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Study of Manufacturing Conditions of Medicines Derived from Traditional Pharmacopoeia in Benin and Burkina Faso

Étude des conditions de préparation des médicaments issus de la pharmacopée traditionnelle au Bénin et au Burkina Faso

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Abstract *Introduction*: Traditional medicine has become an important component in the care system of African populations. Many products derived from it are increasingly used in the therapeutic arsenal. This work is an inventory of the production of these drugs in two countries of West Africa, Burkina Faso and Benin.
Methods: A cross-sectional descriptive study that listed the drug manufacturing units producing medicines derived from the traditional pharmacopoeia (MDTP) identified by the health ministries in the two countries was carried out.
Results: Thirty-three production facilities, including 10 in Burkina Faso and 23 in Benin, were surveyed. Seven units surveyed in Burkina Faso and 16 in Benin were illegally installed. Only 16 of the 33 units obtain their raw materials from botanical gardens. The rest obtain theirs through picking which is not favorable to the perpetuation of the plant resource. In addition, among the 1041 MDTPs manufactured by the units surveyed, only 1.44% are registered. Finally, shortcomings in applying good practices for harvesting raw materials and manufacturing finished products were noticed.
Conclusion: Management and capacity building efforts of MDTPs production facilities by political authorities are still needed to optimize the contribution of traditional medicine to the health care of African populations.

Keywords Traditional medicine · Traditional pharmacopoeia · Drugs · Production · Raw material

Résumé *Introduction* : La médecine traditionnelle est devenue un maillon important du système de soins des populations africaines. De nombreux produits qui en sont issus sont de plus en plus utilisés dans l'arsenal thérapeutique. Ce travail fait l'état des lieux de la production de ces médicaments dans deux pays de l'Afrique de l'Ouest, le Burkina Faso et le Bénin.
Méthodologie : Une étude transversale descriptive, qui a recensé les établissements de production des médicaments issus de la médecine et de la pharmacopée traditionnelles (MIPT) répertoriés par les ministères en charge de la santé des deux pays, a été réalisée.
Résultats : Trente-trois établissements de production, dont 10 au Burkina Faso et 23 au Bénin, ont été enquêtés. Sept établissements de production au Burkina Faso et 16 au Bénin enquêtés sont illégalement installés. Seulement 16 des 33 établissements obtiennent leurs matières premières à partir des jardins botaniques, le reste les obtient par la cueillette, ce qui n'est pas favorable à la pérennité de la ressource végétale. En outre, parmi les 1041 MIPT fabriqués par les établissements recensés, seulement 1,44 % sont homologués. Enfin, des insuffisances d'application des bonnes pratiques de récolte des matières premières et de fabrication de produits finis ont été constatées.
Conclusion : Des efforts d'encadrement et de renforcement des capacités des établissements de production des MIPT par les pouvoirs politiques restent encore nécessaires pour

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optimiser la contribution de la médecine traditionnelle aux soins de santé des populations africaines.

Mots clés Médecine traditionnelle · Pharmacopée traditionnelle · Médicaments · Production · Matière première · Burkina Faso · Bénin

Introduction de la rédaction

Dans cet article, les auteurs, Daniel Dori, Huguette W.B. Ouedraogo, Perrin D. Houngue, Fernand A. Gbaguidi, Brigitte Evrard, Joëlle Quetin-Leclercq, Rasmané Semdé, nous invitent par ce texte en anglais à comprendre les difficultés qu'ont deux pays de l'Afrique de l'Ouest (le Burkina Faso et le Bénin) à identifier des plantes médicinales et à les transformer en médicaments.

Ce défi est des plus difficile à relever dans ces pays pauvres en ressources médicales où la phytothérapie serait un apport important pour la population si elle est convenablement menée. Or, les « laboratoires » sont généralement de très petite taille, et les pouvoirs publics semblent incapables de mettre en œuvre des solutions plus adaptées.

Il s'agit d'un « cri » de chercheurs qui s'investissent dans la promotion de la production locale de médicaments qui pourrait faire bouger les lignes, et il nous a paru dans ce but nécessaire de publier leurs constatations.

Introduction

A large proportion of people in developing countries do not have access to the care provided by "modern medicine"[1]. In 2002, the World Health Organization (WHO) estimated that one-third of the world population did not have regular access to basic medicines, and that, in the poorest regions of Africa and Asia, this number amounts to more than 50% [1–4].

To overcome this shortcoming, "traditional medicine" has regained interest. It is considered today as an alternative to the problem of accessibility to health care and drugs [1,3]. From scarce data about the medicinal plants market in Africa, it remains possible to estimate the economic importance of traditional medicine. This market was estimated in Ghana in 2010 up to 951 tons of raw herbal medicines with a total value of about 7.8 million USD [5]. In Benin, it was estimated in 2012 up to 655 tons worth 2.7 million USD [6]. And in Gabon it was estimated in 2012 up to 27 tons valued at 1.5 million USD [7]. Indeed, WHO estimates that in Africa, nearly 80% of the population uses traditional medicine, either alone or alongside with modern medicine [1,8]. As a result, traditional medicine is increasingly taken into account in the health policies of African countries [9–11].

Products from traditional medicine, which continue to be studied by scientists around the world, remain important sources for the development of new drugs [12–14]. This explains the increased interest from health authorities in African countries for research on traditional medicines, and the establishment of related regulations [10,15–17]. Indeed, medicines derived from traditional pharmacopoeia (MDTP), as well as modern medicines, must be of good quality, effective, safe and affordable to help achieve the goal of universal health coverage and economic development [3,15,18].

The quality of MDTPs cannot be guaranteed without satisfactory control of local production conditions. In Benin, the production of any medicine is governed by the provisions of the ordinance n° 75-7 of Jan 27, 1975 related to medicine regulations in Dahomey which require that the resulting compositions be submitted to systematic studies by a medical-pharmaceutical research institute in order to ensure its safety and determine its best dosage [19]. A decree and its implementing order, adopted in 2012 and 2013, define the specific terms of the 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 the commitment of a responsible pharmacist [20–22].

The approval process leading to the granting of a marketing authorization to a health product is a regulatory function of any national pharmaceutical regulatory authority which aims to guarantee the quality, safety and efficacy of medicines circulating in a country.

The approval of MDTPs in Benin is regulated by an order n° 2017 017/MS/DC/SGM/CTJ/DPMED/DA/SA016SGG17 of 05/02/2017 laying down procedures for the approval of herbal medicinal products in the Republic of Benin [23]. In Burkina Faso, the approval of these medicines is specifically controlled by the Dec 14, 2004 decree n° 2004-569 /PRES/PM/MS/MCPEA/MECV/MESSRS and the July 6, 2005 order n° 2005-231/MS/CAB [22,24,25].

This local production is often made by traditional healers or semi-industrial units from plant raw materials [26,27]. However, little data is available on the production conditions and the procurement of raw materials of MDTPs in West Africa. The present work aims at making an inventory of local application of good manufacturing practices of MDTPs and the conditions of obtaining and processing the raw materials in Benin and Burkina Faso. It will provide an important database for a more realistic policy of the promotion of MDTP and will facilitate the successful integration of traditional medicine into the national health systems.

[1] In this study, modern medicine is understood as a medical branch explained by science. That is to say, one that combines biological and clinical work.

Methods

Data collection

The framework for this study is Burkina Faso and Benin, two French-speaking countries in the heart of West Africa having similar health care systems. Their health care systems are organized into public, private and traditional health care sub-sectors. Like the other sub-sectors, the traditional one benefits from the support of ministries in charge of health through national policies and strategies [10,11,15].

We carried out a descriptive cross-sectional study from May to December 2018. All the local MDTP manufacturing facilities (11 in Burkina Faso and 36 in Benin) listed by the departments in charge of traditional medicine of the Health Ministries were included in the study. The data collection was done on the basis 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. After this approval, managers of included MDTPs manufacturing facilities were asked to sign a consent form after being adequately informed about the aims, methods and expected results of the study. Those of these managers who agreed to participate were interviewed in the two countries. During these interviews, a questionnaire was administered face-to-face. It was about the status of the studied facility in relation to the national regulations, the qualification of the technical manager, the types of infrastructure and equipment used for manufacturing, the conditions of obtaining and processing the raw materials and finally, marketing authorization status of the MDTPs.

Data analysis

All data on facilities were classified by country and for both countries after entering on the Epidata software. The data were analyzed using number and percent to describe an overview of the situation in the two countries involved in the survey.

Results

The participation rate of the manufacturing facilities is 70% since fourteen of them (one out of 11 in Burkina Faso and 13 out of 36 in Benin) did not respond favorably to our request and were excluded from this study.

Characteristics of the manufacturing facilities surveyed

The technical managers of the manufacturing facilities surveyed were pharmacists, physicians, biologists and traditional healers. Table 1 shows the distribution of MDTPs manufacturing facilities according to their status in relation to the regulations and the qualification of the technical manager.

Table 1 Distribution of MDTPs manufacturing facilities according to their status in relation to the regulation and the technical manager's qualification

Technical manager's qualification	Burkina Faso	Benin	Total
Pharmacist	4 (1)	1	5 (1)
Physician	–	1 (1)	1 (1)
Microbiologist	–	1	1
Traditional healer legally recognized by the Health Ministry	4 (4)	14 (9)	18 (13)
Traditional healer not legally recognized by the Health Ministry	2 (2)	6 (6)	8 (8)
Total	**10 (7)**	**23 (16)**	**33 (23)**

(x): Number of facilities illegally installed

These technical managers were assisted by other types of personnel, including nurses, laboratory technicians, agronomists, food processing engineers, foresters, warehouse keepers and workers. In addition, in the two countries, eight out of the 26 traditional health practitioners who were technical managers of the facilities did not have any authorization delivered by the Ministries of Health permitting them to practice traditional medicine. The majority of facilities owned by traditional healers, recognized or not, were illegally installed.

With regard to infrastructure, six out of the 33 facilities (3 in Benin and 3 in Burkina Faso) had a single place, usually one room, intended for preparation, storage of raw materials, sales of finished products and consulting. In the case of facilities with premises specifically used for preparation activities, the products were also manufactured in the same premises. However, special precautions such as seasonal production (separation per period) followed by appropriate cleaning and strict rules for the movement of goods and people were insufficiently observed. Most of the equipment used is still of the traditional type (manual capsule fillers, pots, jars, traditional dryers, mills, stoves, sieves) or semi-industrial (automatic capsule fillers, bagging machines, fillers, crushers, grinders, blister packers, tablet presses). The main equipment of the facilities surveyed in the two countries is reported in table 2.

Procurement mode of raw materials by the manufacturers

The method of obtaining plant raw materials varies according to the producers. In Benin, 21 out of 23 facilities are

Table 2 Main equipment's of MDTPs facilities in Benin and Burkina Faso

Equipment	Burkina Faso (N = 10)	Benin (N = 23)
Scale	10	23
Sieve	10	23
Manual capsules filler	8	0
Automatic capsules filler	0	1
Dryer	8	7
Thermosealing device	5	0
Mixer	1	3
Grinder	7	6
Bagging machines	1	1
Crusher	2	6
Filler	2	2
Blister packer	1	1
Tablet press	1	1
Hotplate	1	5
Cooker	4	10
Pot	2	20
Jar	1	10

N: total of facilities

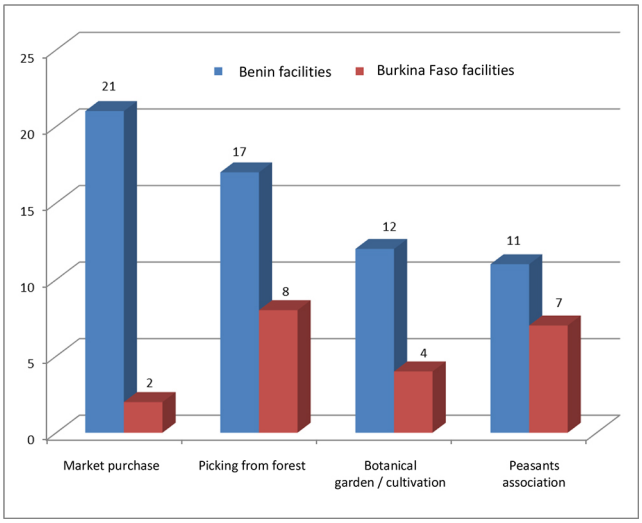

Fig. 1 Distribution of the raw material procurement modes by MDTPs facilities in Burkina Faso and Benin

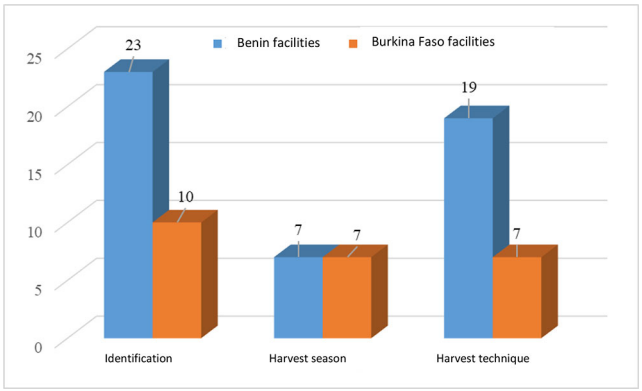

Fig. 2 Distribution of the facilities according to the precautions taken in harvesting raw materials

purchased directly from the market and 17 out of 23 by picking from the forest. In Burkina Faso, collection from the forest was practiced by eight out of the ten producers. Figure 1 shows the different procurement modes of raw materials.

All the interviewed claimed to carry out the identification of the plants before harvesting in the two countries. Only 19 in Benin and 7 in Burkina applied specific harvesting techniques (selection of the cutting device, respect of the regeneration conditions of the species collected, protection of aerial parts in contact with soil, removal of soil from aerial parts after harvest) according to the part of the desired plant. Finally, 7 in each country established schedules or defined the optimal stage of collection. These results are illustrated in figure 2.

After obtaining the plant raw materials, 18 from Benin and 9 from Burkina Faso used only a drying procedure under shade for the aerial parts of the plants or under the sun for the roots. Five of the 33 producers (4 in Benin and 1 in Burkina Faso) also used solar dryers. For raw material packaging, producers used jute bags, plastic rice sacks, cans, baskets, barrels or plastic bags. For the transport of packaged raw materials to the facilities, 82%, 45%, 33% and 15% of the facilities surveyed used private cars, public transport, motorcycles and tricycles respectively. In addition, no precaution (protection against bad weather, contamination, temperature and moisture) was taken to guarantee the quality of the raw material during transport.

Characteristics of the products identified

During this study, 1041 MDTPs, including 513 in Burkina Faso and 528 in Benin were identified, all of the category 2. Only 6 out of 10 facilities in Burkina Faso and 2 out of 23 in Benin had already obtained approval of at least one of their products. Also, the proportions of MDTPs having expired and valid marketing authorization were respectively 1.15% (12 out of 513 in Burkina Faso) and 1.44% products (9 out of 513 in Burkina Faso against 6 out of 528 in Benin).

Discussion

Characteristics of the manufacturing facilities surveyed

The examination of the data in table 1 shows irregularities with regard to the current national regulations [19,28–31]. First, the majority of facilities (23/33, including 7 in Burkina Faso and 16 in Benin) were illegally installed. Indeed, they did not have, as required by the national regulations, exploitation licenses delivered by the ministries in charge of health.

In addition, in the two countries, the majority of facilities owned by traditional healers, recognized or not, were illegally installed, contrary to the situation where the technical manager is a pharmacist. This situation was due to the fact that in Burkina Faso, only those units whose manager is a pharmacist are eligible for an exploitation authorization [26,27]. In Benin, 5 out of the 7 facilities legally installed were under the technical responsibility of traditional healers. This situation was in accordance with Ordinance n° 75-7 of 27/01/1975 on the Dahomey drug regime, which states that "healers registered at the provincial directorate of health are authorized to prepare, package and sell all drugs, substances or medicinal compositions meant for traditional medicine" [19].

The situation of the infrastructure, described above, was contrary to the applicable rules of good manufacturing practice, and would cause cross-contamination and hygiene problems [32]. The main equipment of the manufacturing facilities reported in table 2, which were mostly of the traditional type or semi-industrial, show that the MDTPs facilities in Benin and Burkina Faso had low capacity, corroborating the observation already made by the African Intellectual Property Organization on the situation of local pharmaceutical production in African countries [2]. It is a reflection of the embryonic pharmaceutical industry in sub-Saharan Africa [10,16,33,34]. Thus, all the facilities surveyed in the two countries subcontracted part or the entire quality control of their productions with external quality control laboratories belonging to ministries of health, universities and research centers, probably due to their low production capacities.

Procurement mode of raw materials by the producers

Collection in the forest or from botanical gardens, acquisition from peasant associations and direct purchase from the market were the main methods of obtaining plant raw materials by producers. Among these practices, the development of botanical gardens or fields for the cultivation of medicinal plants is more recommended since it contributes to the preservation of species while ensuring a better availability of raw materials [35,36]. The other methods that do not promote the sustainability of medicinal plants may explain the observation made by the majority of interviewees, who underlined difficulties in obtaining some plants they have easily found previously. In 2011, this observation was made by Zerbo et al., who noted that some medicinal species had become rare or even disappeared from their biotope [37]. The situation could worsen if national policies do not encourage the cultivation of medicinal plants, especially since national and international demands for medicinal plants are getting higher and higher [38]. For example, sensitizing and supporting traditional health practitioners for the creation of forest reserves and botanical gardens, plant cultivation and implementation of good practices and harvesting techniques are strategies for sustainable management of useful species [1,10,15].

As it can be seen in figure 2, many interviewed producers did not apply specific harvesting techniques and did not use a harvest schedule. These results are similar to those of Mounkaila et al. in Niger, which found that the roots of medicinal plants were harvested without observing the precautions of plant survival [39]. Good agricultural and harvesting practices for medicinal plants constitute the first step in ensuring the quality of herbal medicines, which will partly depend on their safety and effectiveness. Indeed, the richness of the active compounds of plants often depends on the stage of growth of the plant or the harvesting seasons [40,41].

During the drying of the plant raw materials, no special measures were taken by the producers to ensure the quality of the drying process. However, the drying phase can influence the physicochemical, organoleptic and microbiological qualities even though the natural method is used [40,41]. In addition, artificial drying using solar dryer can cause a greater denaturation of the active principles if the operator does not respect the recommendations of use of the manufacturer (quantity of material, ventilation, temperature, frequency of turning over) [41]. The choice of the packaging materials for the raw material by the producers was based on their local availability and not on their technical grounds, as recommended by the current legislation [40,41]. Indeed, the packaging must ensure compatibility with the contents, the protection of the product with respect to moisture, air, light, contaminants and its stability.

Characteristics of the products identified

All the 1041 MDTPs identified in Burkina Faso and Benin were of category 2. In a 2013 study in the city of Abidjan in Côte d'Ivoire, Kroa et al. found a lower proportion of 71% of category 2, probably because their census, which totaled 456 traditional medicines, concerned only 15 centers of traditional medicine [42]. According to the 2010 WHO Africa Region guidelines, the authorization of traditional consulting and care should take into account only the production of category 1 MDTPs. The production authorization of category 2 MDTPs, which corresponds to the category of

products of the structures identified here, should be submitted to a request made to the competent national authority. It is then assumed that all these facilities should be duly authorized before any production of category 2 MDTPs. This is not the case, since only 10 out of 33 production facilities are authorized.

Also, the relative high level of the expired marketing authorizations (1.15%) and the low rate of the approved products (1.44%) observed in this survey show that the local MDTPs manufacturers have little interest in the marketing authorization. Comboïgo in 2006 found a rate of 5.8% of approved products in the pharmacies in Ouagadougou [43]. This observation means that the approval procedure of the MDTP remains inaccessible to the local manufacturers or the marketing authorization brings little added value to the sale of the product.

Limitations of the study

The constraints of budget and time have limited this survey to two countries in West Africa. The analyses were performed on only 70% of the well-known MDTP production facilities of the Ministries of Health because of non-participation. Also, only the statements of the interviewees, that can be subjective, have been considered.

Conclusion

This work made it possible to identify several facilities offering a thousand MDTPs in Burkina Faso and Benin. They are generally characterized by a low production capacity and use of traditional and semi-industrial production equipment. Moreover, we noticed irregularities abiding by current regulations. The implementation of good practices in harvesting raw materials and manufacturing finished products is not a reality. These results pinpoint the need to strengthen awareness and capacities.

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