural products research and support the principles of biodiversity conservation.

NAPRECA

NAPRECA, the Natural Products Research Network for East and Central Africa, was conceived by East and Central African scientists who attended the 14th International Symposium on the Chemistry of Natural Products in 1984 in Poland. Its establishment was borne from the realization that Africa was rich in biodiversity, but poor in research and development in natural products. NAPRECA became a fully-fledged network and started operating in earnest in 1988 when in 1987 it became affiliated to UNESCO as one of UNESCO's network programmes. A NAPRECA Coordinating Board had its first meeting in Addis Ababa on 24th March 1988 (2,3).

The main objective of NAPRECA is to initiate, develop and promote research in the area of natural products in the countries in Central and Eastern Africa sub-region and to coordinate and maintain inter- and intraregional links among different research groups (4). The countries in this Network are Botswana, Cameroon, Democratic Republic

of Congo, Ethiopia, Kenya, Madagascar, Rwanda, South Africa, Sudan and Uganda.

The activities of the Network include biannual Natural Products Symposia and workshops designed to expose young scientists in the natural products research area to the state-of-the-art techniques and to maintain vitality in the Network's activities in the various member countries (5) (NAPRECA, 2009). Reports of scientific development are also made during these workshops which are very well attended not only by natural products research scientists from the two regions, but also by scientists from other African countries and from other continents.

In addition to UNESCO the International Foundation for Science (IFS) (6) provides funding for NAPRECA, especially, funding for specific projects. NAPRECA also receives financial support from the International Programme in the Chemical Sciences (IPICS) of Uppsala University's International Science Programme (ISP), as well as from the Organization for the Prohibition of Chemical Weapons (OPCW). The International Educational Exchange Programme (DAAD) of Germany provides scholarships for students to undertake postgraduate degree programmes in the universities belonging to this Network (7).

The NAPRECA headquarters is located in the country of residence of the Executive Secretary and the Assistant Secretary/Treasurer for the duration of their term of office. The headquarters rotates among the member countries within the Network. Currently, it is located in Nairobi, Kenya. Local branches of NAPRECA are found in the countries in the Network.

NABSA

Founded in 1992, the Network for Analytical and Bioassay Services (NABSA) is a network of laboratories in the Chemistry Departments of three East African Universities, namely, Addis Ababa University in Ethiopia, University of Nairobi in Kenya and University of Botswana located in Gaborone, Botswana. The purpose was to find ways of assisting scientists working in isolation and in various institutions in Africa who were constrained because of inadequate facilities and less enabling environments. The International Organization for Chemistry in Development (IOCD) encouraged the creation of NABSA (8).

NABSA was created to encourage phytochemical research underpinned with bioassay of natural products, by pooling existing analytical facilities in African research laboratories. Its

objective is to "promote closer cooperation among African scientists and institutions in order to reduce undue dependence on the North and to enhance the growth of science in Africa by mutual assistance, sharing and effective utilization of available facilities in the continent."

The laboratories in this network are equipped with the necessary scientific equipment for isolation of pure compounds, structural elucidation and profiling and fingerprinting of extracts. They include chromatographic systems for HPLC and MPLC, preparative HPTLC and GC, all types of spectroscopic equipment, including NMR (300 and 600 MHz) and MS (low resolution EI, CI, ESI). Scanning and Transmission electron microscopes are found at the University of Botswana in Gaborone.

Some of the analytical services provided are not found in most of the laboratories on the African Region and the continent. These include spectral services which utilises NMR (one and two dimensional; proton and carbon), MS and CD linked directly to the chromatographic separation systems.

NABSA also provides for shortterm research visits. Research scientists from various countries on the continent can also access these services by sending samples for analysis after prior approval of the Coordinator. Raw NMR spectral data generated at the laboratories is uploaded on an ftp server set up for the purpose. Scientists at the University of Dschang in Cameroon and the University of Dar es Salaam in Tanzania with more remote NMR workstations can access the data directly through the Internet. Scientists without remote workstations receive hardcopies of processed data by courier.

NABSA also has CD-ROMbased library search on natural products literature.

The bioassay services offered are rather general and include anti-feedant, larvicidal and brine shrimp assays.

NABSA is able to provide these services because of its adequately resourced laboratories. The International Foundation for Science (IFS) works with NABSA to provide proper maintenance and functioning of these pieces of scientific equipment.

WANNPRES

The success of NAPRECA led to an attempt to create a similar network in the West African subregion, with the name Natural Products Network for West Africa (NAPRWA), also with UNESCO



support. However, the attempt was not successful and a West African regional network for research into natural products could not materialize until 2002, during a conference held in Burkina Faso at which participants made presentations, which highlighted issues such as National Policy on scientific research in member states, ongoing research and areas of specialisation as well as strengths and weakness of their research projects.

This network, which was named the Western Africa Network of Natural Products Research Scientists (WANNPRES)(9) was initiated by the then West Africa Regional Secretariat of the Committee on Science and Technology in Developing Countries (COSTED), an erstwhile regional body of the International Council for Science (ICSU), the world-wide body

for the voice of science based in Paris. Its overall objective is to help improve infrastructure and communication among scientists in the sub-region to enable them carry out research for the development of natural products, and to work towards the establishment of Centres of Excellence.

Like many similar research networks, the conference at which WANPRESS was established, ended with participants making several recommendations, notable among which were:

- Strengthening of the capacities of Units/Departments in the universities and research institutions with potential for use by all members of the Network
- The need for both electronic and physical networking to upgrade and use the facilities at members' sites in a communal manner.

- Development of strong links between organic chemists and other natural products research scientists to ensure a multidisciplinary and holistic approach to the study of natural products
- Identification of sources of scholarship for young scientists in the sub-region to enable them work on natural products
- Benefit-sharing agreements with herbalists to enhance free flow of information
- Researchers to be conscious of sustainable use of biodiversity
- The need to engage in relevant pre-clinical studies to ensure safety and efficacy of natural products of medicinal value
- Lobbying government and policy makers to overcome some of the difficulties encountered by natural products research scientists
- Consideration of natural products other than those of medicinal value, such as nutraceuticals from our indigenous foods
- The Network to consider setting up standards based on good laboratory practices (GLP) for mutual acceptance of data generated in the various laboratories within the Network

During the meeting to formally establish WANNPRES priority areas (in terms of diseases) for which medicinal plant research would focus were identified to be: Malaria and other parasitic diseases, HIV/AIDS, and Maternal and Child Health diseases, especially malnutrition.

The focus of research could vary in each country. However, the emphasis is on finding the scientific basis for the cure of medicinal plants and their products; be they crude extracts, fractions of these extracts or the pure compounds isolated from them. Validation of the medicinal effects of herbs to corroborate the claims of herbalists forms a large part of the research agenda of WANNPRES. Characterization of isolated chemical compounds is an important component of the research but it is not the flagship project of the Network.

An important activity that was agreed upon was the biennial scientific meetings, during which papers of research results would be presented, peer reviewed and published as WANNPRES Proceedings. Subsequent to the establishment of the Network, Scientific Meetings have been held every two years; 2004, 2006, 2008 and the fourth is to be held this year 2010 in Burkina Faso, where the rotating Executive Committee is currently located.

The proceedings of the first Scientific Meeting held in 2004 was published in the African Journal of Traditional, Complementary and Alternative Medicines, an online journal (10). However, publication of proceedings of subsequent scientific meetings has not been possible owing to a number of constraints.

WANPRES is run by an Executive Committee, whose members must come from the same country. The location of the Executive Committee changes every four years and this committee is responsible for organising the Scientific Meetings. Country Coordinators are responsible for the in-country activities of WANNPRES.

Unlike some other networks, WANNPRES does not enjoy a regular source of support from donor agencies and organisations. However, the Scientific Meetings have received funding from International Foundation for Science (IFS) (for grantees who are making presentations), from WHO Regional Office for Africa. Some support has also been received from the Organisation for the Prohibition of Chemical Weapons (OPCW) and the Academy of Sciences for the Developing World (TWAS) and recently the West African Health Organisation. Ministries, departments and agencies of governments in the countries hosting the scientific meetings also offer support.

AAMPS

At a Medicinal Plants Forum for Commonwealth Africa held in Cape Town in 2000, the lack of suitable technical specifications and quality control standards for African medicinal plants and herbal medicines was identified as a major constraint and a significant barrier to regional and international trade. It was also recognized as an important barrier to integrating traditional medicine into African public health services (11).

In an attempt to overcome this challenge, a two-phased project to prepare 50 herbal product profiles/standards for key African Medicinal Plants was proposed. These product profiles included most of the important African plants presently traded as well as others considered to be of sustainable long term importance. The criteria used for inclusion were the following:

- Scientifically well investigated species;
- Species which required further investigation, but are well integrated in traditional medicine, yet largely unknown outside Africa.
- Plant species which already are commercially successful and are only locally used and traded.

Information normally contained in drug monographs with data usually found in medicinal plant trade specifications and quality control sheets were some of the materials used to start the project from the Department of Phytomedicine, University of Pretoria, in association with other medicinal plant specialists from Africa and Europe. A meeting to review progress on the first 23 herbal profiles was organised at Centurion Lake in South Africa in May 2005. Twenty seven experts invited to the meeting, unanimously agreed to the establishment of the African Association of Medicinal Plant Standards (AAMPS) by signing a declaration as Founding Members (12).

In the declaration, the Founding Members had a major objective of improving the health, welfare and livelihood of the people's of Africa by, among others:

- developing quality control and quality assurance standards for African medicinal plants and herbal medicines to support the African herbal industry and regulatory authorities.
- offering membership of the newly formed association to any individual or organisations dedicated to the establishment of such standards and to the creation of an African Herbal Pharmacopoeia

- preparing and publishing an African Herbal Pharmacopoeia based upon 50 herbal profiles and promoting its use nationally and internationally
- helping to obtain international validation for these herbal standards and the subsequent herbal pharmacopoeia and to lobby health authorities throughout Africa to use such standards as the basis for licensing safe and effective herbal medicines in Africa
- promoting capacity building in Africa for the establishment of regional training centres for certification, compliance and quality control of herbal medicines.
- promoting the safe, sustainable national and international trade in the fifty profiled African medicinal plants

AAMPS aims to support the production, processing and trade of African medicinal plant species from Sub-Sahara Africa. AAMPS, registered in Mauritius, is dedicated to the development of quality control and quality assurance standards for African medicinal plants and herbal products (13).

One major aspect of the work of AAMPS is the quality control/quality assurance of medicinal plants. Therefore, suitable methods for this have been

investigated and the outcome is the identification of a set of uniform methods which are relatively easy to apply and replicate, such as:1) Macroscopic, microscopic and organoleptic properties of the plant, 2) Thin Layer Chromatography (TLC) and 3) infrared scan.

Where active and/or marker compounds cannot easily be identified with these methods, more specific, identification methods are used. In order to conduct the testing AAMPS establishes Reference laboratories in countries in Sub-Saharan Africa to be part of these testing procedures, a process that should also aid certification in the country when this is required.

AAMPS' major task is the formulation of standards for commercially important African medicinal plant species. However,

by integrating these standards in national regulatory systems, the objective of integrating herbal medicine into the health delivery system of a nation is achieved. In addition, by producing quality medicinal plants for trade, there is value addition to local products and therefore advantage to local business.

Regional experts for the relevant medicinal plant species from the continent of Africa were involved in the work of AAMPS. The profile produced for each plant was peer-reviewed by experts with relevant scientific and/or commercial background. Authors and reviewers were from the following countries: Belgium, Botswana, Burkina Faso, Canada, Ethiopia, Germany, Ghana, Madagascar, Mali, Mauritius, Namibia, Nigeria, South Africa, UK, and from the two commercial organizations, PhytoTrade and ASNAAP (Agribusiness in Sustainable Natural African Plant Products).

For the dissemination of information contained in the work of AAMPS, there is an online presentation, the African Medicinal Plant Standards Database, which is to be constantly updated and this is available to AAMPS members only. The accessibility of the AAMPS database to the members, some of whom are medicinal plant researchers, makes it a viable network for medicinal plant research. When Reference laboratories have been established in a number of countries in Africa, an excellent network in quality assurance for researchers in medicinal plants would result.

AAMPS received funding from the Centre for the Development of Enterprise (CDE) – an EU donor organization for the promotion of trade with African, Caribbean and Pacific (ACP) countries - in collaboration with the Technical Centre for Agriculture and Rural Co-operation (CTA). Some of the members of AAMPS make handsome personal contributions to the project.

The AAMPS organisational structure is such that there are two units; one responsible for the trade aspects of its work, the other for the scientific aspect.



WAHO COMMITTEE OF TRADITIONAL MEDICINE EXPERTS

When WANNPRES was established in 2002, there was a list of organizations and institutions that the new network was advised to have a relationship with. One such organization was the West African Health Organisation (WAHO). WAHO later organized a consultative meeting in November 2008 in Ouagadougou, Burkina Faso, which reviewed research data on West African medicinal plants and one of the outcomes of the meeting was the establishment of an ad hoc Committee of Experts on Traditional Medicine (14).

In March 2009, a meeting of the *ad hoc* Committee of Experts was held in Accra, Ghana, to consider the process of developing a West African Herbal Pharmacopoeia proposed by WAHO. A format for presenting the monographs for the pharmacopoeia was agreed upon and additionally, a list of 57 medicinal plants common to the countries of ECOWAS, was prepared on the basis of an agreed criteria, including medicinal plants commonly used in the subregion, priority diseases common

in the sub-region and availability of scientific studies(15). Another paper in this special issue focuses on the Pharmacopoeia.

The main objective of establishing the Traditional Medicine Expert Committee is primarily to promote WAHO's traditional medicine agenda that aims at ensuring the institutionalization of traditional medicine in the health systems of Member States. However, it also promotes traditional medicine research expertise in the sub-region because of the way it operates.

Medicinal plant databases, journals, existing national and regional pharmacopoeias, were used to compile a draft of all the monographs based on the agreed format and these were sent to the traditional medicine experts for editing. The Traditional Medicine Experts Committee has been meeting, together with other experts in the field to review and finalize the monographs in preparation for the production of the West African Herbal Pharmacopoeia. The data collected on the medicinal plants showed up gaps and methods were proposed to fill the gaps.

The process of producing these monographs makes the Traditional Medicine Expert Committee a kind of network. The Experts come from different countries, with different expertise, which is shared thereby improving not only each other's research effort, but also making use of research results. In the discussions during the meetings, different experts stress different aspects of medicinal plant research and in the end there is a consensus as to what is essential in the health aspects of medicinal plant research. This is an excellent mode of networking for a more effective outcome of research.

Pharmacopoeias exist, some national (e.g. Ghana (16) and Nigeria (17)) and others regional or even continental (e.g., the African Pharmacopoeia (18-19)). However, the pharmacopoeia under production is health-focused and therefore data on some sections in the monographs of the selected plants would be critical and could not be compromised: safety data; ethno-medical uses; test for identity and quality; pharmacological or clinical data. Selected plants without adequate information on these sections will not be considered for inclusion in the pharmacopoeia. The data collected so far has shown that there is very little information on safety studies and therefore a decision has been taken to commission a laboratory or laboratories to carry out toxicity studies to supply the necessary information for all plants considered for inclusion, which did not have safety data.

WAHO is a specialized agency of the Economic Community of West African States (ECOWAS) with the mandate of implementing high impact health interventions in the 15 ECOWAS Member States. The WAHO traditional medicine programme, like all the other priority orientations of the Organisation, therefore derives its main source of funding from ECOWAS. In addition, the World Health Organization, Regional Office for Africa, and PROMETRA International, a non-governmental organisation with the general objective of promoting TM and forging links between cultures across the world, are partners with WAHO in developing the West African Herbal Pharmacopoeia.

ANDI

The first meeting of the African Network of Drug and Diagnostics Innovation (ANDI), at which the network was launched, took place in Abuja Nigeria in October 2008 (20). Following the launch meeting, a Task Force was constituted to oversee the development of a business plan defining the roadmap for the implementation of the Network's activities. The membership of the Task Force included researchers, ambassadors, pharmaceutical companies, bank executives, university dons

as well as a representative of Africans in the Diaspora and of the European Union. The WHO Secretariat represented by the WHO Regional Offices for Africa, for East Mediterranean and the Special Programme on Tropical Disease Research (TDR) are also members of the Task Force. The Business Plan (2010–2015) was formally launched and unanimously endorsed at the 2nd ANDI Stakeholders Meeting in October, 2009 in Cape Town, South Africa (21). The ANDI Task Force is to meet to begin implementation, including the establishment of a Board and identification of projects to be supported. A third stakeholders' meeting is planned to formally launch the organization in October 2010.

ANDI was set up to address the problem of less spending on health product discovery and development in Africa by increasing and strengthening networks throughout Africa that would build capacity from early drug discovery and development right through to manufacturing. There was a felt need for Africanbased solutions to African problems, with the involvement of African-based institutions and researchers capable of identifying the priorities and doing the work.

The network would focus on research for new drugs

and diagnostic tools for the diseases and health problems most affecting Africa. Most African-based researchers hardly communicate with their colleagues due in large part to the lack of financial and organizational support to link researchers throughout the continent. ANDI would strengthen these intra-continental links, providing funding for networked collaborative research across countries, as well as supporting IT infrastructure and the negotiation and management of intellectual property rights, including patents.

In 2008 an agreed part of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) was adopted through a World Health Assembly Resolution WHA 61.12 (22); whereas the budget and indicators for monitoring progress was adopted in 2009 by Resolution WHA 62.1623. For the implementation of this strategy, it has been realized that Africa possesses a unique knowledge base and resources that could be better harnessed and applied to overcome the challenges resulting from the high disease burden, leading to economic development and poverty alleviation. ANDI has received recognition by the World Health Assembly (WHA62.16) as a unique organization able to contribute to the implementation of GSPOA in Africa.

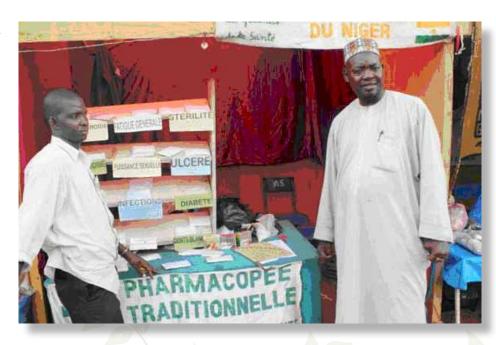
The African Development Bank and WHO support the network. Support is also being sought from several African governments through their Ministries of Health, Science and Technology, Africans in the Diaspora, international organisations such as UNESCO, WIPO, WTO, the World Bank and development agencies for ANDI's development.

The organizational structure is still unfolding. However, ANDI is expected to have an African Innovation Fund, an ANDI Board and Scientific and Technical Advisory Committee (STAC).

CONCLUSION: A WEB?

There are other networks not discussed in this article, which deal with research and development of medicinal plants in Africa. An example is the network for Southern African Plant Resources Exploration (SAPRE), which was established in 1996 on the initiative of the Commonwealth Science Council for the documentation and sustainable exploitation of plant resources through a collaborative effort between scientists and institutions in Southern Africa.

As unique or useful as each network may be, it may be more



worthwhile for collaborative links to be established among them for reasons already mentioned.

NAPRECA, which preceded all these networks, has been very successful probably because of the support it received and continues to receive from organisations outside the African continent. Such support is also forthcoming probably because of the nature of the major activity in the network, which is specific to the development of chemistry in the universities in the subregion, something the donors can relate to. One can regard the establishment of NABSA as a logical extension of NAPRECA, because the absence of needed pieces of equipment for R&D together with their maintenance is the base of medicinal plant research.

Chemistry is only a part of the focus of activities for the West African analogous organisation, WANNPRES. Although much younger than NAPRECA, the focus on efficacy of the herbal preparations through research on pharmacological and, sometimes, clinical data makes it a natural complement to NAPRECA. According to information available, NABSA carries out bioassays. But these are generalized bioassays as mentioned above to evaluate possible biological activities of isolated compounds. More specific assays, relating to diseases especially diseases prevalent in the region, are carried out in the laboratories of researchers in the WANNPRES network. These bio-assays would be more beneficial if used in the efforts of the researchers within the NAPRECA network

to establish the efficacy of the isolated compounds in some specific diseases. Otherwise there would be research yielding a huge library of isolated chemical compounds of known structure but with very little development from them. Worse still, a pharmaceutical company could get interested in a compound and could decide to develop it into the kind of medicament that it is familiar with in a manner that brings very little reward to the researchers and the source country. NAPRECA and WANNPRES must collaborate more closely and effectively.

That the advancement of chemistry as a subject in the universities in the Eastern and Central African countries is due to NAPRECA and NABSA cannot be denied. The same advancement can be achieved in countries in the West African subregion through networks if the same support from organisations outside the continent would come to the sub-region. Just as a better development of isolated chemical compounds can be achieved through better collaboration between NAPRECA and WANNPRES, advancement of chemistry as a subject in the universities is possible with the same collaboration between the two networks, which could lead to support from the same or similar organisations that support NAPRECA and NABSA.

NAPRECA and WANNPRES can therefore collaborate for a win-win situation where isolated compounds may be tested using a wide range of bioassays; and chemical compounds from fractions which are known to have medicinal value may be isolated and characterized.

Researchers of medicinal plant research must not be forced to choose between safety, efficacy and quality studies or structural elucidation of chemical compounds isolated from medicinal plants. We need both and we should do both.

AAMPS focuses on standards. another critical factor in the development of medicinal plants. The fine work done by AAMPS is necessary to enhance the work of any network on medicinal plant research. However, the work that the WAHO Traditional Medicine Experts Committee is involved in cannot be complete without excellent work on the identification and quality of the medicinal plants in the monographs making up the pharmacopoeia. There is every reason for this Committee to establish a relationship with AAMPS so that the laboratory that was responsible for the quality control/quality assurance aspects of AAMPS work could carry out some aspects of the identification/quality of the monographs for the West African Herbal Pharmacopoeia. The data provided by the WAHO TM Expert Committee can also be beneficial to AAMPS. Some of the sections in the WAHO monographs cover safety data, therapeutic indications and therapeutic actions. Such information would be important in the selection of medicinal plants to trade in.

One of WANNPRES' recommendations at its establishment was the setting up of standards based on Good Laboratory Practice (GLP). AAMPS has done this and therefore WANNPRES should benefit from the work of AAMPS through collaboration. The synergy existing between the activities of WANNPRES and the WAHO Traditional Medicine Expert Committee is obvious.

As indicated above, strong networks already exist in Africa attracting partnerships from the North and increasing capacity on the continent. There are also examples of university networks with significant presence in Africa (24). However, these networks help build capacity in Africa, although they have many challenges, mostly financial and related sustainability. A suggestion has been made for ANDI to consider the integration/ involvement of already existing networks in its structure, and for it to be responsible for coordination and inter-country and/or intersub-regional collaboration. ANDI will then be seen as synergizing existing efforts to create health products. With all these possible collaborations between the networks, one is working towards an African-wide web (AWW) of medicinal plant research and development and countries of the African Region and the African continent would be better for it.

There are enormous benefits that networking and collaboration in medicinal plant research and development could bring to the poor and deprived populations of the WHO African Region. However, for the populations to benefit from these networks, there is a need for those having common specific health research interests, to forge relevant partnerships for information sharing, provision of orientation and training and to develop joint collaborative health research projects. It is also imperative to engage the media (e.g. REJOUMETRA, the Réseau des journalistes pour la promotion des médecines traditionnelles - Network of Journalists for the Promotion of Traditional Medicine) to help in the dissemination of new knowledge using the language of the people. WHO and relevant partners should support the networks on medicinal plants research to realize their objectives.

With all these possible collaborations between the networks, one is working towards an African-wide web (AWW) of medicinal plant research and development and the African Region in particular and the continent in general, would be better for it.

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TOWARDS SUSTAINABLE LOCAL PRODUCTION OF TRADITIONAL MEDICINES IN THE AFRICAN REGION

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Corresponding author: Ossy MJ Kasilo Email: kasiloo@afro.who.int 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.

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.

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 actuais 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 melhoramento de produtos para a utilização comercia de plantas medicinais.

SUMÁRIO

The basis for promoting the local production of traditional herbal remedies is to provide costeffective 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.

he 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 socioeconomic 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 bioactivityguided 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, Myanmae, 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 lessendowed African countries. from local departments universities o r 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

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

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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.

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 postharvest 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 inbuilt 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.

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 a n d s c i e n t i f i c 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. 60

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INTELLECTUAL PROPERTY APPROACHES TO THE PROTECTION OF TRADITIONAL KNOWLEDGE IN THE AFRICAN REGION Emmanuel K. A Sackey¹ Ossy MJ Kasilo² 1 African Regional Intellectual Property Organization (ARIPO) 2 World Health Organization, Regional Office for Africa Corresponding author Emmanuel KA Sackey E-mail esackey@aripo.org; yoofisackey@yshoo.com

Traditional knowledge has played a significant role in the healthcare systems in countries of the African Region for centuries. Traditional medicines are presently used by nearly 80% of the population. Owing to the global resurgence in the use of natural products and the advent of the biotechnological industry, traditional knowledge is increasingly becoming a source of modern drug development and biotechnological inventions. Despite the important role of traditional knowledge, traditional communities are unable to protect their knowledge through the existing intellectual property system owing to the failure of the knowledge to satisfy the requirements for intellectual property protection, incompatibility in most cases between the traditional knowledge concepts and intellectual property as well as the prohibitive costs involved in patent registration. Studies conducted recently and the outcomes of global debates have suggested some policy and legal approaches that can be used to effectively protect traditional knowledge, including traditional medicine. This paper discusses concepts of traditional knowledge and provides policy and legal measures that have been developed at the international and regional levels for the protection and utilization of traditional knowledge for the benefit of the knowledge holders and society at large.

RÉSUMÉ

Pendant des siècles, les connaissances traditionnelles ont joué un rôle important dans les systèmes de soins médicaux des pays de la Région africaine. A l'heure actuelle, les médicaments traditionnels sont utilisés par près de 80% de la population. En raison de la réapparition dans le monde entier de l'utilisation de produits naturels et de l'arrivée de l'industrie biotechnologique, les connaissances traditionnelles deviennent de plus en plus une source de développement des médicaments modernes et d'inventions biotechnologiques. Malgré le rôle important des connaissances traditionnelles, les communautés traditionnelles sont incapables de protéger leurs connaissances en avant recours au système de propriété intellectuelle existant, cela en raison de l'insuffisance des connaissances pour répondre aux exigences en matière de protection de la propriété intellectuelle. Dans la plupart des cas, il y a incompatibilité entre les notions de connaissances traditionnelles et la propriété intellectuelle Les coûts d'enregistrement des brevets sont également prohibitifs. De récentes études ainsi que les conclusions des débats conduits au niveau mondial, ont suggéré que certaines approches politiques et juridiques pourraient être utilisées pour protéger efficacement les connaissances traditionnelles, y compris la médecine traditionnelle. Ce document aborde les concepts des connaissances traditionnelles. Il propose des mesures politiques et juridiques qui ont été développés à l'échelle internationale et régionale pour la protection et l'utilisation des connaissances traditionnelles au profit des détenteurs de savoirs et de la société dans son ensemble.

SUMÁRIC

O conhecimento tradicional tem desempenhado durante séculos um papel significativo nos sistemas de saúde em países da Região Africana. Os medicamentos tradicionais são presentemente utilizados por cerca de 80% da população. Devido ao ressurgimento global do uso de produtos naturais e ao advento da indústria biotecnológica, o conhecimento tradicional está a tornar-se cada vez mais numa fonte de desenvolvimento e invenções biotecnológicas de fármacos modernos. Apesar do importante papel do conhecimento tradicional, as comunidades tradicionais são incapazes de proteger o seu conhecimento através do sistema de propriedade intelectual existente, devido ao facto deste tipo conhecimento ser incapaz de satisfazer os requisitos de protecção da propriedade

intelectual, à incompatibilidade na maioria dos casos entre os conceitos do conhecimento tradicional e da propriedade intelectual, assim como aos custos proibitivos envolvidos no registo de patentes. Estudos conduzidos recentemente e os resultados dos debates globais sugeriram algumas abordagens políticas e legais que podem ser utilizadas para proteger eficazmente o conhecimento tradicional, incluindo a medicina tradicional. Este documento discute os conceitos de conhecimento tradicional e apresenta medidas políticas e legais que foram desenvolvidas aos níveis internacional e regional para a proteção e utilização do conhecimento tradicional em benefício dos detentores do conhecimento e da sociedade em geral.

Intellectual Property (IP) is a legal concept which deals with creations of human ingenuity. Such creations, whether they be inventions, designs, trademarks or artistic works such as music, books, films, dances, sculpture or photography are considered and protected as property for a certain period in time provided that the creations meet a certain criteria. The intellectual property system is dynamic, characterized by its ability to evolve and adapt to current technological advances, especially in information technology and biotechnology as well as the evolution of society itself.

raditionally, IP laws have been made as statefacilitated contracts between the public and the creators. Yet Intellectual property rights (IPRs) are not ends in themselves but provide humanity with a decentralized system of innovation in science and culture as well as give us a way of protecting and rewarding innovators thereby encouraging firms to produce quality products and allowing consumers to rely on the identity of the products they purchase.

As intellectual property protection has expanded exponentially in breadth, scope and terms over the last 30 years, the fundamental principle of balance between the needs of the public and the creators have been questioned. The various forms of IP protection are generally tailored to fulfil various legal, economic and social functions. These terms of protection can vary from one jurisdiction to another so long as they comply with the minimum requirements set forth in international agreements such as the TRIPs

Agreement. The primary purpose of most branches of the intellectual property system (excluding trademarks and geographical indications) is to promote and protect human intellectual creativity and innovation. IP law and policy does so by striking a careful balance between the rights and interests of innovators and creators on the one hand, and of the public at large on the other 1. Thus, by granting exclusive right in an invention, for example, the IP system encourages further innovation, rewards, creative effort and protects the investment necessary to make and commercialize the invention. The promotion and protection of IP can also spur economic growth, create new jobs and industries and enhance the quality and enjoyment of life.

However, IP regimes have been based on notions of individual property ownership, a concept that is often alien and can be detrimental to many local and traditional communities. An important purpose of recognizing private proprietary rights is to

enable individuals to benefit from products of their intellect by rewarding creativity and encouraging further innovation and invention. Many traditional communities experience difficulties in attempting to protect their knowledge through the existing IP system due to the failure of traditional knowledge (traditional knowledge) to satisfy the requirements for IP protection. In cases where this is possible, the prohibitive costs of registering and defending patents and other IPRs may curtail effective protection. incompatibilities Many between traditional knowledge and IPRs have begun to surface with the rapid global acceptance of the conventional IP concepts and standards. These incompatibilities occur when ownership of traditional knowledge is inappropriately claimed or traditional knowledge is used by individuals or corporations that belong to local communities primarily in developing countries.

This article discusses the know-how aspect of traditional

knowledge which includes traditional medicine The broader concept of traditional knowledge incorporating elements of folklore and traditional cultural expressions has not been covered in this paper. The aim of the article is to create awareness on this subject and what has so far been done by the various stakeholders including countries, the African Union, regional organizations on intellectual property, WIPO and the world health organization.

GLOBAL RESURGENCE IN THE USE OF TRADITIONAL KNOWLEDGE AND ITS ASSOCIATED GENETIC RESOURCES

Over the past two decades, biotechnology, pharmaceutical and human healthcare industries have increased their interest in natural products as sources of new biochemical compounds for medicines, chemical and agroproduct development. This has brought about the resurgence of interest in traditional knowledge and associated genetic resources. This interest has been stimulated by the importance of traditional knowledge as a lead in advancing the frontiers of science and technology. traditional knowledge has been extensively used to gain useful understanding of how ecological systems generally work and interrelate. This knowledge has contributed to the production in modern economy and played significant role in the Research and Development programmes of industry. traditional knowledge has been and continues to be an element in the commercialization of natural products. It is currently supplied to commercial interests through databases, academic publications or field collection. This undue exploitation needs to be paid for in some form. Concern over the growing interest in and economic importance of traditional knowledge has generated a wide range of public policy issues including those associated with IP protection.

In spite of the important role traditional knowledge plays in sustainable development, it continues to be largely disregarded in development planning. It currently plays only a marginal role in biodiversity management and its contribution to the society in general is neglected. Furthermore, traditional knowledge is being lost under the impact of modernization and the ongoing globalization processes, yet, it may contribute to improved development strategies in several ways. These include helping identify cost-effective and sustainable mechanisms for poverty alleviation that are locally manageable and locally meaningful; a better understanding of the complexities of sustainable development in its ecological and social diversity, and helping to identify innovative pathways to sustainable human development that enhance local communities and their environment.

CHARACTERISTICS OF TRADITIONAL KNOWLEDGE

The swell of academic and institutional interest surrounding traditional knowledge has resulted in a wide array of terms and definition that attempt to gather within their meaning all that indigenous people know including indigenous science, traditional knowledge, local knowledge, traditional ecological knowledge and traditional environmental knowledge. Nonetheless, there are working definitions that have been developed by researchers, institutions and indigenous people's organizations that attempt to cover the range of meanings associated with traditional knowledge such as Brooke (1993) (3) and ARIPO Protocol on the Protection of traditional knowledge and Expressions of Folklore (2009). This later defines traditional knowledge as: "any knowledge originating from a local or traditional community that is

the result of intellectual activity and insight in a traditional context, including know-how, skills, innovations, practices and learning, where the knowledge is embodied in the traditional lifestyle of a community, or contained in the codified knowledge systems passed on from one generation to another. The term shall not be limited to a specific technical field, and may include agricultural, environmental or medical knowledge and knowledge with genetic associated resources" (4).

In considering the characteristics of traditional knowledge, it is to be understood that humankind has used this informal knowledge system for thousands of years, being transmitted and developed by one generation to the next. It refers to the human tradition of passing down knowledge throughout the ages and improving it with experience over time; and is the basis for local level decision making in areas of contemporary life, such as natural resource management, nutrition, food preparation and health. The existence of traditional knowledge is dependent on and determined by the maintenance of the culture from one generation to the other.

In order to effectively protect traditional knowledge, a deeper understanding is required to enable the determination of appropriate policy choices for its protection. There are two schools of thought about how traditional knowledge is perceived: one views traditional knowledge holistically and believes that the various component of traditional knowledge cannot be segregated; the other views traditional knowledge as having different components that could be considered on their own merits, for example traditional medicine. In determining the most appropriate means of protecting traditional knowledge, these views should be carefully considered and taken into account.

THE INTERSECTION BETWEEN MODERN SCIENCE AND TRADITIONAL KNOWLEDGE

It is widely acknowledged that the development of modern science in leaps and bounds was substantially bolstered by the input of traditional knowledge. At the core of mainstream science is the desire to negotiate nature through sequential processes such as hypothesis formulation, experiment and prediction. Knowledge production in mainstream science includes phases of experimentation through trial and error or

otherwise. But there are some areas of non-convergence between traditional knowledge and mainstream science. Traditional knowledge seems to be relatively less transferable than conventional science, given its holistic socio-cultural and even spiritual dimensions. traditional knowledge appears to be largely communitarian in terms of discovery and experimentation and the mode of transmission and sharing is often collective rather than individualistic. Embedded in the products and services associated with traditional knowledge are proprietary systems which are often more flexible and negotiable than modern science. The engine of growth and sustenance is neither the market nor the profit motive nor is it prone to large-scale mass production and economies of scale.

The main difference between mainstream science and traditional knowledge systems is in format. The scientific knowledge is essentially in an explicit format. The knowledge is articulated in a formal language including grammatical statements, mathematical expressions, specification etc. It is therefore easy to be transmitted between individuals formally and has been the dominant mode of knowledge accumulation and transfer. With respect to the traditional knowledge, the format is mostly tacit. It is embedded in the experiences in the form of beliefs, perspectives and value systems of indigenous people and in most cases not articulated in formal language. For instance, in biomedicine, the knowledge is well documented with scientific evidence whereas evidence of safety and efficacy of traditional medicines has not been well documented. However. these have been field-tested for centuries and a lot of empirical knowledge has been accumulated in local communities and has been maintained and transmitted orally from generation to generation by traditional health practitioners (THPs) and knowledge holders. traditional knowledge provides excellent examples of community-based research. Its weakness lies in its close reliance and over dependence on demographic stability and morality. The community is a source of strength for traditional knowledge in terms of the discovery process and knowledge production.

TRADITIONAL KNOWLEDGE SYSTEMS IN THE AFRICAN REGION

Countries of WHO African Region are endowed with rich and highly diverse biological resources and traditional knowledge which have been practiced centuries before



the advent of colonialization. This knowledge reflects the cumulative body of knowledge and beliefs handed down through generations by cultural transmission and the relationship of the local people with their environment. The development of African traditional systems has developed as a matter of survival of the communities in the management of socioeconomic and ecological facts of life. It has been generally believed that centuries of association with the environment by traditional/ local peoples have produced a deep understanding of the inter-relationship among the different elements of the habitat and helped in the preservation, conservation and sustainable biodiversity management. This has enabled local communities to acquire expertise in the development and adaptation of plants and crops to different ecological conditions. It has been reported that most of the ecological systems of traditional/local communities were codified through language and culture (6).

The strength of traditional knowledge systems can best be seen at the level of economic sustainability, self-reliance and cost-effectiveness. It is within this context that the African traditional knowledge continues to derive its viability and strength. The survival of the informal sector is testimony of the strong capacity for resilience

and growth of African traditional knowledge which invariably persists not only at the level of material culture and natural environment, but also fields such as business management, banking and hospitality services. The development of traditional knowledge systems in the African Region has been a matter of survival to the communities that generated these systems. The oral and rural nature of traditional knowledge had made it largely invisible to the developments community. traditional knowledge has often been dismissed as unsystematic and therefore has not been captured and protected under any international treaty or stored in a systematic way. In grappling with the question of their agricultural and biological heritage, which constitute the bedrock of traditional knowledge, Africans have staked out clear positions in favour of protecting communities' rights over their resources and knowledge.

AFRICAN TRADITIONAL MEDICINE AND TRADITIONAL MEDICAL KNOWLEDGE

Since colonial times, Western medicine was the only formally accepted medicine in the African Region. All traditional medicine practices were categorically condemned as witchcraft or sorcery and banned. Yet the practice of traditional medicine has survived in countries of the African Region for many centuries and today 7% of the household health budget goes to traditional medicines. One of the main reasons Africans favour traditional medicine is because they cannot afford pharmaceuticals or conventional medical care. The 2002 Report from the Ministry of Public Health in Cameroon confirms that the economic crisis and the failure of the Social Security System have created an intense return to traditional health services (7). The second reason for the continued use of or reliance on traditional medicines is one of heritage and custom. THPs understand the social problems and cultural experience of the communities, they use this knowledge in their diagnosis to better treat the sick. THPs in the Region view sickness as the failure of complex social and spiritual relationships, and begins with an examination of both human and supernatural interactions. Unlike conventional medical practitioners who are expected to restore their patients' physical health only, THPs are also responsible for re-establishing social and emotional equilibrium based on traditional community rules and relationships.

Undoubtedly, modern science and technology has revolutionalized

human health. In spite of the development of resistant strains of micro-organisms, mortality associated with common infectious diseases has declined significantly with attendant increase in life expectancy. The eradication of smallpox globally is further evidence of the efficacy of orthodox medicine. According to WHO, over 33% of the world's population has no regular access to the most basic essential medicines and in the poorest countries in Africa and Asia, over 50% of the population lack access to major healthcare services. However, THPs far outnumber western-trained medical doctors: for example, in Ghana and Zambia the ratio of medical doctors to the population is 1 to 20,000 while the corresponding figure of THPs to the total population is 1 to 200. Unlike in China, South Korea and Vietnam, African traditional medicine is not sufficiently integrated into the health systems despite the policy directions that have been provided through the adoption of various resolutions and declarations by WHO governing bodies (8-11).

International and regional block protection systems cannot affect local communities without national legislation. To this end, a number of countries have started preparing pieces of legislation on genetic resources and indigenous knowledge. Most of these appear to be fragmentary and will need

to be more comprehensive. Even then, most countries have not yet made significant progress on protecting intellectual property rights of traditional medicine and indigenous knowledge. Some of the national experiences include Eritrea which has integrated access and benefit sharing provisions into its broader regime on biological diversity, Uganda that has prepared detailed regulations on Access and Benefit Sharing. The Zimbabwe Traditional Medical Practitioners Act (revised 1996) that established the Council only provides for the registration and regulation of the practice of THPs. The Act only limits itself to the administrative issues related to the functions of the Council and its members. However, South Africa developed the indigenous knowledge systems (IKS) policy and a Biodiversity Act in 2004 and established a national office of IKS in 2006 (12).

Nigeria developed national legislation and Bill on IPRs in 2006 and 2007 whereas between 2005 and 2007 Mali organized a series of national and sub-regional sensitization workshops for the protection of traditional medical knowledge. Tanzania organized sensitization workshops on IPRs in 2007 and is in the process of developing a national policy on protection of biological diversity of medicinal value. Cameroon developed a

framework for the protection and valuing of inventions and innovations related to traditional medicine and the following year Ghana developed a national policy on protection of IPRs (12). It worth noting that currently IPR issues are handled by the Ministries of Trade and Industry which are working in collaboration with other stakeholders including the ministries of health (MOH). However, because of the implications of IPRs on public health, the MOH should be involved from the outset in all discussions related to this subject.

POLICY AND LEGAL OPTIONS FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE

The call for an effective and equitable protection of traditional knowledge is a broad policy challenge that requires critical analysis of the issues and concepts that are central to the policy debate about traditional knowledge protection. This section therefore examines the various policy options and discusses how each of the options can effectively strengthen, protect and nurture traditional knowledge so that the fruits can be enjoyed by future generations and enable the traditional communities to continue to thrive. In order to assess the policy options and develop appropriate protection mechanisms for the protection of traditional knowledge, clear policy objectives would need to be defined as well as understand the special characteristics of traditional knowledge that is intended to be protected. A good protection system for traditional knowledge in the African Region has to define where the priorities or interests lies-legal or economic. Clarifying these issues is a prerequisite to the development of any possible forward-looking policy objective. Some possible objectives of protection of traditional knowledge could be to:

- 1. Preserve and conserve traditional knowledge
- 2. Enable communities to continue using traditional knowledge in the context of their traditional lifestyle
- 3. Safeguard against thirdparty claims of IP rights over traditional knowledge subject matter
- 4. Protect distinctive traditional knowledge related commercial products
- 5. Encourage and promote traditional-knowledge-based innovations
- Encourage sustainable use
 of traditional-knowledge related biodiversity and
 equitably share the benefits
 arising from the commercial
 use of traditional knowledge,
 etc.

It has been argued that a onesize-fit-all approach will not be practical and operational. Instead, an analysis of composite approaches and exchanges of best practices and worst experiences on the protection of traditional knowledge may be a good way to develop participatory and long lasting solutions (13). So far as IP protection is concerned, the main options are:

- 1. Making better use of existing IP rights by capacity building, administrative initiatives, community-based initiatives, and programs for better recognition and defending traditional knowledge as legitimate and valuable IP assets of the communities that have developed them.
- 2. Extending or adapting the conventional systems of IP rights, to include *Sui generis* elements that are especially designed to improve the

- way these systems serve the particular interests of traditional knowledge holders
- 3. Creating a distinct category of rights in traditional knowledge as such, through *Sui generis* IP systems designed specifically for this subject matter.
- 4. Using customary laws and establishing contractual arrangements for benefit-sharing should the traditional knowledge become commercially exploited.

USE OF EXISTING INTELLECTUAL PROPERTY RIGHTS

IPRs provide legal protection in the form of exclusive rights to individuals or corporate entities over their creative endeavours for a limited period of time. It focuses on the promotion of economic exploitation of human creativity with the view to advancing the frontiers of knowledge through further research and development. Article 1 of the Paris Convention for the Protection of Industrial Property (1883) defines the scope of industrial property (14). It states in para 3 that "Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products..." It is thus possible for innovations of traditional and local peoples to be protected. Patents, utility models, trademarks, industrial designs, geographical indications and trade secrets have therefore been extensively used to protect traditional knowledge subject matter. Article 7 also provides for the protection of collective marks belonging to associations the existence of which is not contrary to the law of the country of origin, even if such associations do not possess an industrial or commercial establishment.

Many materials developed in traditional context have been successfully patented under the existing IP system. These include formulations of traditional medicines that show synergistic or new effects, extracts from plants and animals, process technologies, agricultural and



industrial tools, plant varieties, nutritional formulations and ecological managements systems. The key to realizing benefits from the existing IP rights is the understanding of how the IP system works and identifying those kinds of traditional knowledge that can be protected.

The relationship between traditional knowledge and IP rights has however become the subject of many debates. Many incompatibilities have begun to surface as a result of increasing misappropriation and bio-piracy. It is also argued that the existing IP systems increase the risk of misappropriation and therefore, may be partly responsible for the loss of traditional knowledge. There is also concern that the current IP regimes fail to provide positive incentives for local and traditional communities to preserve and, if they wish, to capitalize on the traditional knowledge. It is clear that existing IP instruments such as patents are largely inappropriate to protect traditional knowledge: they are often expensive and difficult to access, and are unable to safeguard traditional knowledge that is often communally held and passed through generations. Other forms of IP instruments such as geographical indications, copyrights and trademarks may offer some promises but their effectiveness have proven to be limited. Furthermore, it is also

held that the existing IP rights are not suitable for the protection of traditional knowledge due to its holistic nature, and the fact that it has generally been free-flowing and not bound by space and time.

There are a number of obstacles that have been identified in applying the existing IP regimes to protect traditional knowledge. These include the difficulty of identifying ownership (most traditional knowledge is held by the community at large), the long period of time the knowledge has existed, IP rights are protected for a limited time and the requisite legal standards for IP Protection (such as novelty and inventive step in industrial property law) which some traditional knowledge may not easily satisfy. The utilitarian objective of the IP system also presents some difficulty for protecting traditional knowledge which is deeply embedded in the social and religious life of the communities.

CREATING AN INTERNATIONAL SUI GENERIS SYSTEM

A *sui generis* option has been suggested by many interested parties as the most appropriate alternative for the protection of traditional knowledge. In this case, *sui generis* (the

Latin for, "of its own kind") indicates that the protection granted exists independently of other categorizations (such as existing patent, copyright or trademark systems) because of its singularity. Such a system would enable a focus on defining values and standards that could be applied to the protection of traditional knowledge. The need for sui generis protection of traditional knowledge arises from the perceived shortcomings of the existing IP system. Potentially, a sui generis system could be defined and implemented differently from one country to another. In addition, a sui generis system may adopt measures of protection specific to traditional knowledge.

In spite of the efforts made to provide a comprehensive sui generis framework for protecting traditional knowledge, a number of constraints need to be overcome. These are problems of dysfunctional equivalence of terms, the legal doctrine that could form the basis of protection of traditional knowledge, scope of the subject matter, formal requirements for acquisition of rights, substantive eligibility for protection and limitation of rights (15). In countries of the African Region, the expertise in legal drafting required under a sui generis system, the lack of public enlightenment and institutional structures are some of the major constraints in the design and implementation of an effective administration and enforcement of *sui generis* protection of traditional knowledge.

USE OF CUSTOMARY LAWS AND PROTOCOLS

For many traditional knowledge holders, their own customary laws should form the basis of the legal protection of their traditional knowledge. A number of existing sui generis systems utilize references to customary laws and protocols as an alternative or as a supplement to the creation of modern IP rights over traditional knowledge. For example, the African Model Law (16) and the sui generis laws of Peru (17) and the Philippines (18) incorporate by reference certain elements of customary laws into the sui generis protection of traditional knowledge. The relation between modern sui generis laws and customary laws ranges between two principles: on the one hand, independence of the rights granted by the modern and traditional systems, and on the other, the direct recognition by the state of rights as they are enshrined and protected under the customary law found in the concerned local and traditional communities, whether such law is written or not. One important function of customary law is to

determine ownership of elements of traditional knowledge, other responsibilities and equitable interests associated with traditional knowledge, rights of customary use of traditional knowledge that should be permitted to continue (and indeed encouraged) under a traditional knowledge regime, and entitlements to share benefits from the use of traditional knowledge. Customary law may help clarify how these various rights and entitlements are identified and distributed within traditional communities.

At the community level, customary laws and protocols continue to be maintained and form part of the legal systems which rule daily life including distribution of communal work and access to biological resources (19). This legal system has been transmitted orally from generation to generation and has been used to regulate various forms of traditional medical knowledge and the use of traditional medicines. Even though customary laws of traditional communities have been recognized in different constitutions in countries of the African Region, there is no precise definition. The International **Labour Organization Convention** 169 (20) recognises the rights of indigenous peoples to conserve their customs and institutions and provides that when applying

national legislation, customs and customary law should be taken into account without necessarily defining what is understood by customs or when customary law is required. Unfortunately, the lack of impact of customary laws on African traditional medicine has led to high levels of secrecy by THPs. These secret behaviours of the Practitioners are attributable to lack of effective protection system and low levels of income generated from their practise. It has however been argued that within traditional communities, the customary laws and protocols have rather enabled THPs to succeed in various medical applications, among them are bone setting, child delivery, herbal medicine and inoculation. The implication is that there is need to conduct intensive research into the activities of this group as contributors to economic growth (21).

It is commonly reported that traditional societies often have highly-developed, complex and effective customary systems for protecting traditional knowledge. This approach has therefore been put forward as possessing long standing mechanisms for producing some practical measures for traditional knowledge protection. The shortcomings, however, in this option is that it is based on inadequate enforcement measures and adherence to

them are seen as a voluntary matter. The challenge to the use of customary laws and protocols relate to the creation of an international practice and the institutionalisation of such laws in national legal systems.

INTERNATIONAL AND REGIONAL CONTEXT

International and Regional organizations dealing with the issues of IP and traditional knowledge have over the years engaged themselves to find answers to the complex issues involved in the legal protection of traditional knowledge. Policy objectives and principles relevant to the protection of traditional knowledge are under discussions in international forums to provide the foundation and elements for the development of international instruments to protect the knowledge and its manifestations. World The Intellectual Property Organization (WIPO), a specialized UN body with the mandate to deal with IP matters has for the past 9 years engaged its member states on international norm setting for the Protection of traditional knowledge. At the Sixteenth Session of the Intergovernmental Committee on IP and genetic resources, traditional knowledge and Expressions of Folklore (IGC) that took place in Geneva from 3

to 7 May 2010, the Committee agreed to undertake text-based negotiations with the view to developing international instrument or instruments for the protection of the resources by 2011 (22). This historic decision will enable for the establishment of an international framework for the protection of traditional medicines.

Efforts by international organizations such as the United Nations Environmental Programmes' Convention on Biological Diversity (CBD), the Food and Agricultural Organization (FAO), the World Trade Organization (WTO), the WHO and United Nations Conference on Trade and Development (UNCTAD) have all developed frameworks or are in the process of doing so

in their quest to providing a comprehensive protection for genetic resources, traditional knowledge and expression of folklore. At global level, the 61st and 62nd World health Assembly adopted the Global Strategy on Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property in 2008 (23).

The OAU Model Law (14) was developed in 2002 and WHO has developed four documents with effective participation of the WHO Regional Expert Committee on traditional medicine, African Union's Scientific and Technical Research Commission, the African Regional Intellectual Property Organization (ARIPO) and l'Organisation Africaine de la Propriété Intellectuelle (OAPI). These documents are Tools for documenting African traditional



medicine, Guidelines on Policy (24) and Regulatory Framework for the Protection of traditional Medical Knowledge and Access to Biological Resources (25) as well as Public Health, Innovation and IP: Regional Perspective to implement the GSPOA (26) adopted by the 59th session of WHO Regional Committee for Africa. It has been widely stressed that any protection for the benefit of traditional knowledge holders should be both effective in practice and tailored to the specific needs and resource constraints of the communities. It should also ensure that the necessary institutional mechanisms including capacity building, documentation initiatives and infrastructural development will enable for realization of the economic potential of the resources.

For its part, ARIPO and its sister organization, OAPI, have developed harmonized Regional legal instruments for the protection of traditional knowledge and expressions of folklore. These instruments cover all manifestations of traditional knowledge including traditional medicines and have been used as a basis for the international normative process at WIPO. The OAPI instrument was adopted through a Diplomatic Conference in 2007 while ARIPO Protocol on the Protection of traditional knowledge and Expressions of Folklore were due to be adopted at a Diplomatic Conference at Swakopmund, Namibia from August 9 to 10, 2010 (3). ARIPO has also developed draft regulations for implementing the ARIPO Protocol on traditional knowledge and Expressions of Folklore, which will be adopted by the Administrative Council at its Thirty-fourth Session in November, 2010 (27). These instruments address issues on trans-boundary traditional knowledge, Misappropriation, Bio-piracy, Illicit claim on traditional knowledge in patent application, Prior Informed Consent (PIC), Benefit Sharing and Commercial and Industrial uses of the knowledge and its associated genetic resources. The Protocol has been used as a model for national policy and legislative initiatives in Botswana, Ghana, Kenya, Malawi, Mozambique, Namibia,, Uganda and Zambia.

The Protocol aims to provide protection for the holistic forms of traditional knowledge that have been generated, maintained and transmitted from generation to generation. It recognizes the intrinsic value of traditional knowledge including its intellectual, scientific, medical, technological and industrial values. The protection under the Protocol will also encourage and reward authentic creativity and innovation resulting from traditional knowledge systems.

The Protocol has also addressed the issues of misappropriation, bio piracy and unlawful grant and exercise of IPRs over traditional knowledge and its associated genetic resources. It will also empower ARIPO to administer traditional knowledge that are multi-cultural in nature and cuts across national boundaries - the so-called "regional traditional knowledge'. For example, if a traditional knowledge is held by one community that extends across national borders such as the case of *Hoodia*, the appetite suppressant, which is held by the San tribe in Botswana, Namibia and South Africa, then the community will need to have its rights recognized in each of the different countries in which the community dwells. This would raise the question of whether the community would have the same legal protection in the different jurisdictions. In this case, the ARIPO Protocol provides a regional mechanism for the administration and management of such rights.

CHALLENGES FACED BY MEMBER STATES

Challenges include:

(a) The oral nature of the knowledge transmitted in various forms from past generations, which are largely shared in

- unstructured contexts. This has made it largely invisible to the development of the community and to science. However, there is need for documenting and verifying this knowledge and this requires collaboration between modern and THPs. so that they can develop a framework for deciding which herbal medicines are valid and putting in place an education scheme for effective contribution of THPs to mainstream healthcare (28).
- (b) The formalities or registration of the knowledge by a competent authority (29). This challenge can only be overcome if national legislations on the protection of traditional knowledge are operationalized to provide best practices. Identifying appropriate right holders has been generally considered one of the most difficult elements in establishing effective IP protection for traditional knowledge especially regional traditional knowledge. Countries have taken diverse approaches to this aspect of traditional knowledge protection. Most IP rights are originally vested in the individual originators, who can then transfer their rights through contracts or legal arrangements. But traditional knowledge is generally understood as a
- collective product of the community even though individual traditional knowledge holders may have distinct personal rights within the community structure. This ownership question has engaged international community for some time and forms part of the contentious issues that have not been fully resolved.
- (c) The utilization and commercialization of the technologies associated with the knowledge, the lack of international standards and harmonized frameworks on the protection of the knowledge.

THE WAY FORWARD

As we strive to develop a comprehensive framework and strengthen our capacities to safeguard, protect and develop traditional knowledge, action will be required to:

1. Develop well-considered legislative framework and/or complementary arrangements to protect traditional knowledge that recognize the collective nature of local innovation, promote its documentation, development and application, encourage individual innovation within this community framework,

- and shield biodiversity and traditional knowledge from privatization.
- 2. Establish institutional structures needed for effective protection and utilization of traditional knowledge through the establishment of regional measures to administer and enforce transboundary and multicultural traditional knowledge, the establishment of supportive mechanisms and capacity building activates at the country level as well as the development of registries and databases on traditional knowledge.
- 3. Coordinate and develop partnerships among stakeholders and communities to present a united body of opinion.
- Create awareness especially among traditional holders including Traditional Health Practitioners on their rights and obligations.
- 5. Efforts should be made by Governments in the African Region to integrate traditional medical practice into the Health Delivery System as a matter of urgency.

CONCLUSION

Some developing countries have taken steps to establish *Sui generis* system of protection of

traditional knowledge including traditional medicines and would be important for countries in the African Region to take initiatives to protect African traditional knowledge for the exploitation by the knowledge holders. There is the need to develop appropriate policies and legislative frameworks to enable custodians of traditional knowledge to derive maximum benefits from their knowledge. In our quest to realize this noble objective, it would be critical for

countries in the African Region to establish institutional structures to support the protection, documentation, development and promotion of the innovation and creative aspects of the knowledge. Strengthening the innovative capacity of traditional and local communities to further develop their traditional knowledge can offer potential for addressing problems for rural and urban development. It would be essential for national governments to create special

supportive mechanisms and enabling environment to facilitate collaborative research on useful herbs and traditional medicines, exchange of experiences and skills among local communities and commercialization of traditional knowledge-based innovative products including traditional medicines. This would generate the economies of scale needed for national development and poverty alleviation.

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NEWS AND EVENTS

GUIDELINES FOR THE PREVENTION AND CLINICAL MANAGEMENT OF SNAKEBITE IN AFRICA

Snakebite is a neglected public health problem. Rural populations are frequent victims as they go about their daily food production and animal-rearing activities and even as they enjoy the comforts of their home lives.

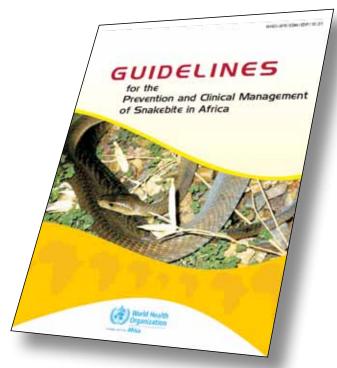
Unfortunately, many of these snakebite cases go unreported and thus do not appear in official epidemiological statistics. Health workers often have little or no formal training in the management of snakebite, and appropriate antivenom is rarely available. Therefore, the World Health Organization's Regional Office for Africa has developed Guidelines for the prevention and clinical management of snakebite in Africa with contributions from technical experts.

The guidelines are designed to provide useful information and guide the work of various levels of health workers in dealing with snakes and snakebite to improve medical care for snakebite victims. Some sections of the guidelines provide useful and easily understood information for the general public on topics such as snake characteristics and distribution, prevention of snakebite, first aid in case of snakebite, easily observable venom effects in a snakebite victim, and what not to do in case of snakebite.

The guidelines discuss snakes, snake venoms and snakebites and their consequences with emphasis on those causing serious envenoming or the so called medically important snakes. The volume contains over a hundred photographs of snakes, clinical signs of envenoming and the consequences. Various annexes provide further information on such topics as the geographical distribution of African venomous snakes, as well as their classification, habitats and clinical toxinology.

The guidelines also mention traditional practices and beliefs in relation to snakes and snakebite. They emphasize the fact that there are no scientifically proven traditional antidotes to snake venoms. However, in many rural settings, traditional healers may have a good knowledge of snakes within their environment and they can be useful resource persons in the conduct of community education programmes about snakes and snakebite. Therefore, research should continue to develop more knowledge on effective traditional antidotes.

The guidelines can be accessed through the following website: http://www.afro.who.int/http://www.afro.who.int/en/divisions-a-programmes/dsd/essential-medicines/highlights.html



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AFRICAN TRADITIONAL MEDICINE LOGO

The WHO Regional Office for Africa developed the African Traditional Medicine logo in collaboration with schoolchildren who participated in a logo contest. The logo was unveiled in October 2003 at the WHO Regional Office in Brazzaville.

In the logo, the map of Africa denotes African ownership of African Traditional Medicine. Superimposed is the medicinal plant Catharantus roseus (Madagascar periwinkle, rosy periwinkle or Vinca rosea), which is native to Madagascar. This represents the main raw materials used in traditional medicine. The green of the map of Africa denotes the rich African biodiversity. The blue colour surrounding most of the African continent represents the bodies of water which are additional sources of traditional medicines. The golden ring which encircles all the other elements is a reflection of the golden competitive advantages that African Traditional Medicine offers with potential impact on the health, economy and development of African communities. The logo is now being used in advocacy materials on African traditional medicine.



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