



## Veterinary medicines in Togo: legislation and distribution channels for antibiotics used in poultry

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Received: 07-02-2024

Accepted: 25-04-2024

Published: 30-04-2024

### ABSTRACT

The poultry farming sector contributes enormously to the satisfaction of the needs of the Togolese population in meat products. One of the inputs to the development of this poultry industry is the use of antibiotics to combat sanitary constraints in the farms. Legislation on Veterinary Drugs (VD) and quality assurance of these products is therefore an essential factor for the poultry sector. In Togo, little surveys have yet evaluated the distribution circuit of VD, the quality and quantities of antibiotics used in the poultry sector. The objective of this study was to describe the official VD distribution system and to evaluate the quality and quantity of antibiotics distributed through this system by means of marketing authorizations (MAs) and the turnovers of VD wholesalers. The study approach consisted of direct interviews with officials from the Livestock Directorate to describe the official VD circuit and the legislative texts governing this distribution. On the other hand, surveys were conducted among professional wholesalers of VD in Togo to evaluate the turnover of antibiotics consumed and the availability or not of MAs for antibiotics. Excel software was used to collect and analyze the data. This study took place from September 2<sup>nd</sup> to September 22<sup>nd</sup>, 2022. The study revealed that the VD in Togo is governed mainly by decrees and orders. There are two parallel markets. The players involved in this official circuit are wholesale distributors, retailers, and representatives of pharmaceutical companies. All the VD distributed by these players in the official circuit comes from imports. There are eight VD wholesalers in Togo. The most imported drugs are antibiotics. The illicit market constitutes a significant non negligible competitive market. The share of drugs from Asia is significant because it is cheaper. The monetary value for the purchase of VDs in Togo was estimated at 7,080,704,605 FCFA from 2018 to 2021. It was observed also that the most used antibiotics are in solid form, especially in poultry. The solid antibiotic mostly used in farms (16780520 Kilograms (kg)) as well as in poultry (9229286 kg) is penicillin G while in the liquid form, oxytetracycline is the widely used with 1216.05 liters (l) for poultry farming out of 2211 liters for all animal farms. A significant proportion of VDs comes from the official circuit but does not have a marketing authorization. This is mainly due to the lack of strict enforcement of the regulations. It is therefore important to review the quality of the regulations on the distribution of VD, which will benefit the consumer of poultry products in Togo.

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**Keywords:** Veterinary drugs, wholesalers, legislation, antibiotics, poultry.

## **INTRODUCTION**

Livestock farming contributes around 6.7% to Togo's GDP (TOGO/MAEDR, 2020). A large proportion of the population lives directly from this activity, which contributes to the country's food and nutritional security through its various products. In recent years, the sub-sector has undergone an evolution, marked by a gradual increase in production in various sectors. In West Africa, demand for animal products is growing in line with population growth, urbanization and rising incomes (Sounon et al., 2019). Despite this evolving trend in the livestock subsector and the support of public and private players, difficulties remain, and the country still has a structural deficit in meat products. The deficit is estimated at 45% compared to domestic needs, leading the country to turn to large imports with the result of enormous currency losses estimated to be more than 21 billion CFA francs per year (TOGO/MAEDR, 2021). The poultry sector has experienced sustained growth over the past decade, rising from 8 to 25 million broilers between 2011 and 2017, and this growth could continue over the next few years. In fact, the annual production of poultry meat, established in 2020 at 23,360 tonnes could triple and increase to 61,702 tonnes in 20 years. In the same line, the production of eggs for consumption also follows the trend, estimated to rise from 188 million units to 250 million over the same period (TOGO/MAEDR, 2020). This sector therefore plays an important role to alleviate the deficit in meat products. Furthermore, poultry products are a highly appreciated food and an important and cheaper source of protein for the population. Despite its vital socio-economic role, the development of livestock farming is hampered by several constraints, including the health issue, which forces farmers to use veterinary drugs in general and antibiotics in particular (Bedekelabou, 2022) to protect their flocks and minimize losses. To meet the needs of the growing population, the use of drugs to improve animal performance became a common practice (Gnikpo et al. 2016). Regarding veterinary drugs, it should be noted that the organization of the veterinary

drugs market in French-speaking West African countries has major shortcomings. These include the lack of specific legislation following the liberalization of veterinary drugs, the lack of inspection of veterinary drugs before their selling on markets and, above all, the lack of systematic recording or exhaustive monitoring of consumption due to the existence of parallel channels alongside the official distribution channel for veterinary drugs (Mensah, 2014). The consequence of all these shortcomings is, on the one hand, the large-scale misuse of antimicrobials on farms to combat the low productivity and high mortality caused by infectious diseases and, on the other, the development of antimicrobial resistance. The remarkable efficacy of these antibiotics has been accompanied by their massive and abusive use, leading to the emergence of bacterial resistance (Ben et al., 2005; Gafon et al., 2019). The uncontrolled use of antibiotics in breeding leads to the selection of resistant germs, a resurgence of infections, increased mortality and lower chicken meat productivity in Tchad (Abba et al., 2017). Unfortunately, data on antimicrobial use and resistance in these countries are still limited compared to developed countries and even to the English-speaking countries of the West African sub-region. (Bedekelabou, 2022). Thus, in view of the adverse consequences that informal practice of antibiotic therapy in poultry farms may have and due to the lack of available data on consumption of veterinary antibiotics, it was necessary through this study to review the regulatory framework, describe the official VD distribution circuit and assess the quality and quantity of antibiotics distributed through this circuit based on marketing authorizations (MAs) and the turnover of VD wholesalers.

## **MATERIALS AND METHODS**

### **Study period and location**

The study was conducted between 02<sup>nd</sup> September 2022 and 22<sup>nd</sup> December 2022 in Lomé, Togo. Togo is a small country of West Africa. It is bordered by Ghana to the west, Benin to the east and Burkina Faso to the north. It is a tropical country with a surface area of

56,785 square kilometers, and its economy is essentially based on agriculture. Togo had a population of 8,954,498 inhabitants according to the fifth general population and housing census (RGPH-5) held in 2022. Lomé is the capital of Togo and the country's cultural, economic and commercial center. The city is located on the Gulf of Guinea. Its location on the Atlantic Ocean is important for the country's economy, as well as for trade with neighboring and Western countries via the container terminal at the autonomous port of Lomé. This port serves as a platform for veterinary medicine imports, which are mainly carried out by sea.

### **Data collection**

Information for this study was collected through direct interviews with officials of the Directorate of Livestock, the chairman of the National Order of Veterinary Physicians and the president of the Togolese veterinary medicine wholesalers, in order to gather information on the legal texts in force relating to veterinary pharmacy and to describe the official distribution circuit for veterinary drugs.

Furthermore, a cross-sectional questionnaire survey coupled with direct interviews with veterinary drug importers evaluated the quantities of the veterinary medicinal product imported and distributed in Togo; those with marketing authorizations (Mas) and those without (MAs); and the problems associated with the distribution of the VD in Togo. This cross-sectional survey was carried out using the complete database of importing wholesalers legally registered in Togo and provided by the Directorate of Livestock and the President of the National Association of Veterinary Medical Drugs Importers of Togo. (ANIVET). The data collected covered the period from 2018 to 2021.

### **Data analysis**

The data collected during the surveys were first entered in Excel and descriptive was performed using Excel software (version 2016).

## **RESULTS**

### **Official texts governing veterinary medicinal products in Togo**

The exchanges with the pharmacy and veterinary drug authorities revealed that there are several categories of texts relating to veterinary pharmacy in Togo. First the international texts, which are mainly the texts of the World Organization for Animal Health (WOAH) and those of the regional organizations (ECOWAS, WAEMU) and then the national texts consisting of laws and decrees.

### **International texts relating to veterinary pharmacy : World Organization for Animal Health (WOAH) and Codex Alimentarius texts**

The Terrestrial Animal Health Code of the World Organization for Animal Health takes into account, in some of its lines, veterinary legislation in the form of recommendations or guidelines that countries should include in their respective legislation. For example, countries should: (i) provide an exhaustive definition of a veterinary product, including any exclusions; (ii) regulate the import, manufacture, trade, distribution, and use of veterinary products. Countries must then rely on WOAH texts to fill the gaps in their national legislation. In addition, antimicrobial agents in veterinary medicine are specifically covered in chapters 6.6 to 6.10 of the Terrestrial Code.

At the international level, there are also the standards of the Codex Alimentarius, of which the country is a member, and which sets global maximum residue limits (MRLs) for purposes of international trade and exchange, while stipulating that stakeholders may define their own maximum residue limits and risk management recommendations relating to residues of veterinary drugs in foodstuffs to the extent that this is justified and does not constitute an obstacle to international trade.

### **Texts of sub-regional organizations: ECOWAS and UEMOA**

As a member of sub-regional organizations such as WAEMU, Togo is

subject to the regulatory provisions of the ECOWAS and WAEMU.

Primary legislation in force (Laws)

- Law No. 98-019 of 23 December 1998 on the exercise of the veterinary profession
- Law No. 99-002 of 12 February 1999 on animal health in the Togolese Republic.
- Law No. 2004-020 of 30 September 2005 on the creation of the national order of veterinary surgeons.

Secondary legislation in force (decrees and orders)

- Decree No. 2012-015/PR regulating veterinary pharmacy in Togo.
- Order No. 32/MAEP/SG/DEP regulating the activities of village livestock auxiliaries.
- Order No. 44/MAEP/SG/DEP setting the conditions for undertaking the veterinary profession.
- Order No. 73/MAEP/SG/DEP fixing the conditions for the exercise of the profession of wholesaler, distributor of veterinary products.
- Order No. 84/10/MAEP/Cab/SG/DE laying down the conditions for importing and collecting veterinary drugs
- Decision No. 92/15/MAEP/SG/DE related to good practice in the manufacture, import and distribution of veterinary drugs.
- Order No. 93/15/MAEP/CAB/SG/DE establishing the system of authorizations and other measures relating to pharmacy.

Draft laws are also under way as part of the modernization of veterinary legislation in Togo. These include:

Draft primary legislation: Draft law amending Law No. 98-019 of 23 December 1998 on the practice of the veterinary profession

Draft law on animal health (replacing Law No. 99-002 of 12 February 1999 on animal health in the Togolese Republic)

### **Actors, organization and official distribution channels for veterinary drugs in Togo**

#### ***Veterinary drug operators in Togo***

Eight (08) wholesale importers of veterinary drugs were identified in Togo, sheared among 3 regions: the maritime region

(06), the central region (01) and the savannah region (01).

In summary, the conditions for operating as a wholesaler and the import procedures are as follows:

- Be registered with the national association of veterinary surgeons (1st manager of the import structure owning more than 50% of the company's shares),
- be authorized to set up in private practice as a wholesaler of veterinary products
- Hold an economic operator's card,
- Submit an import authorization application to the Minister for Livestock, with a pro-forma invoice,
- Study of the conformity of the application by the Department of Livestock (DE),
- Receive a favorable opinion from the Department of Livestock DE,
- Launch order if favorable opinion,
- Request for removal authorization issued by the Department of Livestock DE,
- Decanting/Compliance inspection after favorable opinion,
- Collection and storage

In addition to wholesalers, the other actors involved in the distribution of veterinary medicinal products are: i) Veterinary Doctors and Pharmacies: There are 49 of these entities, unevenly distributed across the country, with a higher concentration in the maritime region (50%). They are mainly responsible for the retail distribution of veterinary drugs. ii) State services: These are mainly responsible for the distribution of veterinary products such as vaccines. These entities also have small quantities of veterinary drugs available for use on livestock farms through the network of livestock technicians officially appointed as chief veterinary officers (CPVe) in the country's cantons and villages not served by the network of private veterinarians.

#### ***Distribution of veterinary medicinal products in Togo***

The official market is the distribution channel for veterinary drugs authorized by the competent authorities. The main actors are

obliged to follow the various provisions imposed by the regulations in force.

Investigations have shown that two distribution channels coexist: the official or authorized channel and the parallel or illicit channel, as illustrated in Figure 1.

### **Quantities of veterinary drugs products imported and distributed in Togo**

#### ***Monetary estimate of quantities imported and sold in Togo***

Veterinary drug consumption in Togo followed a growing curve between 2018 and 2021 in terms of monetary value. The distribution of turnover over the 4 years of the study is shown in the figure below (Figure 2). We noticed that every year the consumption increases.

### **Antibiotics imported and distributed in Togo from 2018 to 2021**

#### ***Types of antibiotics imported into Togo***

The Table 2 shows the different types of antibiotics marketed in Togo.

### **Origin and form of antibiotics used in livestock farming in Togo**

#### ***Origins of antibiotics marketed in Togo***

In Togo, almost all the veterinary drugs marketed come from imports from European Union countries, Asia, America, and a very small proportion from Africa. For example, trade with wholesalers of the veterinary medicinal product has shown that a variety of veterinary pharmaceutical firms from different continents export to the territory of Togo. These laboratories are listed in Table 3.

#### ***Form of antibiotics marketed in Togo***

Table 4 shows the quantities of antibiotics imported in solid form and sold in Togo. The most used antibiotics in Togo's livestock farming are penicillin G, followed by the tetracycline family. These antibiotics are used a lot because of their efficacy. In treatment of large bacterial infections. It is noted that a considerable proportion is used in poultry farming (more than half is used for poultry farming).

Table 5 shows the quantities of antibiotics sold in liquid form. It is observed that antibiotics used in liquid form are rarely used in poultry farming and are less and less in demand by poultry farmers because, liquids forms of antibiotics need to be used with some cares and precautions as temperature cares.

Tetracyclines and the sulfamids are most widely used. Sulfamids are widely used because of their quick effect to reduce the evolution of bacterial growth. While macrolides of the norfloxacin class are less and less used.

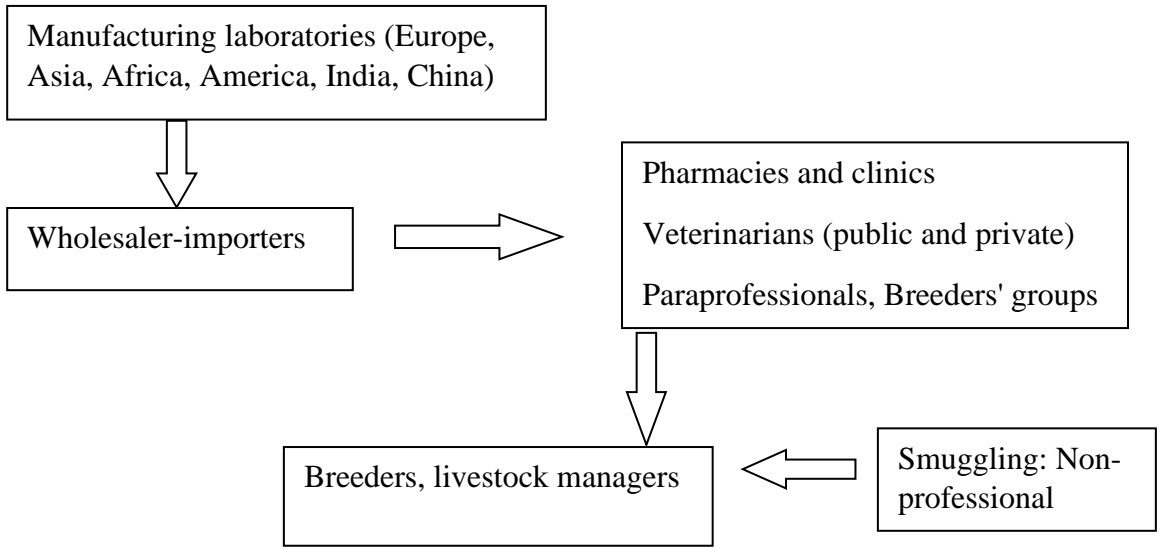
### **Management of unsold stocks by wholesalers**

Table 6 and 7 show the quantities of solid and liquid antibiotics not sold, respectively. It is noticed that it happened that wholesalers of the veterinary medicinal product did not sell all the antibiotics that were intended for distribution.

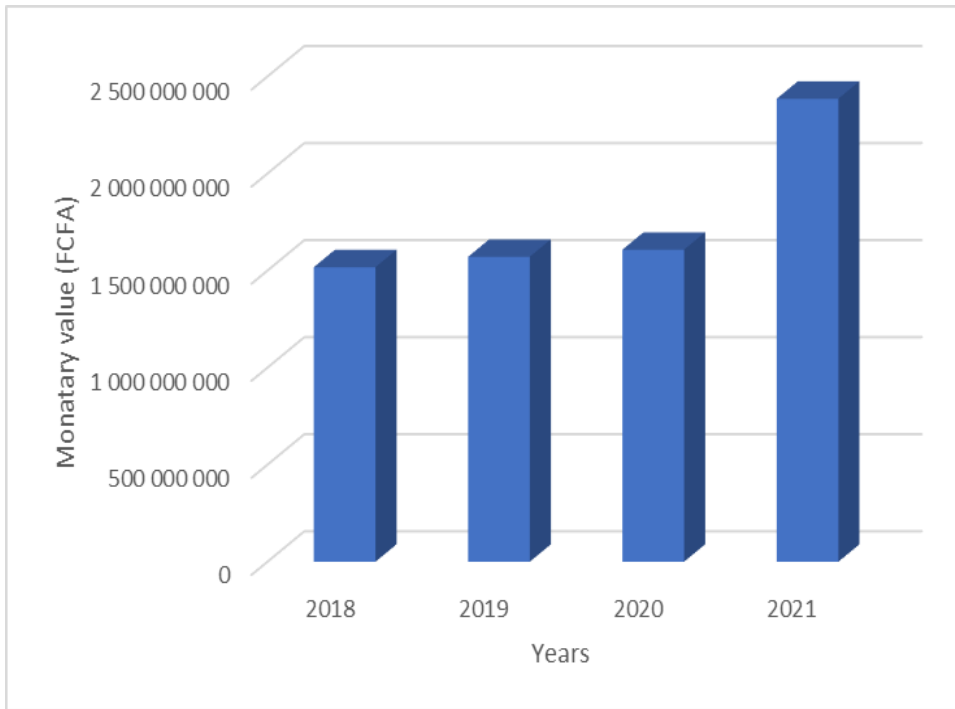
Unsold antibiotics that have reached their expiration date are automatically burnt in the presence of the relevant authorities from the veterinary services of the Livestock Directorate.

### **Quality of veterinary drugs imported and distributed in Togo**

Togo uses the WAEMU list of Marketing Authorization Holders. A substantial proportion of the marketing authorizations issued relate to vaccines and antibiotics. During the study, it was noticed that most wholesalers had an application for a veterinary medicinal product that was still awaiting a marketing authorization. As far as antibiotics are concerned, 31.43% of marketed antibiotics still do not have marketing authorization in Togo. Table 9 shows the antibiotics in compliance with WAEMU marketing authorization in Togo. Out of 93 antibiotics marketed by wholesale distributors in Togo, 43% do not yet have marketing authorization because they are currently being evaluated by the WAEMU commission.



**Figure 1:** Distribution circuit for veterinary drugs in Togo.



**Figure 2:** Consumption of veterinary drugs products in Togo in monetary terms (FCFA). (Source: DE, FY 2022).

**Table 1:** Breakdown of the number of players approved to distribute veterinary drugs in Togo.

<b>Region</b>	<b>Number of VD distributors</b>
<b>Savanes</b>	7
<b>Kara</b>	5
<b>Central</b>	5
<b>Plateau Est</b>	4
<b>Plateau Ouest</b>	3
<b>Maritime</b>	25
<b>Total</b>	49

**Table 2:** Lists of antibiotics sold by wholesalers (legally present on the Togolese market)

<b>Family</b>	<b>Antibiotics</b>
<b>Tetracycline</b>	Oxytetracycline, Doxycycline
<b>Polymyxin</b>	Polymyxin E or Collistin
<b>Quinolone</b>	
<b>Fluoroquinolone or carboxylic</b>	Flumequine
<b>Macrolides</b>	
<b>Oxapenems or clavulanic acids</b>	Enroflocin, Norfloacin
<b>3<sup>rd</sup> generation cephalosporins</b>	
<b>Penicillin G</b>	Tylosin, Erythromycin, Norfloxacin
<b>Aminopenicillin</b>	Amoxicillin + clavulanic acids
	Ceftiofur
<b>Sulfamides</b>	Benzyl penicillin, Procaine penicillin
	Amoxycilin
<b>Aminosides</b>	Sulfamerazine ou diaveridine
<b>Sulfamethoxazole</b>	
<b>Streptomycin TMP Trisulmycine</b>	Streptomycin, Neomycin

**Table 3:** Pharmaceutical laboratories selling poultry antibiotics in Togo.

<b>Country of origin</b>	<b>Laboratory</b>
<b>Holland</b>	Interchimie, VMD, Kela, Mercodi, Kepro, Alfasan
<b>Switzerland</b>	Lemanab
<b>France</b>	Vetoquinol, Supelco, Sandoz, ceva, Lobbs, Qualian, Laprovet
<b>Morocco</b>	Medvet
<b>USA</b>	Pubchem, Pfizer

<b>England</b>	Delprim, Genevet Ltd
<b>China</b>	Hebeilihua, Shijiazhua
<b>India</b>	GMP, Tylan
<b>Jordan</b>	VAPCO
<b>Tanzania</b>	Nicrop
<b>Italy</b>	Arion Fasoli
<b>Philippines</b>	Filipinonet
<b>Spain</b>	Ovejero, Hipprasa, Invesa

**Table 4:** Quantities of imported solid antibiotics sold in Togo and proportion used in poultry farming (Kilograms).

<b>Family of antibiotics</b>	<b>Antibiotics</b>	<b>Total antibiotics (kg)</b>	<b>Poultry antibiotic (kg)</b>
<b>Tetracycline</b>	Oxytetracycline	640126,67	352069,669
	Doxycycline	155537	85545,35
<b>Macrolide</b>	Tylosin	1125260	618893
<b>Polymyxin</b>	Colistin	76288,33	41958,5815
<b>Oxapenem or clavulanic acid</b>	Amoxicillin	1565	860,75
<b>Penicillin G</b>	Benzylpenicillin	16780520	9229286
<b>Fluoroquinolone</b>	Enrofloxacin	160	88
<b>3rd generation cephalosporin</b>	3 <sup>rd</sup> generation cephalosporin	480	264
<b>Quinolone</b>	Flumequine	44580	24519
<b>Sulfamide</b>	Trimethoprim	450	247,5
	Sulfadimidine	37458	2060,9
<b>Aminoxide</b>	Streptomycin	33912	18651,6
	Neomycin	32091,33	17650,2315

**Table 5:** Antibiotics sold in Togo in liquid form.

<b>Family Antibiotics</b>	<b>Antibiotics</b>	<b>Sold (liter)</b>
<b>Tetracycline</b>	Oxytetracycline	2211
<b>Macrolide</b>	Tylosin	1500
<b>Fluoroquinolone</b>	Enrofloxacin	567,33
	Norfloxacin	24,56
<b>Sulfamids</b>	Thrimetropin	1920



**Table 6:** Antibiotics in solid form not sold.

<b>Family of antibiotics</b>	<b>Antibiotics</b>	<b>Sold out (%)</b>
<b>Tetracycline</b>	Oxytetracycline	2
	Doxycycline	-
<b>Macrolide</b>	Tylosin	-
<b>Polymyxin</b>	Collistin	7,08
<b>oxapenema or clavulanic acid</b>	Amoxicillin	8,33
<b>Penicillin G</b>	Benzylpenicillin	-
<b>Fluoroquinolone</b>	Enrofloxacin	7,08
<b>3<sup>rd</sup> cephalosporin generation</b>		
<b>Quinolone</b>	Flumequine	0,46
<b>Alfatriam</b>	Trimethoprim	0,44
<b>Aminoxide</b>	Streptomycin	-
	Neomycin	-
<b>Sulfamid</b>	Sulfadimidine	-

**Table 7:** Antibiotics in liquid form not sold.

<b>Family of antibiotics</b>		<b>Non sold (%)</b>
<b>Tetracycline</b>	oxytetracycline	3,4
<b>Macrolide</b>	Tylosin	0,4
<b>Fluoroquinolone</b>	Enrofloxacin	-
	Norfloxacin	-

**Table 8:** Breakdown of WAEMU MAs by category (Updated list of Community MAs issued by the WAEMU).

<b>Categories</b>	<b>Number of MAs</b>	<b>Percent</b>
<b>Antibiotics</b>	133	31
<b>Pest control</b>	118	27,5
<b>Vaccines</b>	142	33,1
<b>Vitamins and trace elements</b>	23	5,4
<b>Others</b>		
<b>Total</b>	13	3
	429	100

**Table 9:** Status of antibiotics used in Togo according to MAH.

Wholesalers	Total number of antibiotics sold by the wholesale distributor	Number of marketing authorizations validated by the UEMOA commission	Number of antibiotics not validated by the UEMOA commission (no MA)
1	7	5	2
2	19	14	5
3	2	2	0
4	15	7	8
5	16	11	5
6	27	14	13
7	7	0	7
<b>Total</b>	93	53	40

## DISCUSSION

### Official texts governing veterinary medicinal products in Togo

Veterinary legislation is an essential element of the national provisions that enable veterinary authorities to fulfil their key functions, including surveillance, early detection, and control of animal diseases and zoonoses, and food safety, among others. Most WHO member countries have received a PVS evaluation, and some, such as Togo, received a follow-up mission dedicated to advise and assist in the modernization of their national veterinary legislations. The new WHO guidelines have thus been used to update national legislation where weaknesses in existing texts have been identified. In the area of veterinary pharmacy segment, several legislative texts regulate veterinary medicinal products in Togo in accordance with the critical competencies of the PVS Tool and the WOSHA Terrestrial Code (WOSHA, 2021). These texts are both Community and national. The authorization system for veterinary drugs, for example, is subject to the Directives and various WAEMU Regulations adopted in 2006, and whose conditions of implementation in the territory of Togo are provided in the Presidential Decree No. 2012-015/PR regulating the veterinary pharmacy. This very comprehensive national text provides all the necessary clarifications regarding regulations

on imports, marketing, and wholesale distribution, as well as rules on prescription and labelling in Togo. The decree also requires that owners of animals producing food intended for human consumption are required to register the acquisition and administration of veterinary medicinal products prescription. Retail dispensing is subject to authorization and is reserved for authorized persons, which are veterinary doctors holding a veterinary office, pharmacy doctors and veterinary schoolteachers. A draft law is currently being prepared to modernize the 1999 Health Police Act and will consider all the gaps and inadequacies in current legislation on veterinary pharmacy. Title VII of the draft of animal Health Police Act, which deals with veterinary pharmacy, sets out the rules and main principles governing imports, marketing authorizations and the production and wholesale and retail sale of medicinal products are recalled. It is also suggested that principles and good practices for the distribution and use of veterinary medicinal products should be included in the future Primary Act. This will provide the country with a comprehensive and readable law easy to understand. Although current legislation on veterinary pharmacy defines an appropriate legal framework for the production and distribution of veterinary drugs, the effectiveness of the legislation and its application remain a challenge. Indeed, there is

no effective system for monitoring the enforcement of the regulation. Despite many awareness campaigns and enforcement actions, the impact on the ground remains insufficient and the effectiveness very limited. Moreover, as there are currently no criminal provisions to punish illegal trafficking, it would be advisable for Togo to introduce such provisions in the current draft law.

Similar studies were carried out by Dognon in 2018 in Benin and in the West African sub-region. Their study showed, for example, that in Benin, the import of veterinary drugs is regulated by interministerial decree No. 425 of 07 October 1998, while the terms and conditions for practicing the veterinary profession are set out in decree No. 2004-292 of 20 May 2004. Recently, Decree No. 2014-352 of 02 June 2014 on the veterinary drugs' diet was issued. In Niger, after Law No. 70-19 of 18 September 1970 on the Livestock Code with its implementing decrees and orders, Law No. 2004-048 of 30 June 2004 on the framework law relating to livestock (MRA Niger, 2004) is the main veterinary regulatory text for the practice of veterinary medicine. Unlike Niger, veterinary legislation in Mali was recently updated by Law no. 2016-004 of 12 February 2016 (repealing Law no. 01-062 of 2001) governing veterinary pharmacy. In Senegal, it was in 2008 that the practice of the profession of veterinary medicine and pharmacy was regulated by Law No. 2008/07 of 24 January 2008 (JO, 2008). In short, West Africa is poor in legislation regulating the market of veterinary medicinal products Unlike the European Union, which is rich in regulatory texts on veterinary antibiotics and their residues in food. It is essential that the countries of West Africa adopt regulatory texts to limit the level of antibiotic residues in foodstuffs. On the other hand, it should be said that African countries should take inspiration from some of the approaches that are being taken in Europe, because these will play an important role in animal health rather than in human health and globally in one-health. They should follow the example of the European regulation (Directive 2001/82/EC and EU Regulation 712/2012) which requires for any

antibiotic for veterinary use the assessment of its quality, its safety to the user, the consumer, the environment, and the animal to which it is intended, as well as the evaluation of its effectiveness. A marketing authorization shall be granted if the scientific study concludes that its use exceeds the risks involved. In addition, the National Veterinary drugs Agency (ANMV) monitors antibiotics after they are placed on the market, whether in terms of manufacturing (control of good manufacturing practices, quality control), marketing (control of advertising) or adverse reactions (pharmacovigilance).

In summary, it is noted that until 2017, the WAEMU had only six legislative texts (four Regulations and two Directives) regulating the veterinary medicine sector. No functional legal text for searching for drug residues in foods of animal origin yet exists (CEMAC-UEMOA, 2017).

### **Problems relating to the distribution of veterinary drugs in Togo**

The deficiencies found in the regulatory texts and, in particular, the weaknesses associated with the application of the existing texts would explain to a large extent the malfunctions observed in the sector of the import and distribution of the veterinary medicinal product. The results showed that some operators would be granted authorization to open distribution establishments and subcontract their authorization to individuals who do not belong to the veterinary profession. There is also no centralized system for the allocation of geographical areas to players to ensure adequate coverage of the national territory by wholesalers and veterinary retail distributors. This leads to distribution failures characterized by the absence of players in some areas, such as the north of the country, where there is only one wholesaler of the veterinary medicinal product. Another challenge in the VD distribution chain is the non-differentiation between wholesaler distributors and retailer-distributor. During the surveys, it was observed that some wholesalers do not prevent themselves from delivering the VD directly to livestock farmers. Import and wholesale by

some having an authorized retailer have also been observed. These observations are like those reported by other authors such as Mouiche et al. (2018) in Cameroon. Indeed, this author also reported anomalies in the VD distribution chain in this country. The findings are also similar to those of M. Lobry and Gazzali et al. (1988, 2016), who stated that the distribution of veterinary medicinal products poses particular problems in developing countries.

The results corroborates that the findings of Messomo Ndjana, 2006, who stated that the import of veterinary drugs was initially handled by state entities in most West African countries. With the liberalization of the veterinary profession, governments transferred the distribution of veterinary products to private entities. Therefore, the deployment of veterinary medicinal products in West Africa is carried out by both wholesalers, semi-wholesalers, and retailers, which are veterinarians, pharmacists, engineers, breeding technicians, breeder groups and authorized traders. (Soumana, 2013). Retail distribution is mainly carried out by pharmacies and veterinary offices under the responsibility of veterinarians. In addition to this official circuit, there are parallel markets for the illicit sale of veterinary products in most West African countries (Dognon et al., 2018). According to Dognon (2018), the veterinary drugs marketed in this parallel circuit come from the official market and the counterfeit market on the one hand, and from smuggling on the other. The relatively low cost of sale of these products and the legislative gaps in the regulatory texts in force in the West African countries favor this market. Furthermore, the difficulty of the official market in covering the enclave areas of West African countries reinforces this situation.

### **Quantity and quality of imported veterinary medicinal products**

Although the data collected during the survey addresses the regulatory and organizational aspects of all players involved in the veterinary medicinal product market in Togo, it also covers quantity and quality

aspects. The study shows that the legal provisions against the repression of counterfeit medicines circulating in Togo, especially in towns and villages bordering Benin and Ghana, require strong action. The use of counterfeit medicines is hampering the development of livestock farming through the persistence of animal diseases, thereby confirming the lack of development of the farming and a loss of earning for all the players involved in this phenomenon.

All (100%) of the veterinary drugs circulating in the country come from imports of finished packaged products from the countries of origin. The main suppliers are European and Asian countries. No products are manufactured in Togo. This implies that the absence of pharmaceutical industry to manufacture veterinary drugs. Studies conducted showed similar results in Côte d'Ivoire, where 87.5% of imports came from European countries, 4.6 from India and 3.6 from Africa (Assoumy, 2009). In Cameroon, 47% of products come from Europe, followed by 28% from Asia (Mouiche et al., 2018). Also, Officially, the countries of West Africa import most veterinary pharmaceutical products from countries of the European Union (EU) including France in particular (Soumana, 2013). Part of the African veterinary pharmaceutical market is supplied by products from North America (Canada), Latin America (Brazil), Asia (India, Pakistan, China) and Africa (Nigeria, Ghana) (Soumana, 2013; Mensah et al., 2014a). This leads us to conclude that a great deal of effort needs to be made by African states, in this case our country needs to have laboratories to produce veterinary drugs with enormous monetary resources, which can create jobs and increase GDP.

The presence of counterfeit medicines and generics (from Asia) on the Togolese market could be explained by the fact that these products are cheaper, despite the fact that Asian countries are ranked number 1 for counterfeit veterinary drugs (Messomo, 2006). On the other hand, this could be explained by the fact that the veterinary drug control system is inadequate or almost non-existent. To

remedy this, there will be an increasing need to train highly qualified personnel and to invest in control. Indeed, according to Téko-agbo et al., 2009, if the identification of sources of supply is imperative to guarantee the quality of veterinary drugs marketed in a country, the production unit is the first link in the chain that must guarantee product quality.

From this study it is found that in the solid form, penicillin G in this case benzylpenicillins are the most used in livestock farms in Togo. This result can be explained by the fact that more than 50% of antibiotics imported to Togo come from Europe. On this continent, however, the requirement for the disposal of AMs is strictly observed. This result is consistent with that of the World Health Organization, 2023 which proved that penicillines are the antibiotics with the highest MA in Europe (12%). Regarding liquid antibiotics, the research showed that tetracyclines, in this case oxytetracycline, were the most used between 2018 and 2021 in Togo; these findings can be explained by the fact that tetracyclines are the most widely used and sold antibiotics by pharmaceutical companies worldwide. Thus, the work carried out by the WHO confirms this trend; where tetracyclines occupy a higher 36.9% (tetracyclines, aminoglycosides + polypeptides + tetracyclines) and the same WHO proves that fewer and fewer third and fourth generation cephalosporins and fluoroquinolones are consumed. These findings match those of Salah in 2017, who claimed that the ever-decreasing use of cephalosporins translates into increased resistance of enterobacteria to cephalosporins

Likewise, the successive work by Mensah in 2014 and Dognon in 2018 also supports these findings because according to these authors, the main classes of antibiotics used in West Africa are tetracyclines, sulfamides, macrolides and  $\beta$ -lactams. (Mensah et al., 2014b; Dognon et al., 2018).

From this study it was found that in Togo 93 antibiotic products are marketed by wholesalers of veterinary drugs, of which almost 40% do not have MA. This result could be explained, on the one hand, by the fact that

the MA is a complex and rigorous regulatory process aimed at ensuring the safety, effectiveness and quality of products intended for animals and is demanding in terms of certain conditions that pharmaceutical companies fail to meet for validation by the competent regulatory authorities or veterinary regulatory experts of the UEMOA area do not yet judge or approve of validating. These reasons include:

- **Insufficient data:** The regulatory authorities require solid scientific data to demonstrate the efficacy and safety of a veterinary medicinal product. If the data provided is insufficient, inconsistent or of poor quality, marketing authorization may be refused.

- **Unproven efficacy:** A veterinary medicinal product must demonstrate its efficacy in the treatment or prevention of animal diseases. If the evidence is not convincing or if the efficacy is not sufficiently established, the marketing authorization may be refused.

- **Insufficient safety:** The safety of animals treated with the medicinal product is a major concern. If concerns about the safety of the medicinal product, such as serious side effects or unacceptable risks, are identified, the marketing authorization may be refused.

- **Quality problems:** Veterinary drugs must be manufactured to strict quality standards to ensure that they are stable, pure and free from contaminants. Manufacturing or quality problems can lead to refusal of marketing authorization.

- **Potential misuse:** If the drug presents a high risk of inappropriate use or misuse, it may not be authorized in the market. This may include concerns about dosage, administration, or drug interactions.

- **Lack of medical need:** If the regulatory authorities believe that there are already sufficient medicines available to treat a specific disease and that there is no proven medical need for a new drug, marketing authorization may be refused.

- **Insufficient data on food residues:** For veterinary medicinal products to be used on animals intended for human consumption, it is important to demonstrate that drug residues in

food products of animal origin do not pose a risk to human health.

- **Ethical issues:** If the veterinary medicinal product raises ethical concerns, such as serious adverse reactions in animals or controversial research practices, this could influence the decision to grant marketing authorization.

- **Regulatory changes:** Veterinary medicinal products regulations may change over time. If the drug no longer meets current regulatory standards, it may not receive marketing authorization.

- **Processing times:** The process of obtaining marketing authorization can take time, and delays in submitting documents or in communicating with the regulatory authorities can lead to a refusal of marketing authorization.

On the other hand, non-validation of marketing authorizations can be explained by the constraints encountered by the UEMOA commission, which are mainly as follows:

- **Lack of transparency:** Some critics may blame the WAEMU Commission for a lack of transparency in its regulatory processes. The lack of clarity and accessibility of decisions and procedures can raise concerns about the fairness and equal treatment of Member States.

- **Inadequacy of regulations:** Regulations adopted by the WAEMU Commission may be perceived as inadequate or outdated, failing to consider the specific economic and social needs and realities of Member States. More flexible and tailored adaptations may be needed to better respond to local challenges.

- **Lack of consultation:** Some stakeholders, including local economic players and citizens, could blame the Commission for not consulting them adequately when drafting and revising regulations. This can lead to dissatisfaction with the legitimacy and relevance of the decisions taken.

- **Poor implementation:** Even if regulations are adopted, their effective implementation may sometimes be lacking due to various obstacles, such as insufficient institutional capacity, gaps in monitoring and sanctioning mechanisms, or budgetary constraints

- **Lack of harmonization:** One of WAEMU's objectives is to harmonize policies and

regulations between Member States. However, criticism could emerge if harmonization efforts fail to resolve economic, social, and legislative disparities between member countries.

- **Concentration of power:** Some observers may criticize an excessive concentration of power within the WAEMU Commission, which could limit the participation of member states and the consideration of diverse perspectives and concerns.

- **Slow processes:** Decision-making and regulatory processes can sometimes be slow, which may impede the organization's responsiveness to changing economic and social challenges.

## **Conclusion**

Liberalization of the veterinary drugs sector in WAEMU Member States (production, distribution, marketing, and veterinary care) has had the main effect of significantly increasing trade in these medicines and the number of operators. This increases the risk that veterinary inputs, which are both productive factors (development challenges) and medicines requiring appropriate use (public health issues), will circulate under conditions that do not guarantee their quality. The weak resources of the Member States, taken individually, required the establishment of a regional harmonization and management scheme to consider all aspects of the monitoring and quality control of veterinary medicinal products. This study showed that legislative efforts are needed, regarding the texts governing veterinary regulations in Togo. The market structure and organization of the veterinary profession must be reviewed regularly. The revision and harmonization of national regulations are the basis of good practice compliance which would contribute to the areas of marketing authorization, quality assurance system of supply for human resources development, pharmacovigilance, good distribution practices and the use of veterinary medicinal products in Togo. A standing committee must be present for the validation or non-validation of marketing authorizations. It would be interesting to explore ways of producing unified documents

(laws, decrees, legislation) in the same country or in a community area. The repression of the illegal market in veterinary drugs must be highly efficient. It would be desirable to establish a framework to bring together policymakers and create a platform for permanent discussion and consensus on the path toward harmonization of veterinary regulations.

### COMPETING INTERESTS

The authors declare that they have no competing interests concerning this article.

### AUTHORS' CONTRIBUTIONS

PBT, APB and MS conceptualize the research project; PBT collected data; PBT and APB analyzed data; MS and ET: supervised data collection; PBT wrote the first draft; APB, ET and MS revised the draft manuscript. All authors agreed to the submitted manuscript.

### ACKNOWLEDGEMENTS

Thanksgiving to University of Lomé (UL), Regional Center of Excellence for Avian Science (CERSA), Molecular Biology and immunology Laboratory of Faculty of Health Science of University of Lomé (BIOLIM/FSS/UL) and the staff of the bacteriology laboratory of the University teaching Hospital of Lomé for their contributions for the success of this study. Acknowledgement to the World Bank and Doctoral grant program of the project to support the reform of higher education in science and in engineering (PARESI/Togo) for their financial contributions. Recognition to Livestocks Departement of Togo and Veterinary medicine Wholesaler association of Togo for all their help for data collection.

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