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Comparative study of the harmonization of pharmaceutical regulations in the western and central sub-regions of Africa

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ABSTRACT

The harmonization of pharmaceutical regulations in Africa aims to offer States a coherent body of texts and practices by combining limited resources. The objective of this study was to describe policies to harmonize pharmaceutical regulations in West and Central Africa in order to highlight similarities and disparities. The methodology used consisted of visiting the historical stages of the process in the two regions and comparing the preferred methodological approaches as well as the achievements obtained. It emerges from this work that if choices, guided by the health priorities of the regions in question, have led the actors to favor, depending on the sub-region, certain areas of pharmacy rather than others, in terms of harmonization, reality the aim pursued is the same namely the protection of public health by the availability of medicines safely and cheaply. It is hoped that cooperation not only between the two sub-regions but also with other pharmaceutical regulatory systems will optimize the processes initiated for better protection of public Health.

Keywords: Pharmaceutical Regulation - Harmonization - West Africa - Central Africa

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1. Introduction

The harmonization of pharmaceutical regulations can be understood as the adoption by a group of countries of consensual texts and procedures governing the drug and the pharmaceutical sector in general. Without being confused with standardization, harmonization aims to offer the Member States of the sub-regions a coherence in the implementation of the regulatory functions of pharmaceuticals. The ultimate goal of the harmonization of pharmaceutical regulations is to provide the African populations with quality medicines and, if possible, at a lower cost.

In recent decades, there have been processes of harmonization of pharmaceutical regulations in different regions of the world in order to allow people to have access to quality, safe and effective medicines. Thus, for example, the process initiated in the countries of the European Union (EU) that resulted in harmonized pharmaceutical regulations associated with the establishment of a European Medicines Agency (EMA). Another process was initiated by entire regions (USA, EU and Japan) and resulted in the ICH area (International Conference on Harmonisation) (1,2).

In Africa, the cross-border nature of health problems, the increase in treatment costs associated with the scarcity

of resources have finally convinced the need to pool efforts for a synergy of actions in favor of protecting health public. Thus, by sub-regions, economic communities have served as a basis for the initiation of pharmaceutical harmonization processes, the Economic Community of Southern African States (SADEC), the Community of East African States EAC), the Economic and Monetary Community of Central Africa (CEMAC) and the Economic and Monetary Community of West Africa.

The objective of this work is to compare the processes of harmonization of regulations in West and Central Africa using historical benchmarks (I) and considering the different methodological approaches (II) and the achievements obtained (III).

2. History of harmonization procedures in pharmaceutical regulations in Africa

For more than a decade, processes of harmonization of pharmaceutical regulations have emerged around the world at several levels, be they regional or international. According to WHO, the driving force behind this harmonization effort is the need to improve the availability of pharmaceuticals and to respond to international trade pressures by providing sufficiently comprehensive and standardized technical rules on safety, quality and the efficacy of drugs.

In Africa, the Harmonization of Drug Endorsement in Africa (HHMA) initiative, led by the African Union (AU), made it possible to formulate proposals for the harmonization of pharmaceutical regulations within the different economic communities sub-regional level.

The devaluation of the CFA Franc by more than 50% of its value in 1994 was an important moment in the pharmaceutical economy of African countries and highlighted the need for the availability of medicines through development generic drug policy and local drug production through synergy of resources. Launched in 2003 by the WHO, the process of harmonization in Africa has grown significantly since the first National Pharmaceutical Regulatory Authorities (NPRA) conference in Addis Ababa, Ethiopia from 31 October to 3 November 2005, an alarming diagnosis of the state of pharmaceutical regulation in Africa characterized, inter alia, in most countries, by a lack of national regulatory authority or a weakness in the countries where they exist, a lack of policy a lack of financial, logistical and technical resources for the implementation of the traditional pharmaceutical regulatory functions, namely the control of authorizations to exercise the pharmaceutical activity, medicines, quality control, pharmacovigilance, advertising and clinical trials and the implementation of pharmaceutical inspection. All this, coupled with inadequate legislative and regulatory frameworks for pharmacy and medicines. Thus, starting from these benchmarks of the early 2000s, in the various sub-regions of Africa, under the aegis of the sub-regional economic organizations, the harmonization processes began.

In West Africa, within the West African Economic and Monetary Union (UEMOA), which is of interest to us in the framework of this study, reflections culminated on 4 July 2005: the adoption of Regulation N ° 02 / 2005 / CM / UEMOA on the harmonization of pharmaceutical regulations in WAEMU member states, which constitutes the legal basis for the process of harmonization of pharmaceutical regulations in this union. Subsequently, the conduct of the process culminated in 2010 with numerous Community texts relating to various fields of pharmacy.

In Central Africa, the process of harmonization is essentially carried out by the Economic Community of Central African States (CEMAC), which after a situational analysis in 2005 prompted the adoption

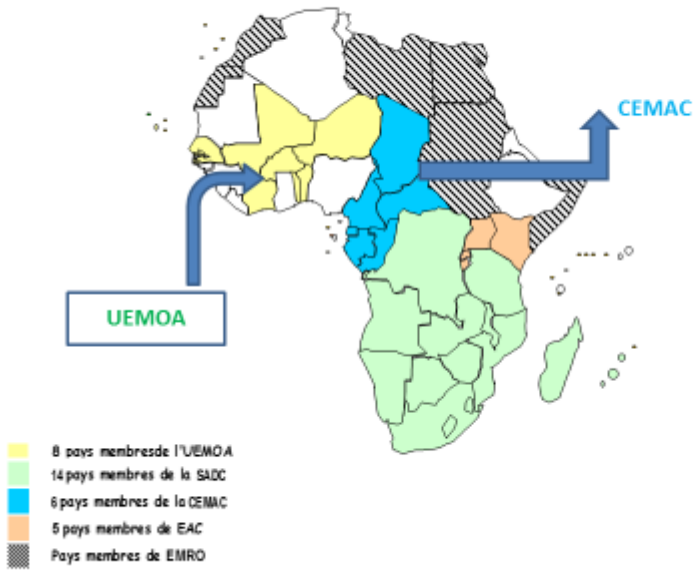


Figure 1. Sub-regions and harmonization of pharmaceutical regulation in Africa

3. Strategic approaches

A. Common points

The processes of harmonization of pharmaceutical regulations generally are based on regional economic organizations. This has been the case for the European Union in Europe, ASEAN in Asia and all the processes currently taking place on the African continent. This is an important methodological approach given that these organizations already have functional bodies and the accession of the Member States with a mechanism of operation of existing legal tools. Harmonization in the western and central regions of Africa does not escape this logic. For example, WAEMU in West Africa (although the Economic Community of West African States and ECOWAS also conducts harmonization actions), and CEMAC in Central Africa constituted essential bases harmonization of pharmaceutical regulations in these two sub-regions.

In addition to this important characteristic, the harmonization processes benefit from technical and financial support from the Development Partners (WHO, African Union, European Union, etc.) as well as institutional support from the various Member States (national pharmaceutical regulatory authorities, as well as the participation of national and international experts in the conduct of the process.

B. Harmonization by field of activity

In the WAEMU zone, each Member State has its own national pharmaceutical policy. The strategic approach favored gradual harmonization by areas of activity. Thus, Regulation No. 02/2005 / CM / WAEMU on the harmonization of pharmaceutical regulations in WAEMU Member States lists the areas to be harmonized (3); quality assurance, drug registration, pharmaceutical inspection, pharmacovigilance, quality control and practice. This procedure, which juxtaposes national policies with the common objectives of the Community, requires the transposition of Community legal provisions into national law. This integration is sometimes long and presents the disadvantage or at least the risk of certain provisions not applied or delayed applied. This is the case of Directive No. 06/2008 / CM / UEMOA on the free movement and establishment of pharmacists who are nationals of the Union within the UEMOA area.

C. Harmonization by a common pharmaceutical policy

The countries of the CEMAC zone have been innovative in adopting since 2007 a common national policy document which was enshrined in Additional Act No 07/00 / CMAC-OCEAC adopting the Common Pharmaceutical the community. Although the Pharmaceutical Policy document. although the common policy documents identify the areas to be harmonized, namely the legal and institutional framework, human resources, access to care, quality assurance, drug registration, pharmaceutical inspection, pharmaco-vigilance and quality control, areas that largely mirror those identified by the WAEMU Regulation, the common policy approach provides greater coherence in terms of the possibility of integration and appropriation of Community Member States. Its aim is to achieve harmonization more quickly by avoiding the need to transpose Community rules into national law. Moreover, it should be noted that all the Community standards in force in the CEMAC zone are regulations, legal norms of immediate application in all its aspects and immediately applicable to the Member States.

4. Community acquis

A. In West Africa

We will analyze the achievements of the harmonization process essentially under the prism of WAEMU actions, but aware that ECOWAS is also taking steps towards harmonization and has achieved important results such as the harmonization of training of pharmacists in the 16 Member States and the harmonization of codes of ethics and deontology of the practice of pharmacy in space in ECOWAS. WAEMU actions have resulted in the adoption of Community regulations, directives or decisions covering several areas ranging from the approval of medicines and certain health products such as food supplements and cosmetics, circulation of health professionals in the union as well as the registration of veterinary drugs scientific information and advertising for the drug (4).

The table 1 present the overall achievements of the harmonization of pharmaceutical regulation in WAEMU.

Table 1 Community legal standards for the harmonization of pharmaceutical regulation in WAEMU

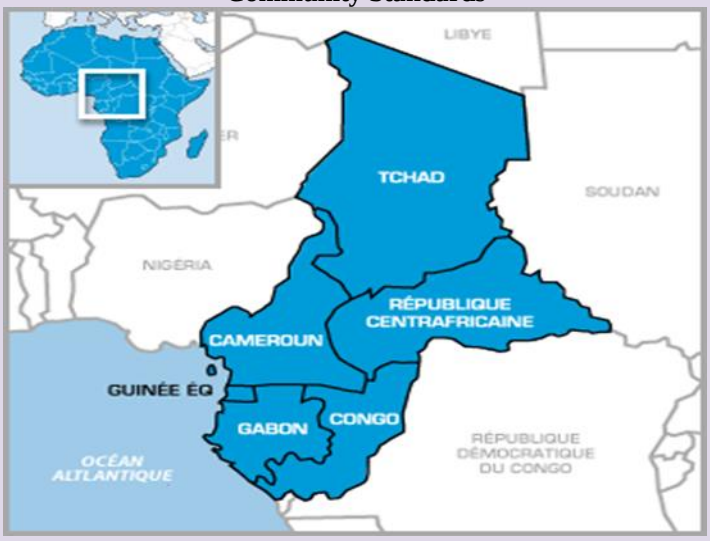
Regulatory domain	Community standards
	
Approval of veterinary	Regulation No. 01/2006 / CM / UEMOA establishing and operating a veterinary committee

Medicinal products	within the UEMOA (5).
	Regulation No. 02/2006 / CM / UEMOA establishing Community procedures for the marketing authorization and supervision of veterinary medicinal products and establishing a regional committee for the veterinary medicinal product (6).
	Regulation No. 03/2006 / CM / UEMOA establishing fees in the field of veterinary medicinal products within the UEMOA (7).
Homologation of Medicinal products for human use	Regulation No. 06/2010 / CM / UEMOA on the harmonization of the procedures for the approval of pharmaceutical products for human use (8).
Approval of Food supplements	Decision No. 06/2010 / CM / UEMOA adopting guidelines for the approval of food supplements in the WAEMU member states (9).
Approval of Cosmetic products	Decision n ° 07/2010 / CM / UEMOA adopting guidelines for the approval of cosmetic products in the WAEMU member states (10).
Good Manufacturing Practices	Decision No. 08/2010 / CM / UEMOA adopting Guides of Good Practices for the Manufacture of Pharmaceuticals for Human Use in WAEMU Member States (11).
Good Distribution Practices	Decision No. 09/2010 / CM / UEMOA adopting Guides of Good Practices for the Distribution and Importation of Pharmaceuticals for Human Use in WAEMU Member States (12).
Control of advertising	Decision No 10/2010 / CM / UEMOA adopting guidelines for the control of information and advertising on medicinal products to professionals in the WAEMU member states (13).

B. In Central Africa

In the CEMAC area, in addition to the regulations on the approval of medicinal products for human use (veterinary medicinal products have not yet been harmonized), important areas have been regulated at Community level. These include pharmacovigilance, pharmaceutical inspection or the supply of medicines, and even combating counterfeiting and illicit drug trafficking. Table 2 presents the set of Community CEMAC standards for the harmonization of practices (14).

Table 2 Community legal standards for the harmonization of pharmaceutical regulation in the CEMAC space

Regulatory Domain	Community Standards
	
Supply of essential drugs	Regulation No. 02/13 / ECAC-OCEAC-CM adopting the guidelines on the supply of essential medicines (15).
Pharmacovigilance	Regulation No 03/13 / ECAC-OCEAC-CM adopting the guidelines on pharmacovigilance (16).
Pharmaceutical Inspection	Regulation No. 04/13 / ECAC-OCEAC-CM adopting the Pharmaceutical Inspection Procedure Manual (17).
Approval of Medicinal Products for Human use	Regulation No 05/13 / ECAC-OCEAC-CM on the harmonization of procedures for the approval of medicinal products for human use (18).
Fight against Counterfeit Medicines	Regulation No. 07/17-UEAC-OCEAC-CM-31 adopting the Operational Action Plan 2016-2020 for the coordinated fight against counterfeit medicines and illicit drug trafficking in the CEMAC zone (19).

C. Summary

On observation, we see that the texts harmonizing the pharmaceutical regulations in the CEMAC zone are all regulations while in the WAEMU zone, in addition to the regulations, we also have decisions and directives that require prior implementation for their application in the Member States. This finding is explained by the uniqueness of the pharmaceutical policy in the CEMAC

zone, which necessarily minimizes the necessity of nationalizing supra-national provisions (20).

On the other hand, it can be seen that, apart from the approval of medicinal products for human use, which have been subject to a harmonization regulation in the two sub-regions, the harmonized areas are different as if the Prioritization of priorities had different foundations depending on the area. This dichotomy is a good illustration of the possibility of cooperation between the two sub regions for optimizing regulations, each drawing on the experience of the other in an area it has not yet regulated.

It can also be noted that the fight against counterfeit medicines, a priority issue identified in the common pharmaceutical policy document of the CEMAC, has recently been the subject of a regulation intended to combat this scourge.

As regards certain peculiarities, it can be noted for example that Pharmacovigilance has given rise in the CEMAC area to the drafting of a legal text, while at WAEMU level the drafting of legal texts concerning it is still ongoing. However, the organization of the pharmacovigilance system is carried out at the national level for each country in the CEMAC area, as is the case in WAEMU countries, unlike EU countries or in addition to a national organization. pharmacovigilance system, there is a community organization. Nevertheless, the use of the same data processing software in the national pharmacovigilance centers of each CEMAC Member State shows a cooperation concerning the pharmacovigilance between their NMRAs.

Pharmaceutical inspections are governed in the CEMAC space by the manual on pharmaceutical inspections which addresses the technical and practical aspects of the inspection of different pharmaceutical establishments. This approach is a little different from that observed in the field of pharmaceutical inspections for WAEMU countries which have also developed a checklist for inspection but that sites for the manufacture and distribution of drugs. This greater number of types of pharmaceutical establishments covered by the manual on pharmaceutical inspections in the CEMAC space can be explained by the fact that within CEMAC there was no prior manual on the inspections of pharmaceutical establishments and that the pharmaceutical inspections were little or not carried out.

It must therefore be concluded that, in both regions, the process of harmonizing pharmaceutical regulations is dynamic and not yet completed. The different African sub-regions need to draw inspiration from each other's specific experiences to optimize the process of harmonizing pharmaceutical regulations in Africa.

5. Conclusion

Although pharmaceutical regulatory processes in western and central Africa have distinctive elements, they are based on existing economic communities and benefit from the commitment of member states and the support of development partners. The different strategic approaches adopted have the same objective of making quality drugs available to the public at a lower cost. The disparities in the choice of the already harmonized fields are certainly due to the abundance of the health problems to be solved in the immediate future and, in view of the dynamic character of the process of harmonization, suggests a fruitful collaboration with a view to " optimize the different harmonization processes in the UEMOA and CEMAC zones.

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Conflict of interest

The authors declare that there are no conflicts of interest, financial or otherwise.

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