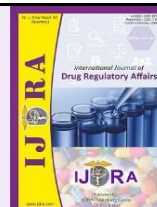


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Review Article

**Strengthening Veterinary Pharmacy Regulations through the harmonization process in the UEMOA region: the case of Niger and Côte d'Ivoire****Guiet Mati Fatima^{a,b}, Vidjro Sandra Wotsa^{c,b}, Ouoba Kampadilemba^{b,d}, Moumouni Ramatou^e, Amari Serge Antoine^f, Pabst Jean-Yves^b**^a Pharmacist, Direction of Pharmacy and Traditional Medicine, Ministry of Public Health, Population and Social Affairs of Niger Republic^b Laboratory of Health Law and Economics, EA7307-CEIE, University of Strasbourg – France^c Direction of Pharmacy, Medicines and Laboratories, Ministry of Health and Social Protection of Togo Republic^d Laboratory of Drug Development, Centre for Training, Research and Expertise in Drug Sciences, Joseph KI-ZERBO University, Ouagadougou, Burkina Faso^e Direction of Veterinary Pharmacies and Privatisation of the Veterinary Profession, Ministry of Livestock of Niger Republic^f Direction of Pharmaceutical Activity, Ministry of Health, Public Hygiene and Universal Health Coverage, Côte d'Ivoire Republic. Department of Galenic Pharmacy, Cosmetology and Legislation, UFR Pharmaceutical and Biological Sciences, Félix Houphouët-Boigny University of Cocody, Abidjan- Côte d'Ivoire**Abstract**

The livestock sector is faced with many constraints, including animal diseases. According to the World Organization for Animal Health, 60% of human diseases are of animal origin. Veterinary drugs are widely used in the fight against these diseases. These, like human medicines, are subject to strict regulation. Before the harmonization of veterinary drug regulations in French-speaking West Africa, Cote d'Ivoire was the only country with specific regulations in this area. In 2006, the UEMOA Commission adopted a set of regulatory texts as part of the community harmonization of veterinary pharmaceutical regulations, thus providing Member States with an adequate legal framework governing veterinary medicines and the practice of veterinary pharmacy and the veterinary profession, in particular through a centralized system of marketing authorisation for veterinary medicines, a single system of quality control for veterinary medicines and a community system for the inspection of veterinary pharmacy. This has enabled countries to strengthen their existing texts, as in the case of Côte d'Ivoire, or to develop specific national regulations for veterinary pharmacy, as in Niger, taking into account the principles and requirements of the community regulations.

Keywords: Harmonization, Veterinary pharmacy, Regulation, Côte d'Ivoire, National Order of Veterinarians of Niger, UEMOA, WAEMU, World Organisation for Animal Health (OIE).

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1. Introduction

The liberalisation of the veterinary drug sector in UEMOA Member States (production, distribution, marketing and veterinary care) has had the main effect of significantly increasing trade in these drugs, multiplying the number of operators and making it difficult to control the circulation of veterinary products within the Community. (1) This development increases the risk that veterinary inputs, which are both factors of production (development issues) and medicines requiring appropriate use (public health issues), circulate under conditions that do not guarantee their quality, (2) and

thus lead to a reduction in the progress made by countries in the field of public health. (3) Veterinary medicines are an essential tool for controlling the health status of livestock and thus ensuring their quality and productivity. However, these products are not without risks, as evidenced by the sanitary, economic, scientific, technical and environmental issues that their residues can have on human health, through the interaction of humans with animals and the environment. (4)

To ensure the safe and responsible use of these products, the World Organisation for Animal Health has developed codes and guidelines for the veterinary drug

industry, practitioners, pharmacists and farmers. The World Organisation for Animal Health also assists Member States in the good governance of veterinary medicines. In addition, a study conducted in 1999 on the situation of legislation relating to veterinary pharmacy in UEMOA member countries reported the weakness of the countries' means and that only Côte d'Ivoire had specific texts on the subject at that time. (5) This study highlighted the heterogeneity of national legislative provisions and the insufficiency or absence of regulatory texts allowing the application of legislative texts and the implementation of pharmaceutical regulatory functions (approval, quality control, market surveillance, etc.) to ensure the quality of medicines, with the exception of texts concerning access to the veterinary profession. The study therefore concluded that there was a need for a regional harmonisation and management scheme to take into account aspects related to the surveillance and quality control of veterinary medicines. The UEMOA Commission has therefore initiated a reform on the harmonisation of veterinary pharmaceutical regulations within the Union, which has led to the adoption of a set of community texts. This sub-regional organisation is a tool for integration for the eight member states through the reinforcement of the competitiveness of economic activities within the framework of a common market with the help of a harmonisation of the legislation of the member states. This reform is based on the attribution to the Commission of the power to take decisions on the regulation, marketing authorisation (MA) and

organisation of quality control of veterinary medicinal products. Member States retain responsibility for the control of imports, veterinary pharmaceutical establishments, distribution of products and effective quality control. (6–9) This article analyses the legal provisions of veterinary pharmacy in Côte D'Ivoire and Niger and the contribution of the UEMOA harmonisation process to their strengthening.

2. Legal provisions governing veterinary pharmacy in CI and Niger before Community harmonisation

The national provisions relating to veterinary pharmacy in the two countries followed different processes as shown in Table 1. In the light of these texts, it appears that Côte d'Ivoire has a virtually complete framework for veterinary pharmacy, covering access to and practice of the profession, the quality assurance system for veterinary medicines and the rules of good manufacturing, import and distribution practice. The approach has been quite different in Niger, where until recently the provisions have focused more on access to the profession and the private operation of establishments than on pharmaceutical quality assurance of veterinary medicines. For example, the approval of veterinary drugs was an administrative formality carried out by the drug selection committee of the Ministry of Health, without monitoring the life of the drug in the distribution circuit. There were also no specific texts on veterinary medicines such as manufacturing, quality control and pharmacovigilance.

Table 1. Summary of legal provisions relating to veterinary pharmacy in Côte d'Ivoire and Niger

Types of texts	References and title	
	Côte d'Ivoire	Niger
Laws/Ordinances	Loi n° 88-683 du 22 juillet 1988 instituant un code de déontologie des vétérinaires [Law 88-683 of Jul. 22, 1988 instituting a code of ethics for veterinarians]. (10)	Ordonnance n° 96-66 du 9 novembre 1996 portant création d'un Ordre National des vétérinaires du Niger [Ordinance 96-66 of Nov. 9, 1996 creating a National Order of Veterinarians of Niger]. (11)
	Loi n° 88-684 du 22 juillet 1988, portant création d'un ordre national des vétérinaires [Law 88-684 of Jul. 22, 1988 creating a national order of veterinarians]. (12)	Ordonnance n° 96-77 du 11 décembre 1996 portant création d'un Etablissement Public à caractère Administratif dénommé « Laboratoire National de Santé Publique et d'Expertise » (LANSPEX) [Ordinance 96-77 of Dec. 11 1996 on the creation of a public establishment of an administrative nature called « National laboratory of Publix Health and Expertise » (LANSPEX). (13)
	Loi n° 96-561 du 25 juillet 1996, relative à la pharmacie vétérinaire [Law 96-561 of Jul. 25, 1996, relating to veterinary pharmacy]. (14)	Ordonnance n° 97-002 du 10 Janvier 1997 portant Législation pharmaceutique [Ordonnance 97-002 of Jan. 10, 1997 on pharmaceutical Legislation], (articles n° 2 et n° 91). (15)
Decrees	Décret n° 2001-487 du 09 aout 2001, portant modalités d'application de la loi n° 96-561 du 25 juillet 1996, relative à la pharmacie vétérinaire [Decree 2001-487 of Aug. 09, 2001 on the modalities of application of the law 96-561 of Jul. 25, 1996, relating to veterinary pharmacy]. (16)	Décret n° 88-207/PCMS/MSP/AS du 9 juin 1988 portant approbation d'un code de déontologie des pharmaciens [Decree 88-207/PCMS/MSP/AS of Jun. 9, 1988 approving a code of ethics for pharmacists]. (17)
		Décret n° 96-428/PRN/MAG/EL du 9 novembre 1996, portant approbation d'un Code de déontologie des vétérinaires du Niger Republic of Niger [Decree 96-428/PRN/MAG/EL of Nov. 9, 1996 approving a Code of Ethics for veterinarians in Niger]. (18)

		Décret n° 97-344/PRN/MAG/EL du 18 septembre 1997 déterminant les modalités d'application de l'Ordonnance n° 96-66 du 9 novembre 1996 portant création d'un Ordre National des vétérinaires du Niger [Decree 97-344/PRN/MAG/EL of Sep. 18, 1997 determining the modalities of application of Ordinance 96-66 of Nov. 9, 1996 creating a National Order of Veterinarians of Niger]. (19)
Orders	Arrêté n°35/MIPARH du 09 Août 2007 fixant les règles de bonnes pratiques de fabrication, d'importation et de distribution des Médicaments vétérinaires [Order 35/MIPARH of Aug. 09, 2007 fixing the rules of good practices of manufacture, importation and distribution of veterinary Medicines]. (20)	Arrêté n° 210/MAG-EL/DEIA du 13 juillet 1995, déterminant les conditions d'exploitation à titre privé des pharmacies et dépôts de médicaments vétérinaires [Order n° 210/MAG-EL/DEIA of Jul. 13, 1995 determining the conditions for the private exploitation of pharmacies and veterinary medicine depots]. (21)
Circular	Circulaire n°840/MIPARH du 12 Septembre 2009 portant application de la Loi N°96-561 du 25 Juillet 1996 et du Décret N°2001-487 du 09 Août 2007 [Circular 840/MIPARH of Sep. 12, 2009 implementing Law 96-561 of Jul. 25, 1996 and Decree 2001-487 of Aug. 9, 2007]. (22)	

3. Basis and process of harmonisation of veterinary pharmaceutical regulation within UEMOA

Created on 10th January 1994, the West African Economic and Monetary Union (UEMOA/WAEMU), comprising eight states (Benin, Burkina Faso, Côte d'Ivoire, Guinea-Bissau, Mali, Niger, Senegal, Togo), (23) is one of the most complete models of economic integration in Africa, with a single currency, a customs union and a common pharmaceutical market under construction with the process of harmonisation concerning production, marketing of products, control and post-marketing surveillance. (24,25)

The free movement of goods in the UEMOA area, applied to veterinary medicines as of 1 January 2000, has had the main effect of significantly increasing trade in these products. (24) However, the still embryonic or outdated state of legislation concerning veterinary pharmacy in the Member States and their weak capacity to implement them and ensure quality control, led to the consideration of harmonising regulations. The diversity of legal provisions and the heterogeneity of national regulations in the UEMOA region relating to veterinary pharmacy were highlighted following the study conducted by the World Organisation for Animal Health (OIE) in the eight countries of the region. (5) The main objective of harmonising veterinary pharmaceutical regulations is to pool the resources and expertise in the management and evaluation of veterinary medicinal products of a group of countries, with a view to ensuring the controlled circulation of these products and their rational use, without posing major risks to animals, humans and the environment, (24) thus contributing to the safeguarding of public health. Since 2006, the UEMOA has adopted several binding texts that will complete, for most of its Member States, the few existing provisions on veterinary pharmacy. These

community legal standards relate to community procedures for the marketing authorisation and surveillance of veterinary medicinal products, the designation of laboratories in the network responsible for the quality control of veterinary medicinal products, the establishment of analytical, safety, preclinical and clinical standards and protocols for the testing of veterinary medicinal products, and the introduction of fees in the field of veterinary medicinal products. These texts also include a general directive on veterinary pharmacy, which gives Member States the latitude to transpose the relevant binding community provisions in consideration of their own legal framework.

Thus, the precocity shown by UEMOA in harmonising the regulation of veterinary medicines allows for a more rapid control of the community circulation of these medicines by reinforcing the related national provisions, thus making the harmonisation of veterinary pharmaceutical regulations a tool for mitigating the risks to human health. (26) Medicines thus benefit from a complete legal framework in the UEMOA area and it is now up to the countries to continue their efforts in the effective application of these provisions in order to achieve the community objectives.

4. Community texts and the integration into national law of Côte d'Ivoire and Niger

The year 2006 was a year of great evolution in the WAEMU area with the adoption of four regulations and one directive; then in 2009, another regulation, this time on the implementation of clinical trials of veterinary medicinal products, the decision designating the laboratories of the network in charge of the quality control of veterinary medicinal products within the WAEMU and the decision setting out the modalities for the submission of an application for a community MA.

A major step forward in the process of community harmonisation relating to veterinary pharmacy is Regulation No. 02/2006/CM/UEMOA of 23rd March 2006, laying down community procedures for the marketing authorisation and supervision of veterinary medicinal products and establishing a regional committee for veterinary medicinal products. (27) The adoption of this regulation offers the advantage to countries of converging national expertise within a regional committee on veterinary medicinal products responsible for studying MA applications. The centralised procedure allows countries to retain their competence in terms of supply and the possibility of manufacturing locally according to their capacity, and also allows the medicinal product to benefit from a

Community marketing authorisation and a single visa number for the eight countries, which can be used against the packaging to facilitate traceability, and opens up prospects for Community production.

In so doing, WAEMU becomes the first regional economic community (REC) to have initiated and succeeded in harmonising the regulation of veterinary pharmacy in Africa. This harmonisation is underpinned by the principle of free movement of persons and goods, which originates in the founding treaty of the Union (28) and also by the specific directives on the free movement and establishment of health professionals in the area. (29,30) The table 2 contains the community texts on veterinary pharmacy in the UEMOA.

Table 2. Community texts adopted at UEMOA level

Number	Title
1	Règlement n°08/2010/CM/UEMOA du 1 ^{er} Octobre 2010 portant modification du Règlement n°02/2006/CM/UEMOA du 23 mars 2006 établissant des procédures communautaires pour l'autorisation de mise sur le marché et la surveillance des médicaments vétérinaires et instituant un comité régional du médicament vétérinaire [Regulation 08/2010/CM/WAEMU of Oct. 1, 2010 amending Regulation 02/2006/CM/WAEMU laying down Community procedures for the marketing authorisation and supervision of veterinary medicinal products and establishing a Regional Veterinary Medicines Committee]. (31)
2	Décision n° 10/2009/COM/UEMOA du 10 septembre 2009 portant désignation des laboratoires du réseau chargé du contrôle de la qualité des MV au sein de l'UEMOA [Decision 10/2009/COM/WAEMU of Sep. 10, 2009 on the designation of laboratories of the network in charge of quality control of MV within WAEMU]. (32)
3	Décision n° 009/2009/COM/UEMOA du 10 septembre 2009 fixant les modalités de dépôt d'une demande d'autorisation de mise sur le marché communautaire [Decision 009/2009/COM/WAEMU of Sep. 10, 2009 laying down the modalities for submitting an application for a Community marketing authorisation]. (33)
4	Règlement d'exécution n° 007/2009/COM/UEMOA du 10 septembre 2009 fixant les normes et protocoles analytiques, d'innocuité précliniques et cliniques en matières d'essais de médicaments vétérinaires [Implementing Regulation 007/2009/COM/WAEMU of Sep. 10, 2009 laying down analytical, pre-clinical and clinical safety standards and protocols for the testing of veterinary drugs]. (34)
5	Règlement n° 04/2006/CM/UEMOA du 23 mars 2006 instituant un réseau de laboratoires chargés du contrôle de la qualité des médicaments vétérinaires dans la zone UEMOA [Regulation 04/2006/CM/WAEMU of Mar. 23, 2006 instituting a network of laboratories responsible for quality control of veterinary medicines in the WAEMU zone]. (35)
6	Règlement n° 03/2006/CM/UEMOA du 23 mars 2006 instituant des redevances dans le domaine des médicaments vétérinaires au sein de l'UEMOA [Regulation 03/2006/CM/WAEMU of Mar. 23, 2006 instituting fees in the field of veterinary medicinal products within WAEMU]. (36)
7	Règlement n° 02/2006/CM/UEMOA du 23 mars 2006 établissant des procédures communautaires pour l'autorisation de mise sur le marché et la surveillance des médicaments vétérinaires et instituant un comité régional du médicament vétérinaire. [Regulation 02/2006/CM/WAEMU of Mar. 23, 2006 laying down Community procedures for the marketing authorisation and supervision of veterinary medicinal products and establishing a Regional Veterinary Medicines Committee]. (27)
8	Règlement n° 01/2006/CM/UEMOA du 23 mars 2006 portant création et modalités de fonctionnement d'un comité vétérinaire au sein de l'UEMOA [Regulation 01/2006/CM/WAEMU of Mar. 23, 2006 on the creation and functioning of a veterinary committee within WAEMU]. (37)
9	Directive n° 07/2006/CM/UEMOA du 23 mars 2006 relative à la pharmacie vétérinaire [Directive 07/2006/CM/WAEMU of Mar. 23, 2006 relating to veterinary pharmacy]. (38)

And according to the requirements of the Community texts, the regulations have a direct, immediate and total application in the national order. Directive 07/2006, on the other hand, must be transposed within two years. It sets an objective to be achieved by the States while leaving them the competence as to the form and the

means, and thus, places on them an obligation of means and not an obligation of results. (39) A directive can therefore be transposed by a law, decree or order, i.e. a legally binding text, but not by a circular or memorandum.

Having regulated the procedures relating to the marketing of veterinary medicinal products and marked out the quality control system for these products, the Commission is specifically moving towards regulating the life of veterinary medicinal products by adopting Directive No. 07/2006/CM/UEMOA on veterinary pharmacy, because of the need to regulate the import, manufacture, preparation, wholesale distribution and possession of veterinary medicines to better manage the risks to human and animal health and the environment, and above all, because of the interest at the community level of proportionate and harmonised regulations. The directive details the modalities of application of Regulation No. 02/2006/CM/UEMOA and aims to describe the provisions that Member States must implement in terms of import controls, circulation within the Union, placing on the market, control of the conditions of opening and operation of manufacturing establishments, holding for commercial purposes, import, wholesale distribution of veterinary medicinal products and retail distribution, including extemporaneous preparation, and market surveillance (inspection, pharmacovigilance) of veterinary products.

Directive No. 07/2006 specifies the profiles authorised to open and operate veterinary pharmaceutical establishments, including pharmacists and veterinary doctors, at different levels of the pharmaceutical chain (manufacturing, importing, distributing, pharmacy). Manufacturing, import and distribution establishments must be owned either by a pharmacist or a veterinary doctor or by a company in whose management or general direction a pharmacist or veterinary doctor participates, in accordance with the provisions of the company law in force in the Member State. The

pharmacist or veterinary doctor is then the person in charge of the pharmacy and is responsible for ensuring compliance with the provisions relating to veterinary pharmacy.

The retail sale and distribution of veterinary products is carried out by persons authorised to do so. These persons are veterinary doctors with a veterinary dispensary, doctors of pharmacy with a pharmaceutical dispensary, and veterinary school teachers for the treatment of animals admitted for consultation or hospitalisation. By way of derogation and for limited categories of medicinal products, veterinary surgeons registered with the Order for activity within groups of breeders or agricultural professionals subject to an approval procedure in the Member State with regard to veterinary medicinal products for everyday use, and State veterinary officers in respect of the medicinal products necessary for the implementation of compulsory prophylaxis directed by them and for other medicinal products insofar as no practising veterinary doctor or group practices in the area, are authorised to hold and dispense veterinary medicinal products.

In the case of Côte d'Ivoire and Niger, the transposition process has also been delayed. While Niger opted for regulatory texts adopted by areas of harmonisation but taking into account the community objectives, Côte d'Ivoire opted for a legislation framing veterinary science in its entirety by adopting a Veterinary Public Health Code by law n° 2020-995 of 30 December 2020. Book II of the Code transposes Directive No. 07/2006/CM/UEMOA of 23 March 2006 on veterinary pharmacy, as shown in Table 3. In doing so, the two countries have complied with the transposition requirements by adopting different procedures.

Table 3. Status of transposition of the EU Veterinary Pharmacy Directive into national law

Countries	Texts	Scope of application
Côte d'Ivoire	Loi n° 2020-995 du 30 décembre 2020 portant Code de la Santé publique vétérinaire [Law 2020-995 of Dec. 30, 2020 on the Veterinary Public Health Code]. (40)	Veterinary public health control and inspection Animal health Veterinary pharmacy Animal welfare Food safety of animals and animal products Organisation of the professions Laboratories
Niger	Ordonnance n°2009-20 du 3 novembre 2009, portant création d'un Etablissement public à caractère administratif dénommé Laboratoire Central de l'Élevage (LABOCEL) [Ordinance 2009-20 of Nov. 3, 2009, creating a public establishment of an administrative nature called « Central laboratory of Livestock » (LABOCEL). (41) Décret n° 2011-617/PRN/MEL du 25 novembre 2011 Réglementant la pharmacie vétérinaire [Decree 2011-617/PRN/MEL of Nov. 25, 2011 regulating veterinary pharmacy]. (42)	Quality control of foodstuffs and control of vaccines Production, control and distribution of biological products, including veterinary vaccines Transposition of Directive n° 07/2006/CM/UEMOA of 23 rd March 2006 on veterinary pharmacy

Décret n° 2011-618/PRN/MEL du 25 novembre 2011 fixant les modalités d'exercice de la profession vétérinaire [Decree 2011-618/PRN/MEL of Nov. 25, 2011 establishing the modalities of practice of the veterinary profession]. (43)	Conditions of practice of the veterinary profession Sectors of activity Delegations Illegal practice Control and inspection Sanctions
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5. Conclusion

The UEMOA Community regulation of veterinary pharmacy is the result of the will of the Member States of the Union to create a common economic space and to encourage freedom of movement, establishment and trade within the Union. The various processes have enabled veterinary medicinal products to benefit from a complete legal framework within the area. Notwithstanding the existence of directly applicable Community provisions (Regulation), Member States are optimising their national regulations by transposing Directive No. 07/2006/CM/UEMOA of 23 March 2006 on veterinary pharmacy or by continuing to apply the relevant national standards. This UEMOA harmonisation of veterinary drug regulation has been taken up in its essential principles by the Economic Community of West African States (ECOWAS), a REC grouping 15 West African countries, thus demonstrating the success of this harmonisation process. However, there is still work to be done, particularly in areas that have not yet been harmonised, such as inspection, laboratory control, pharmaceutical market surveillance and the evaluation of the harmonisation process at community and national levels, in order to determine the impact on the achievement of community objectives and to define new strategic orientations for the economic and scientific development of the member states and the region with regard to the development of veterinary pharmacy.

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Conflict of Interest

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