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Evaluation of National Quality Control Capacity for Herbal Medicines in West Africa: the Case of Benin and Burkina Faso.

Évaluation des capacités nationales de contrôle de la qualité des médicaments à base de plantes en Afrique de l'Ouest : cas du Benin et du Burkina Faso.

Dori Daniel [1], Assanhou Gabin A [2], Gbaguidi Fernand A [2], Evrard Brigitte [3], Quetin-Leclercq Joëlle [4], Semdé Rasmané [1*]

[1] Laboratory of Drug Development, Doctoral School of Sciences and Health, Joseph KI-ZERBO University, Burkina Faso;
[2] Laboratory of Organic and Pharmaceutical Chemistry, Faculty of Health Sciences, University of Abomey Calavi, Benin;
[3] Laboratory of Pharmaceutical Technology and Biopharmacy, Center for Interdisciplinary Research on Medicines (CIRM), University of Liège, Belgium;
[4] Pharmacognosy research group, Louvain Drug Research Institute, Catholic University of Louvain, Belgique.

(*) Corresponding author: Professor Rasmané SEMDE
Phone. (+ 226) 70 44 35 12
E-mail : *rsemde@yahoo.fr*
BP 7021 Ouagadougou 03
Burkina Faso

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Mots clés : Médicament à base de plantes, médecine traditionnelle, matières premières, contrôle qualité, Bénin, Burkina Faso

ABSTRACT

Objective: To assess the capacity of quality control of herbal medicines in two countries in West Africa, thus, Benin and Burkina Faso. **Methods:** This is a cross-sectional descriptive study, through surveys of 33 manufacturing facilities and 5 independent quality control laboratories listed in the two countries. **Results:** Among the 33 production units surveyed, only six had space or premises dedicated to quality control. Furthermore, 29 out of the 33 manufacturers used geographic, organoleptic and macroscopic criteria to verify the quality of the raw materials when buying or harvesting. For finished products, they checked the organoleptic characteristics themselves. For more complex analysis, such as the search for microbial contaminants or pesticide residues, they most often used public laboratories at the national level, which are better equipped with skilled staff. **Conclusion:** These results show that a lot of effort needs to be done in this area by these two countries in order to better ensure the quality and safety of locally produced herbal medicines.

RÉSUMÉ

Objectif : Evaluer les capacités nationales de contrôle qualité des médicaments à base plantes médicinales au Bénin et au Burkina Faso. **Matériels et Méthode :** étude transversale descriptive, par enquête auprès des 33 établissements de fabrication et des 5 laboratoires indépendants de contrôle de qualité répertoriés dans les deux pays. **Résultats :** Sur les 33 établissements de production enquêtés, seulement six disposaient d'espace ou de local dédié au contrôle de qualité. Par ailleurs, 29 des 33 fabricants utilisaient des critères de localisation géographique, organoleptiques et macroscopiques pour vérifier la qualité des matières premières lors de l'achat ou de la récolte. Pour les produits finis, ils vérifiaient eux-mêmes les caractères organoleptiques. En revanche, en ce qui concerne les analyses plus complexes comme la recherche de contaminants microbiens et des résidus de pesticides, ils faisaient le plus souvent recours à des laboratoires publics au niveau national, qui disposaient de matériels, d'équipements et de compétences plus conséquents. **Conclusion :** Ces résultats montrent que beaucoup d'efforts restent à faire par les Etats africains pour mieux assurer la qualité des médicaments à base de plantes produits localement dont la majorité de la population a toujours recours.

INTRODUCTION

About 80% of the African population patronize traditional medicine [1,2]. As a consequence, the demand for medicines derived from traditional pharmacopoeia, which are mainly plant-based, has increased over the past years [1,3–5]. As a result, the World Health Organization (WHO) has enacted some regulatory standards to evaluate and ensure quality, efficacy and safety of plant-based medicines [6,7]. In this regard, several African countries, including Burkina Faso and Benin, have progressively enacted laws that regulate the practice of traditional medicine, as well as the production, distribution and use of herbal remedies [8]. To be on the market, the quality control of the products, specially herbal medicines is the main key among the criteria to apply for a product license. [8–12]. To overcome this difficulties for the control of herbal medicine, several efforts had being made, in Africa as in other regions of the world, to develop specific analytical methods and the standardization of plant based medicines [6,7,13–15]. However, this requires state-of-the-art equipment and skilled personnel due to the multicomponent nature of herbal medicines [6,7,15,16]. Indeed, according to Yang et *al.* (2017), the multicomponent nature and inherent multiple targets of action of herbal medicines require innovative ways of assessing their efficacy and quality [17].

However, the unavailability and inaccessibility of laboratories and technical services to local producers can

constitute a major obstacle to the approval of herbal medicine and thus, to their integration in the medical system of a country. Dori et *al.* (2020) found that only 40% of herbal medicines sold by wholesalers and pharmacies in Burkina Faso had valid product licenses [18]. In this regard, it is necessary to know the actual strength of every nation in terms of assessing the quality control of herbal medicines, so as to better develop policies and strategies for the promotion and integration of these medicines in the health systems of African countries.

The aim of this study was to assess the capacities of two countries in West Africa (Burkina Faso and Benin) in respect of determining the quality of herbal medicines.

METHODS

This study was conducted in Burkina Faso and Benin. The health systems of these two countries are similar and are divided into public, private and traditional subsectors. Like the other subsectors, the traditional sector benefits from the assistance of the Health Ministries through national policies and strategies [19–21].

This is a cross-sectional descriptive study which took place from May to December 2018. It consisted, after obtaining a well-informed and written consent, of interviews with managers of local herbal medicine production units and independent laboratories responsible for the quality of medicines as acknowledged by the health ministries of these two countries. The data collected from these production units were in relation to the availability or otherwise of an internal quality control unit, and the quality parameters determined internally or externally on raw materials and finished products. Concerning the quality control facilities, the data collected were related to human and material resources as well as for the quality control services availabilities and those actually performed. This study was conducted based on the approval of the Ethics Committee for Health Science Research (Deliberation n° 2016-5-064, 4 May, 2016) of Burkina Faso.

The data obtained were analyzed using Stata 12 software. The thematic content of participants' statements was analyzed using the QDA miner Lite v1.4.3 software.

RESULTS AND DISCUSSION

Quality control capabilities of production units

Premises, equipment and personnel

Thirty-three production units (10 in Burkina Faso and 23 in Benin) were surveyed. Only 6 out of the 33 units (13%), had premises dedicated to internal quality control analysis. In addition to this lack of premises, most units had very few quality control equipment. The available equipment were mainly scales and sieves used for weighing and determining grain size in powders. The equipment required for relevant pharmacopoeial tests (friability, hardness, disintegration, dissolution) and the physicochemical analyses (pH, density, viscosity, thin layer chromatography, high performance liquid chromatography etc) were rarely found, if not absent totally. No unit had equipment and material for microbiological quality assessment.

Table I, which summarizes the main personnel profiles in surveyed manufacturing units, also illustrates the insufficiency of qualified human resources in general and those dedicated to quality control in particular.

Table I: Personnel distribution in manufacturing units in Benin and Burkina Faso

Personnel qualification	Burkina Faso (n=10)	Benin (n=23)
Pharmacist	4	1
Medical doctor	-	1
Microbiologist	-	1
Laboratory technician	4	4
Traditional medical healer	7	16
Agronomist	1	-
Food processing engineer	1	-
Stock controller	2	-
Forester	1	-
Nurse	3	1
Other profiles	8	20

n = number of units per country

These observations show that the majority of local herbal medicines producers could not ensure their own the batch release productions. The procedure for batch release, according to the guidelines for good manufacturing practices for member states of the West African Economic and Monetary Union (WAEMU), stipulates that, in addition to the verification of production parameters, there is a need for conformity of results in terms of quality control of finished products and raw materials [22]. This situation is explained by the lack of financial resources to hire qualified personnel and purchase the necessary equipment and consumables. Thus, some manufacturing units had recourse to independent laboratories for the subcontracting of the analyzes of release of the batches of their products or, failing this, put their products on the market without adequate analysis.

Tests that can be done on raw materials and finished products

A number of quality parameters were determined in the raw materials either internally or by subcontracting to external laboratories. These include geographic location (choice of harvest area), macroscopic parameters (colour, smell, taste, absence of irregular elements, hygiene and cleanliness, drying quality) and physicochemical parameters, mainly phytochemical tests. For finished products, the organoleptic characteristics constituted the most controlled parameters (29 units out of 33), followed by microbial contamination and the presence and level of pesticide residues. The latter parameters were mostly determined by independent laboratories, on the manufacturers' demand. Table II presents the distribution of manufacturing units according to quality parameters evaluated in respect of the control evaluation of raw materials and finished products.

Table II: Quality parameters used by herbal medicine producers for the quality control of raw materials and finished products.

Parameters	Benin (n=23)	Burkina Faso (n=10)	Total (N=33)	Percentage (%)
Raw materials				
Botanical identification	23	10	33	100
Organoleptic characteristics (colour, smell, taste)	23	9	32	97
Presence of irregular elements	21	9	30	91
Geographical location of cultivation/harvest	20	1	21	64
Hygiene and cleanliness (container and plant raw materials)	14	4	18	55
Drying quality	10	1	11	33
Phytochemical screening	4	2	6	18
Finished products				
Organoleptic characteristics (colour, smell, taste)	20	9	29	88
Microbial contamination	16	2	18	55
Content of pesticide residues	10	2	12	36
Pharmacotechnical dosage form tests	7	1	8	24
Heavy metal content	6	1	7	21
Residual moisture content	6	1	7	21
Phytochemical screening	4	2	6	18

[1]**Average volume or weight, mass uniformity, grain size, friability, dissolution time and profile**

It was noticed that, for finished products, most manufacturers who did not have the capacity to determine their quality in-house usually sought the services of external laboratories. This was however not usually done for raw materials. In fact, some controls such as microbiological tests, water content determination, pesticides residue and heavy metals tests, done on the raw material could avoid the production of non-standard medicines and by the same could prevent the waste of time and raw materials. In addition, the phytochemical tests performed were not enough to guarantee batch-to-batch consistency since taxonomic identification or morphological authentication is not adequate to ensure the quality of the botanical. The same medicine from the same plant species, can indeed exhibit different chemical profiles [17,23,24]. The quality of raw medicinal plant materials also depends on intrinsic (genetic) and extrinsic factors (environment, growing technique, methods of harvest, post-harvest conditions, transport, storage etc). The quality can also be compromised by accidental contamination by microbes or chemical agents during production or by other species or plants parts due to misidentification or accidental or intentional adulteration [6,15]. The use of poor quality of plant raw materials is the main underlying reason for substandard finished products [21].

Analytical capacity of independent laboratories

Institutional anchoring of laboratories, personnel and equipment

The quality control facilities not belonging to manufacturers are considered in this work as independent laboratories. A total of five facilities were identified, two in Benin (ECQ1, ECQ2) and three in Burkina Faso (ECQ3, ECQ4, ECQ5). They are referred to by the codes "ECQ" because of the confidentiality clauses contained in the protocol of the study approved by the Ethics Committee. All of them were state-owned facilities either under the health ministries (one laboratory in each country), or universities or research centers (one in Benin and two in Burkina Faso)

The managers of the three independent and state-owned laboratories in Burkina Faso were all pharmacists, specialized in pharmaceutics or pharmacology, researchers. Those of the two laboratories in Benin were not pharmacists, and there were particularly an organic chemist and a biomedical engineer. The managers of both countries were assisted by technical personnel with the requisite qualification for the analysis and quality evaluation of herbal medicines such as pharmacist, engineers or technicians in biomedical analysis, microbiologist, etc. (Appendix 1).

Compared to the laboratories of local manufacturers of herbal medicines, state-owned laboratories had more specific and possess relevant equipment for the quality assessment of both raw material and finished products (Appendix 2). Indeed, the availability of analysis techniques such as ultraviolet-visible (UV) spectrophotometry, thin-layer chromatography (TLC), and mainly high performance liquid chromatography (HPLC) could help for making the differentiation of the wide range of chemical components of plants [23,25]. However, the high-performance liquid chromatograph and gas chromatograph coupled with mass spectrometry (HPLC–MS and GC–MS) are not available in the independent laboratories surveyed. Moreover, these two techniques are often used for the authentication and evaluation of the quality of herbal drugs, extracts and products derived from traditional medicine. Subsequentially, they allow a better characterization of unknown components and determining their content, also used for the research of eventual contaminants [13,17,24,26–28].

Tests that can be done on raw materials and finished products

Table III shows the main parameters that the different state-owned laboratories in Benin and Burkina Faso assess.

Table III: Tests performed by state-owned laboratories in Benin and Burkina Faso.

Parameters	Benin		Burkina Faso		
	ECQ1	ECQ2	ECQ3	ECQ4	ECQ5
Microbial Contamination	X	X			X
Pesticides residues	X	X			X
Grain size	X	X	X	X	X
Residual moisture content	X	X		X	
Dissolution profile	X	X	X	X	
Friability		X	X	X	
Dissolution time		X	X	X	
Hardness	X	X		X	
Raw material Identification	X	X		X	
Organoleptic characteristics	X	X			X
Loss on drying	X				
pH	X	X	X		X
Density	X	X	X		X
Heavy metals (lead, cadmium, mercury)	X	X	X		X
Phytochemical screening	X		X		
Volume of solution		X	X		
Alcohol content		X			
Aflatoxin presence and content		X			X
Adulteration of pharmaceutical products		X			X
Aristolochic acids presence and content					X

Table IV: Number of samples analyzed on herbal medicines in 2017 by state-owned laboratories in Benin and Burkina Faso.

Parameters	Benin		Burkina Faso			Total
	ECQ1	ECQ2	ECQ3	ECQ4	ECQ5	
Botanical identification of raw materials	3	32		58		93
Organoleptic characteristics	3	10				13
Residual moisture content	3	10		58		72
Grain size		10		58		68
Friability		10		58		68
Disagregation		10		58		68
Microbial contamination	3	40			17	60
Hardness				58		58
pH	3	30				33
Density	3	30				33
Pesticide residues	2	30				32
Dissolution		6		1		7
Cell toxicity (larval)	3					3
Heavy metals presence and content (lead, cadmium, mercury)			1			1

The tests were mainly those prescribed by the pharmacopoeia such as microbiological controls, physicochemical and pharmacotechnical dosage form tests, the presence and levels of pesticides and heavy metals (lead, cadmium, mercury) as well as phytochemical screening [26,27]. The capacities of these laboratories therefore permit for the determination of almost all the required quality control parameters for herbal medicines or raw material. Compared to the independent laboratories of the universities and research centers, those of the health ministries, conceived and set up for the control of all medicines entering the country, had more diversified analytical capabilities.

Table IV shows the statistics for parameters tested on herbal medicines in 2017 by state-owned laboratories in Benin and Burkina Faso. As can be observed, there is a demand for laboratory analyses in state-owned laboratories by the local manufacturers. However, the demand remains low for some laboratories or for parameters such as the heavy metals content analysis. Based on the response of some local manufacturers, this situation is either due to insufficient information on the analytical capacities of the state-owned laboratories or the relatively high cost of such analyses. For instance, the cost of screening for four groups of pesticides residues in Burkina Faso was 305 euros per sample, an amount which is too high for most local manufacturers.

CONCLUSION

The findings of this study have shown that local herbal medicine manufacturers in Burkina Faso and Benin are not adequately resourced (both technical and human resource) to carry out the required quality control tests on raw materials and finished products. This study has also brought to the fore, the existence of state-owned laboratories that possess the ability to perform these quality control tests on a subcontractual basis. The implementation of an adapted communication strategy

concerning the analysis capacities of the state-owned laboratories on the one hand, and the subsidies of analysis fees by the state to the benefit of local herbal medicines manufacturers on the other hand, should contribute to strengthen the promotion policies of the African traditional medicine and pharmacopoeia.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this article.

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Appendix 1: Profile of state-owned laboratory technical personnel in Benin and Burkina Faso.

Profile of technical personnel	Benin		Burkina Faso		
	ECQ1	ECQ2	ECQ3	ECQ4	ECQ5
Chemist	1	1	-	-	-
Pharmacist	-	2	6	1	3
Microbiologist	1	1	-	-	-
Engineers/technicians in biomedical analysis	2	2	0	3	6
Senior pharmaceutical assistant	-	-	-	-	3
High school graduate technician	3	6	-	-	-
Total	7	12	6	4	12

Appendix 2: Equipment listed in state-owned facilities in Benin and Burkina Faso.

Type of equipment	Benin		Burkina Faso		
	ECQ1	ECQ2	ECQ3	ECQ4	ECQ5
High performance liquid chromatography (HPLC)	X	X	X		X
Gas chromatography (CPG)	X	X	X	X	X
Atomic absorption spectrophotometry	X	X	X	X	X
UV-Visible spectrophotometry	X	X	X		X
Disintegration apparatus		X	X	X	X
Dissolution test apparatus		X	X	X	X
Densitometry		X	X		X
Friabilimeter		X	X		X
Hardness test apparatus			X	X	X
pH-meter		X	X		X
Optical microscopes	X	X	X	X	X
Precision and analytical balance	X	X	X	X	X
Stirrer	X	X	X		X
Rotavapor	X		X		X
Proofer	X	X	X	X	X
Refrigerator	X	X	X	X	X
Water distiller	X	X	X	X	X
Water bath	X	X	X		X
Chemical hood	X	X	X	X	X
Laminar flow hood		X			X
Centrifuge	X	X	X		X
Climatic chamber for stability study			X		
Muffle furnace					X