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Review Article

Overview of regulations on medicines derived from traditional Pharmacopoeia in Benin and Burkina Faso

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Abstract

The success of the promotion policies of the Medicines Derived from Traditional Pharmacopoeia (MDTPs) requires a regulation that is adapted to realities and guarantees their quality, efficiency and safeness. This study aims to analyze the legal texts and the current guiding principles obtained from the heads of the departments in charge of traditional medicine in Burkina Faso and Benin.

The documents collected from the two countries have been analyzed comparatively and also in relation to WAEMU regulations and the WHO recommendations.

Several texts, dealing with the activity, products, facilities and advertisement related to traditional medicine, have been recorded in both countries. The regulation battery of Burkina Faso is more extensive than that of Benin, especially on traditional medicine and pharmacopoeia facilities. In addition, unlike biomedicines, the West African Economic and Monetary Union (WAEMU) and the West African Health Organization (WAHO) have not yet passed community laws on MDTPs.

To limit disparities in legal frameworks between the countries of the same sub-region, it is important that the WAEMU or WAHO be involved in the harmonization of pharmaceutical regulations by setting Community rules in the domain.

Keywords: WHO, MDTPs, WAEMU, WAHO, Traditional medicine, medicine, regulation, Burkina Faso, Benin

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1. Introduction

The access of populations to quality medicines is a major public health issue in developing countries. (1-4) In Africa, about 80 % of the population use "traditional medicine" either alone or alongside with "biomedicine". (5,6) This explains why traditional medicine is increasingly taken into account in health policies of African countries. (7-9) Indeed, starting from 1970, several national promotion initiatives of traditional medicine such as designing national policies, national strategic plans, regulations framework and training of actors, as well as the annual celebration of the world traditional medicine day have become realities. The initiatives benefited from the assistance of the World Health Organization (WHO), African Union (AU), African Intellectual Property Organization (AIPO) and sub-regional components. (1-3,10,11) They permitted to qualitatively improve the activity of traditional medicine, the medicine preparation practices as well as their approval. (1,3,12) It is the case of products such as MEYAMYCIN in the Democratic Republic of Congo, GUINEX-HTA in Guinea Conakry, FACA in Burkina Faso, MADEGLUCYL in Madagascar, API-PALU in

Benin, etc. (13,14) Thus, by 2012, thirteen African countries had issued Marketing Authorization (MA) of Medicines derived from traditional pharmacopoeia (MDTPs) and seven had included some of these products on their national lists of essential medicines. (2,15,16)

It is in this context that Burkina Faso and Benin, two WAEMU countries, at different levels, have gradually set up systems to regulate the practice and traditional medicine facilities, the production, approval and advertisement of the products derived from traditional medicine.

This study aims at analyzing the domains concerned and the relevance of the regulations in the two countries.

2. Health Systems in Burkina Faso and Benin

The context of this study is Burkina Faso and Benin, two francophone countries located in the heart of West Africa and having similar health systems. Their health systems are organized in public, private and traditional subsectors. As the other subsectors, the traditional one benefits from the assistance of the Health Ministries through national policies and strategies. (8,9,17)

The collection of regulations has been carried out from May 2016 to July 2018 in offices of the Health Ministries which were:

- in Burkina Faso, the Department in charge of the promotion of traditional medicine and the Office of the Regulations and pharmaceutical authorizations;
- in Benin, the national program for pharmacopoeia and traditional medicine and the office of pharmacies, medicines and diagnostic explorations.

The documents collected from the two countries have been analyzed comparatively and also in relation to WAEMU regulations and the WHO recommendations.

The data collection has been carried out in the framework of the distribution of MDTPs that was approved by the Ethics Committee for Health Science Research (Deliberation n° 2016 - 5-064, May 4, 2016) of Burkina Faso.

3. Result & Discussion

International and regional regulation contexts

In the 1978 Alma Ata statement, the WHO recognized traditional medicine and traditional healers as important partners for the attainment of the objective "Health for all" and encouraged their promotion in countries, particularly in Africa. (18)

The regulations on traditional medicine in African countries like Benin and Burkina Faso have then been made on the basis of statements, resolutions, strategies and guiding principles of the WHO and sub-regional organizations. (2,11, 17) Indeed, the WHO has adopted guiding principles for registering traditional medicines and the 2014 – 2023 traditional medicine strategy, respectively in 2010 and 2013. In the sub-region, the AIPO designed a frame of reference for the harmonization of the approval procedures for MDTPs in 2003. The WAEMU, which does not yet have specific regulations on the approval of plant based medicines or those deriving from traditional medicine, has however adopted in 2010 a decision on guiding principles for approval of food supplements, including plant based ones. (19,20)

The analysis of national regulations successively dealt with medicine and traditional pharmacopoeia in general, the practice, production, marketing, distribution, facilities and advertisement.

Traditional medicine and pharmacopoeia

In Burkina Faso, the activity of traditional medicine was accepted in 1970 by the ordinance N°70-68 bis/ PRES/PSP/AS of December 28, 1970 and its organization has been stated in the 1994 Public Health Code. (21) In Benin, ordinance n°75 -7 of January 27, 1975 related to medicine regulations in Dahomey authorizes "healers to prepare, package and sell any drug, substance or medicinal mixture meant for traditional medicine". (22)

Afterwards, institutional systems were set up to manage traditional medicine. Thus, in Burkina Faso, the decree N°2000-009 / PRES /PM /MS /MCPEA /MECV / MESSRS of January 26, 2000 creates and organizes the functioning of a national committee of traditional medicine and pharmacopoeia. (23) To facilitate the work of this authority, the technical commission for examining applications for authorization of traditional medicine practice was set up through a 2013 order. (24) In Benin, the decree 2001-036 of February 15, 2001 sets the ethics principles and conditions of traditional medicine practice. It states the national committee for assistance and monitoring of activities for the promotion of traditional medicine and pharmacopoeia as the national authority in charge of examining and issuing recommendations on the authorizations for the practice and opening of traditional medicine promotion centers. (25) However, it is only in 2017 that the competence, organization and functioning of this authority renamed "National Committee for the regulation of traditional medicine in Benin" were determined through an order. (26)

Practice of traditional medicine

In Burkina Faso, the order N°2013 -552-MS/CAB of June 21, 2013 related to the terms of traditional medicine practice, recognizes as traditional healers the following people: the naturotherapist, the traditional midwife, the ritualist, the chirkinesitherapist, the herbalist, and the medicodrug therapist. To avoid any confusion, the order defined each of these categories of traditional healers. (27) The 2001-036 decree of February 15, 2001 sets the ethics principles and the conditions of traditional medicine practice in the Benin Republic. It recognizes in its article 06, the traditional healer, the traditional midwife, the herbalist and the seller of animal and mineral extracts as the actors of traditional medicine. (25) Unlike Burkina Faso, it does not define the different categories of traditional healers but speaks of an order of the Ministry in charge of public health which will

specify their domains of competence. Until now, that order is not yet issued, thus creating a gap in the law.

The 2001-036 decree of February 15, 2001 in Benin, in its article 12, also stipulates that "No one can practice traditional medicine if the person is not listed and registered according to their specialized fields at the Health Ministry." The decree N°2004 -568 /PRES/PM/ MS / MCPEA/MECV/ MESSRS of 12/14/ 2004 in Burkina Faso also requires this license to practice medicine. (28)

The above decrees also note the ethical and moral obligations of the traditional healer, mainly in practicing, advertising and collaborating with the biomedicine staff and the administrative authorities. The terms of this collaboration between practitioners of traditional and biomedicine was specified in the order N°2013 -551 /MS /CAB of 06/21 / 2013 related to the establishment, organization and functioning of a reference and resort system between traditional and conventional medicines. (29) This collaboration is still not formalized in Benin.

Products derived from traditional medicine and pharmacopoeia

Following the WHO guiding principles and the AIPO frame of reference (3,19), the Burkinabe and Beninese regulations distinguish four categories of MDTPs (30,31):

Category 1: any medicine prepared by the traditional healer for a patient and meeting the following characteristics:

- It is an extemporaneous preparation made according to traditional methods of production;
- The safeness and efficiency are guaranteed by the long-standing use of the product;
- The raw materials are well-known to the traditional healer and can be fresh or dry;
- The conservation time is generally short.

Category 2: any medicine derived from traditional pharmacopoeia and commonly used in the community and meeting the following criteria:

- Prepared in advance, packaged with a batch number;
- The production is standardized;
- The production is semi-industrial;
- The active principles of the medicine are natural raw materials whose chemical groups are known;
- Its efficiency and safeness are guaranteed by ethno-medical proof or through some open clinical tests if judged necessary by relevant authorities;
- The conservation time is set through stability tests.

Category 3: any medicine derived for traditional pharmacopoeia and commonly used in the community and meeting the following criteria:

- Prepared in advance, packaged with a batch number;
- The active principles are standardized extracts;
- The production is semi-industrial or industrial;
- It is made according to good production practices;
- Its efficiency and safeness are guaranteed through pre-clinical and clinical tests following standardized procedures;
- The conservation time is set through stability tests.

Category 4: any medicine from research institutes and having, in addition to the category 3 characteristics, purified molecules in its composition and a proportion specification.

Considering the terms of efficiency evidence described in these guiding principles and regulations, the MDTPs issued from medico-magical processes are not taken into account.

In Benin, the production of any medicine is governed by the provisions of the ordinance N° 75 -7 of January 27, 1975 related to Medicine regulations in Dahomey. In its article 4, it is stipulated that "the healers registered at the Provincial Health Department are authorized to prepare, package and sell all drugs, substances or medicinal compositions meant for traditional medicine." However, it is required that the resulting compositions be submitted to systematic studies by a medical-pharmaceutical research institute in order to ensure its safeness and determine its best dosage. (22) Before 2012, the preparation activities of all the medicines in Burkina Faso were also submitted to an order. (32) Later, a decree and its implementing order, adopted in 2012 and 2013, define the specific terms of opening and running of traditional medicine and pharmacopoeia facilities including the production of plant medicines. These terms contain the requirements of good practices of production and commitment of a responsible pharmacist. (33,34)

The approval of MDTPs in Benin is regulated by a recent 2017 order. (31) Previously, they were regulated by the December 31, 1997 decree n° 97 - 632 related to the terms of registration of medicines meant for human use in the Republic of Benin, then, by the Regulation N° 06 / 2010/CM/UEMOA related to approval procedures of pharmaceutical products for human use. (35) In Burkina Faso, the approval of these medicines is specifically controlled by the December 14, 2004 decree N°2004 -569 /PRES/ PM/MS/MCPEA/MECV/MESSRS and the July 6, 2005 order N°2005 -231/MS/CAB. (30,36) Unlike these two countries, until 2016, Algeria did not have any specific regulation for plant medicines but supplementary comments related to them. (37)

In the two countries, the regulation states that no MDTP can be exchanged for free or against payment if it has not received a marketing authorization except for category 1 medicines. (30,31,36) In this regard, some experts committees are formed to technically assess the approval applications. Then, national commissions for registering health products including MDTPs, give their final recommendations based on the work of experts committees. The competence and the quality of the

members composing these committees and commissions are specified through orders. (38-44)

The analysis of contents of the different regulations shows that their implementation scopes cover only plant medicines and MDTPs of animal or mineral origin are not taken into account.

In Benin, the distribution of MDTPs is regulated by the May 15, 1990 Act N° 90 -005 which sets the conditions of practice of any commercial activity. (45) That Act states that "except some products whose list will be established in an order of the Trade Ministry, the wholesale, semi-wholesale and retail trades must not be done by the same actor in the same store." In Benin, the distribution circuit of approved MDTPs is the same as that of biomedicines, going from the wholesale-distributor to the retailers that are the pharmacies, the hospital pharmacies and the authorized medicine sale storehouses. Until 2012, the legal distribution circuit of MDTPs in Burkina Faso was similar to the one in Benin. Indeed, the decree N°2012 - 1035 and the order N°2013 - 550 allow MDTPs distribution by facilities of sales or distribution of plant medicines and products (retail and wholesale), herbalists' storehouses, and medico-drugstores. (33,34) The distribution circuit in Burkina Faso is thus closer to the one recommended in the African region WHO guiding principles. Indeed, in its guiding principles, the category 2 MDTPs should be sold without prescription in the pharmacies, medicine storehouses and herbalists' storehouses that are duly recognized by the relevant national authority. Those of categories 3 and 4 should be prescribed by a health worker and distributed only in pharmacies. (46)

Traditional medicine and pharmacopoeia facilities

In Benin, the February 15, 2001 decree specifies in its articles 10 and 11 that the venue for the practice of traditional medicine is a Center for the promotion of pharmacopoeia created and managed by an association of traditional medicine practitioners. It is defined as "a health care center where the traditional medicine actors practice their art based on elements drawn from the vegetation, animals and minerals." This center is built inside or beside a public health facility and must have an opening authorization delivered by the health Ministry. (25) This model of working in association, which implies sharing of knowledge, is not always adapted to the African reality in which the traditional healer is often the sole recipient of an ancestral knowledge. (4) However, unlike pharmacies whose opening and transfer terms are specified through law (47), those of the pharmacopoeia promotion center have not yet been defined in the regulation.

In Burkina Faso, the December 28, 2012 decree N° 2012 -1035/PRES/PM/MS/MICA/MATDS/MEF defines five categories of traditional medicine and pharmacopoeia facilities: the traditional consultation and care office, the herbalists' storehouse, the medico-drugstores, the plant medicine preparation unit and the wholesale or retail shop of plant medicines and products. In addition, natural persons (traditional healers, doctors, nurses, pharmacist's assistants, pharmacists and researchers) and legal persons (health science research institutes, health non-governmental organizations, health professionals' associations) can aspire to the opening and exploitation license of traditional medicine and pharmacopoeia facilities. (33) Moreover, wholesale and retail sale facilities of plant medicines and products must be under the responsibility of a pharmacist. (34)

Advertisement on traditional pharmacopoeia products

In Benin, a 2004 interdepartmental order specified the advertisement conditions in relation with the traditional medicine and pharmacopoeia. It has been repealed because of abuses by the June 28, 2018 order N° 2018 -262 related to the prohibition of advertisement on medical professions, activities, medicines and other medicinal products. (48) In Burkina Faso, the provisions related to advertisement on facilities and medicines, including MDTPs, are stated in the public health code, the Act 080 on advertisement regulation, the May 20, 2010 decree N°2010 -244/PRES/PM/MS and its implementing orders. (49-53) Under Act 080, "any advertisement for the general public of pharmaceutical or traditional medicine products is forbidden unless it is authorized by the Health Ministry." This authorization is issued after a favorable recommendation of the Committee for medicine advertisement control whose competence and composition are defined through order. (49)

4. Conclusion

This work has permitted to describe and compare regulation frameworks related to MDTPs in Burkina Faso and Benin. It has shown the existence of substantial differences between these two neighboring French speaking countries, which are members of the same sub-regional organizations that are the WAEMU and the WAHO. This situation can create differences in the contribution of traditional medicine to the national health systems on the one hand, and on the other hand it can hinder the circulation of medicines in the sub-regional community. To limit these disparities, the harmonization process of pharmaceutical regulations in West Africa should take into account the MDTPs.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article. The authors are responsible for the conduct and reporting of this study.

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