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Regulatory framework for local production of herbal medicines in Africa
Boletín Latinoamericano y del Caribe de Plantas Medicinales y Aromáticas, vol. 8, núm. 1, 2009, pp. 1-6
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Available in: http://www.redalyc.org/articulo.oa?id=85680102
Regulatory framework for local production of herbal medicines in Africa

[Marco Regulator de la producción de Medicamentos Herbales en África]

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Abstract
In most parts of Africa, herbal medicines are formulated in small quantities and sold in open markets and stores without appropriate regulation by Government authorities. Most herbal products sold in public places lack scientific evidence for safety, efficacy and quality. Only 8 countries out of 34 that responded to WHO survey (WHO, 2002) had national regulations on Traditional Medicine. In response to this deplorable situation, the WHO has developed generic guidelines on various aspects of the development of herbal medicines including generic regulations and law. In a few countries, the situation is changing. This paper will present case studies on the regulatory situation on local production of herbal medicines in Ghana, Republic of Benin, Egypt, Nigeria and South Africa.

Keywords: Regulatory affairs, Phytomedicines Africa, Ghana, Egypt, Nigeria, South Africa, Benin.

Resumen
En gran parte de África, los medicamentos herbales se formulan en pequeñas cantidades y se venden en mercadillos y tiendas sin la apropiada regulación por parte de las autoridades gubernamentales. Muchos de los productos herbales vendidos al publico carecen de evidencia científica de eficacia, Seguridad y calidad. Solo 8 países de los 34 de este continente respondieron a la reciente encuesta de la OMS (2002) que disponían de regulaciones en materia de Medicina Tradicional. En respuesta a esta deplorable situación, la OMS ha desarrollado guías generales en varios aspectos del desarrollo de medicinas herbales incluyendo regulaciones y leyes modelo. En unos cuantos países la situación esta cambiando. En este artículo se presentan casos-estudio de la situación reguladora local sobre medicinas herbales en la Republica de Benin, Egipto, Nigeria y Sudáfrica.

Palabras Clave: Regulación, Fitomedicinas, África, Gana, Egipto, Nigeria, Sudáfrica, Benin.

Received | Recibido 21 December 2007;
Accepted in Corrected Version | Aceptado en version Corregida: 31 December 2007;
Published Online | Publicado en Línea: 30 November 2008

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INTRODUCTION

A survey conducted by the Roll Back Malaria of WHO in Ghana, Nigeria, Mali and Zambia in 1998 indicated that about 60% of children who had symptoms associated with malaria infection were treated with herbal medicines. Generally, the WHO estimates that about 80% of people living in Africa use traditional medicines for the management of their prevailing diseases (WHO, 2002). Furthermore, about two thirds of AIDS patients in developing countries use traditional herbal medicines (UNAIDS Report, 2002). This situation may be due to accessibility, affordability, availability and acceptability of traditional herbal medicines by majority of the population in developing countries. In addition, in spite of various interventions by development partners and some national governments, majority of AIDS patients have no access to standard care of management in Africa. Such a situation leaves the patients with only one option which is to use herbal medicines. Figure 1(WHO, 2005) shows that 99 out of 120 countries surveyed classified herbal medicines as over the counter products making them easily accessible to the public. The significant role of traditional medicine in public health care delivery system in Africa underscores the various documents developed and capacity building workshops organized by WHO. For example, promotion of local production of standardized herbal medicines is a priority intervention by the WHO Regional Office in Africa. This paper will briefly review the status of local production of herbal medicines and the existing regulatory frameworks in selected countries in Africa.

SOUTH AFRICA

The Bill/Law for regulating Traditional Health Practitioners (THPs) which is part of Complimentary and Alternative Medicine (CAM) was approved by parliament in 2004 (personal communication, Medicines Control Council, Department of Health, South Africa). Subsequently, a separate Bill on African Traditional Medicine was developed which was subjected to mandatory review processes by stakeholders. Presently, formulated African traditional medicines (ATMs) are regulated as nutritional supplements. Over 1,500 herbal products were received by the Medicines Control Council (MCC) of the Department of Health and listed for purposes of monitoring. The MCC would only consider an African traditional medicine for registration after appropriate clinical trials have been done with evidence of safety and efficacy. At the moment, most CAM products are imported from India and China. However, many African traditional medicines are locally manufactured by pharmaceutical companies usually on contract basis and marketed as nutritional supplements. ATMs which target HIV/AIDS patients are marketed as immune boosters and are usually fortified with some relevant vitamins, minerals and amino acids. It has been estimated that the annual turnover of CAM in South Africa was about 2 billion rands (about $90 million) while the corresponding figure for essential conventional medicines was about 10 billion rands (about $ 450 million) in 2005 (personal communication, Medicines Control Council).

Both BIOMOX Pharmaceuticals (Pretoria) and WRAPSA (Pty) Ltd (Pretoria) were duly registered by MCC to produce medicines and operate in accordance with Good Manufacturing Practice (GMP). They both operate essentially as contract manufacturers. The companies are regularly inspected by MCC and had received ISO 9002 certification. WRAPSA manufactures about 150 products while BIOMOX produces over 400 products. The companies have unutilised production capacities. A few of ATMs used in South Africa include immuno-active, products. The Council on Scientific and Industrial Research (CSIR) is actively involved in the research and development of herbal medicines. Similarly, Universities (notably, Pretoria, Cape Town, Western Cape, etc) routinely conduct research on herbal medicines. On the other hand, the Medical Research Council is actively involved in conducting clinical trials of herbal medicines. The main challenges include articulating appropriate guidelines for collaboration between researchers and traditional health practitioners, developing regulations on African traditional medicines and resources for researchers and THPs to undertake appropriate pre-clinical and clinical studies prior to registration of African traditional medicines.

REPUBLIC OF BENIN

The Traditional Medicine policy was adopted in 2002. Subsequently, a Traditional Medicine Programme in the Ministry of Public Health with a Director was established thereby providing the administrative structure for implementing Traditional Medicine programme within the Ministry of Public Health. There are 14 Medicinal Plant Gardens located at different ecological zones in Benin. The Gardens
were established by Government in collaboration with the THP Association. The Gardens are managed by THP under supervision of the Ministry of Public Health. There is limited production of herbal medicines for management of malaria, HIV/AIDS, sickle cell disorder, diabetes and hypertension. However, there is no commercial production of herbal medicines. Centre de Medecine Traditionelle Experimentalle, Takpe developed anti-malarial herbal medicine used widely in Benin and exported to Guinee Bissau, Ghana, Togo and Zimbabwe. The Centre collaborates with institution in France on scientific validation of the product. In addition, Antipolyvirus, VK500 and fagaracyte is used for the management of sickle cell disorder while Teinture here da ło and Akitoby are used respectively for the management of AIDS-related opportunistic infections and diabetes. Interestingly, spirulina is locally produced in Benin in commercial quantities for management of malnutrition in children and as adjuvant in the management of sickle cell disorder, HIV/AIDS, malaria and diabetes. Spirulina is also cultivated at the site of production. Spirulina is widely used in Benin and exported to Niger and Togo.

The main challenges include adequate resources to maintain the Medicinal Plant Gardens (e.g. security services, appropriate equipment and sinking of bore holes). Small scale formulation tools like grinders, mixers and packaging items, are also lacking. There is an urgent need to engage in commercial cultivation of useful and widely used medicinal plants which are being depleted at a fast rate. Training in GMP principles will be necessary when facilities for commercial production of herbal medicines are in place.

EGYPT

Herbal medicine is officially recognized. The national registration requirements for herbal medicines are published. There are four pharmaceutical companies which are engaged in the manufacture of herbal medicines in accordance with GMP. The products are formulated into conventional dosage forms and they are generally well packaged. Herbal medicines are manufactured by MEPACO, SEKEM, ROYAL and NERHADOU. Apart from Nerhadou which is involved in contract manufacture, the rest also maintain large farms for the cultivation of medicinal and aromatic plants. The products of these four companies are marketed internally and exported to Arab countries, Europe and USA. The main herbal medicines of SEKEM Viscum & Fraxini2 used for the management of HIV/AIDS and Cardioton & Atroplex which are used for managing hypertension. ROYAL manufactures Royatens (Hypertension) and Royabetes (diabetes Type 2). MEPACO produces Immulant caps, Immulant C, Immulant Plus which are marketed for the management of HIV/AIDS. Mibaroze & Wheat germ oil (hypertension), Diaglu (diabetes) are manufactured and marketed by Alleurosa. It is remarkable that all the herbal medicines have not been patented. The companies chose to use trade names thereby risking the intellectual properties of their products.

KENYA

The Traditional Medicine Policy is actively being developed. The process has engaged all the stakeholders. Consequently, there are no regulations on Traditional Medicines until the policy is adopted. The complimentary and alternative medicines in the market are essentially imported from India and China.

GHANA

The Traditional and Alternative Medicine Directorate (TAMD) of the Ministry of Health is responsible for policy, institutional and regulatory aspects of traditional medicine. Traditional Medicine Practice Act 575 was adopted in 2000. The directorate has organised all the THP associations in Ghana into Ghana Federation of Traditional Medicine Associations (GHAFTRAM). Based on the National Traditional Medicine Policy, a second National Strategic Plan for the Development of Traditional and Alternative Medicine (2005-2009) was developed. Food and Drugs Board is responsible for registration of herbal medicines for sale in Ghana, monitors advertisements on herbal medicines, issues manufacturing and export licenses of herbal medicines and conducts GMP audit inspection on manufacturing premises. On the other hand, Ghana Standards Board (GSB) is responsible for setting standards for all goods locally manufactured. The Centre for Scientific Research into Plant Medicine (CSRPM) is principally engaged in conducting research into medicinal plants and undertakes quality, safety and efficacy assessments of herbal medicines.
Table 1. Number of Herbal Medicines per manufacturer

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<th>Products</th>
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Figure 1. Regulatory Status of Herbal Medicines in some WHO Member States (WHO, 2005).

Figure 2. Drugs Used for Producing Traditional Medicines in Nigeria.
Furthermore, safety and efficacy assessments of herbal medicines are undertaken by Noguchi Memorial Institute of Medical Research (NMIMR).

There is a National Centre of Pharmacovigilance which routinely conducts safety monitoring of all medicines including herbal medicines. The plant raw materials are collected essentially from the wild. Herbal medicines are produced and marketed by THPs, private entrepreneurs, government institutions, NGOs or imported from India, USA, China, Korea and Egypt. Government supports CSRPM to produce herbal medicines while all other producers of herbal medicines make their own financial arrangements. The challenges include resources and procedures for intellectual property matters, expertise in clinical trials management and resources for research institutions to conduct quality, safety and efficacy studies. Furthermore, active involvement of the private sector through a public private partnership mechanism is at its infancy and poses a challenge.

NIGERIA

The Traditional Medicine policy was adopted in 2005 while the Traditional Medicine Bill was prepared, reviewed by stakeholders and approved by Federal Executive Council in 2006. The Traditional Medicine Bill is pending ratification by the National Assembly. There is a Deputy Director in the Federal Ministry of Health who is responsible for Traditional Medicine programmes. The National Agency for Food Administration and Control (NAFDAC) has developed guidelines for registration of herbal medicines. The agency has listed over 53 herbal medicines. The Nigerian Herbal Pharmacopoeia has been developed in collaboration with the World Health Organization and would be published in 2008. The National Pharmacovigilance Unit was established in 2005 under NAFDAC. Table 1 shows the number of herbal medicines being manufactured locally. Figures 2 and 3 respectively show the plant parts used and the major outlets of herbal medicine products.

The local manufacturers of herbal medicines include Health Forever Product Ltd, Amelia Organise Ltd, Kolaq Herbs Ltd, Eniola Naturalist Care, F. A. Ike & Sons Ltd, African Herbal Med. Nig. Ltd, Dr. Katoka W/A Ltd, Complete Herbal Clinic, Teez-Freez Nig. Ltd, Amexco Co. Nig. Ltd, Mister Guarantee Ltd, Temitayo Natural Clinic, Dr. Piles & Son Nig. Ltd, Channel Mich. Nature Cure, OM-Wonder Link Nig. Ltd, (Homoeopathy) Finni Int. Nig. Ltd, U.J. Abraham Nig. Enterprises, Yem-Kem Int. Nig. Ltd.

The quality assurance systems embracing plant materials, processing, standardization and formulation required to be closely monitored to guarantee the consistent quality of herbal medicines registered by NAFDAC. Most of the plant raw materials are collected from the wild. Consequently, the quality of the plant raw materials may vary due to ecological factors and weather which make it mandatory to institute regular standardization procedures for all batches covering both chemical and biological fingerprints. Commercial cultivation and acceptable harvesting practices which will promote sustainability of the plants present serious challenges. Furthermore, local production of registered herbal medicines generally does not adhere to GMP principles.

CONCLUSIONS

The registration requirements developed by WHO, in collaboration with the national drug regulatory authorities, constitute generic elements which can be adopted by WHO Member states. Countries like Ghana, Nigeria and Mali, among others, that have adopted the guidelines are making reasonable progress vis-à-vis promotion of traditional medicine. Such countries have developed appropriate regulations to guide the national drug regulatory authorities to perform their responsibilities effectively. Training and strict adherence to the WHO Good Laboratory Practice principles will enable researchers in Africa to generate quality research data based on leads obtained through a robust data on indigenous medical knowledge (IMK). An important challenge facing researchers in Africa is management of clinical trials of standardized herbal medicines. The national drug regulatory authorities will not consider a new herbal medicine for registration unless the dossier includes clinical data regarding its safety and efficacy. Subsequently, any registered herbal medicine can be produced locally in accordance with GMP principles. The significance of quality management system needs to be emphasized to guarantee the quality of each batch of herbal medicine produced. The quality of herbal medicines marketed is profoundly influenced by the functional status of the regulatory/legal framework established by the Government. In the interest of the public, an efficient surveillance system utilizing post – marketing pharmacovigilance programme within the public health system will identify adverse drug reactions to the new herbal medicines among the unsuspecting general public who use them. Adequate resources are crucial to the establishment of an efficient regulatory
environment for the local production of herbal medicines. It is noteworthy that WHO has organized various training workshops and developed good quality capacity building documents which are mandatory for capacity building of professionals engaged in regulating the local production of herbal medicines. An important development which is crucial to the development of traditional medicine in Africa is private public partnership (PPP) initiatives. The PPP mechanism is still at early stages in Africa. It is noteworthy that the governments of Nigeria and Ghana are very keen to engage PPP mechanisms in their macro economic development strategies.

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