

## State of Affairs and Level of Knowledge of the Actors/Workers in the Veterinary Medicines Pharmacovigilance`S Sector in Côte d'Ivoire

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### Abstract

### Original Research Article

This study was conducted in order to ascertain the state of affairs of the pharmacovigilance in Côte d'Ivoire, and to estimate the level of knowledge of the workers involved in the veterinary drug sector in the District of Abidjan. The methodological approach applied was first an exploratory survey on the existing regulatory texts and the activities relating to the veterinary pharmacovigilance in Côte d'Ivoire. Then, secondly, a cross-sectional descriptive survey was used to estimate the level of knowledge of the workers/actors in the sector of veterinary pharmacovigilance. The results of our investigations showed the non-existence of a veterinary pharmacovigilance system in Côte d'Ivoire because of the legal vacuum existing at the national level on this subject. This legal void is slightly addressed by a less explicit West African French speaking country organization (UEMOA) pharmaceutical regulation in terms of veterinary pharmacovigilance. The definition of veterinary pharmacovigilance and its current legal basis in Côte d'Ivoire is the Regulation No. 02/2006/CM/UEMOA, and the current law organizing the veterinary pharmacy, are unknown to the majority of the actors questioned. Almost all (97%) of the questioned actors felt the need to be informed and trained on pharmacovigilance.

**Keywords:** Veterinary pharmacovigilance, Drugs, State of affairs, Côte d'Ivoire.

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## INTRODUCTION

According to WHO, the pharmacovigilance is defined as the science and the activities relating to the detection, the evaluation, the understanding and the prevention of adverse effects or any other problem related to medicines. The main objective of veterinary pharmacovigilance is to monitor the adverse events attributable to a veterinary drug and occurring in animals and/or in humans (Veterinary International Conference Harmonization, 2007). However, due to the specificities of veterinary medicines, the additional objectives of veterinary pharmacovigilance are the search for lack of efficacy, the monitoring of resistance, the search for environmental impact, the monitoring of residues in foodstuffs and the monitoring the validity of waiting times (Keck 2005; Enriquez, 2008).

Moreover, for the veterinary drug sector to be able to achieve their objectives, it must first have a

well-established pharmacovigilance system in place, with appropriate legislative texts that are also well known by the actors in charge for its application. It is with this in mind that this study was conducted in order to unveil the current of affairs of the veterinary pharmacovigilance in Côte d'Ivoire and to assess the level of knowledge of its actors in the sector.

## MATERIALS AND METHODS

### Study Area and Period

This study took place from August to December 2010 in the District of Abidjan, which includes 10 municipalities and 3 sub-prefectures (Songon, Bingerville, Anyama). The choice of this District is justified by the fact all the wholesale importer of veterinary drugs are present, the same as the representatives of veterinary pharmaceutical companies and the majority of private veterinary clinicians.

## Methodology

For the execution of this work, two types of surveys were conducted: an exploratory survey and a cross-sectional survey by a questionnaire.

### Exploratory Survey

The exploratory survey consisted of direct interviews with the authorities in charge of veterinary services, specifically those in charge of veterinary medicines in Côte d'Ivoire, in order to collect information concerning:

- The list and addresses of the various players in the veterinary medicine sector;
- The applicable texts related to veterinary pharmacovigilance;
- The organization and operation of a possible structure responsible for the veterinary pharmacovigilance in Côte d'Ivoire.

It also made it possible to meet the officials of the Côte d'Ivoire - National Council of Veterinarians (ONVCI) in order to complete the list and addresses of private veterinary clinicians and the associations of breeders (major users of veterinary drugs).

In addition, the managers of the national public health laboratory and the ecotoxicology laboratory of the National Laboratory for Agricultural Development Support (LANADA) in Abidjan were met with the view to find out about their organization, their operation and their level of knowledge of the pharmacovigilance and the legislation.

### Cross-Sectional Descriptive Survey

#### Target Audience

The cross-sectional survey involved 11 wholesale importer and distributors, 7 private veterinarians with clinics in Abidjan, 6 representatives of veterinary pharmaceutical companies in Côte d'Ivoire and 30 breeders whose addresses were obtained from their associations. Overall, a total of 54 actors were targeted and all were investigated.

#### Data Collection

Data collection was done through a questionnaire, written in French and revised after a pilot survey with 4 veterinarians. The questionnaire consists of 2 parts. The first relates to the identification of actors. The second part is devoted to the evaluation of the level of knowledge of actors with regards to the veterinary pharmacovigilance. To evaluate the level of knowledge of stakeholders in the sector of veterinary pharmacovigilance, the following criteria were taken into consideration:

- Definition of veterinary pharmacovigilance;
- Importance of reporting adverse events;
- Level of knowledge of the legal documentations in force in Côte d'Ivoire relating to the veterinary pharmacovigilance;

- Need of information or not and/or need of training on pharmacovigilance.

### Data Entry and Analysis

The answers to the questionnaires were captured entered using Epidata 3.1 software, and then exported into an Excel spreadsheet. All data were analyzed with R commander 2.12.1 software and Excel.

## RESULTS

### STATE OF PLAY

#### Legal Bases of Veterinary Pharmacovigilance in Côte D'ivoire

##### National Texts

Apart from Order No. 35 of August 9, 2007 setting the rules for Good Manufacturing Practices, importation and distribution of veterinary drugs, which defines pharmacovigilance, no national text mentions veterinary pharmacovigilance. The development of regulatory texts relating to veterinary pharmacovigilance is also in sight for the establishment of a pharmacovigilance system.

##### Community Texts

West African Economic and Monetary Union (WAEMU, UEMOA in french) has harmonized veterinary pharmaceutical legislation based on 4 Regulations and a Directive. Among these Regulations, only Regulation No. 02/2006/CM/UEMOA establishing community procedures for the Marketing Authorization (MA) and monitoring of veterinary medicinal products and establishing a Regional Committee for Veterinary Medicines speaks of veterinary pharmacovigilance. These Regulations only mention pharmacovigilance in articles 6, 43, 44, 45 and 46. In its article 6, it stipulates that the Regional Committee for Veterinary Medicines is responsible for evaluating MA applications and deciding on all measures relating to pharmacovigilance. In its article 43, it mentions that the WAEMU commission and the member states encourage notifications. All reports of adverse effects must be sent to the veterinary authorities who forward them to the WAEMU Commission. This commission will take the appropriate measures after consultation with the president of the Regional Committee for Veterinary Medicines.

Article 44 of the Regulation requires that the marketing authorization holder must have a person responsible for pharmacovigilance. According to its article 45, the marketing authorization holder is required to keep detailed reports of all the presumed adverse effects that have occurred within the WAEMU. He is also required to record any presumption of serious adverse effects and adverse effects on humans that have accompanied the use of veterinary medicinal products. Article 46 of this regulation stipulates that following the evaluation of data on veterinary pharmacovigilance, if the Regional Committee for Veterinary Medicine considers that the MA should be suspended, withdrawn or modified, it immediately inform the WAEMU

commission. In the event of an emergency, this committee may suspend the marketing authorization for a veterinary medicinal product in accordance with the procedures provided for in Article 17.

Directive No. 07/2006/CM/UEMOA relating to veterinary pharmacy is currently in the transposition phase in Côte d'Ivoire. This Directive speaks of pharmacovigilance in its title VII precisely in article 33. This article specifies that the Member States encourage veterinarians and other health professionals to declare to the veterinary authority any adverse effect occurring in humans or animals. Animal likely to be attributed to a veterinary medicinal product. The information is transmitted immediately to the WAEMU commission in the event of a serious adverse effect on humans or animals.

### STRUCTURES CARRYING OUT ACTIVITIES RELATING TO VETERINARY PHARMACOVIGILANCE IN CÔTE D'IVOIRE

#### Department of Veterinary Services (DSV)

The Sub-Directorate for Pharmacy and Veterinary Medicines (SDPMV) of the DSV occasionally receives reports by telephone of cases of adverse effects and/or lack of efficacy of veterinary medicines. After receiving these declarations, the agents of the SDPMV often go to the scene to make the report, but most of these declarations are not used.

### Toxicology Laboratories

#### LANADA Ecotoxicology Laboratory

Its mission is to ensure the prevention of poisoning caused by xenobiotics, in particular health products, pesticides, household products, industrial products and plants, the improvement of their management and the monitoring of their effects about health. This laboratory has a very wide field of action and aims to create a pharmacovigilance unit and a toxicological information center (CIT).

#### National Public Health Laboratory (LNSP)

The national public health laboratory is responsible for participating in the establishment of a system for detecting, evaluating and preventing the adverse effects of any health product occurring in the population. For this, it has several units including a toxicology center.

### LEVEL OF KNOWLEDGE OF ACTORS ON VETERINARY PHARMACOVIGILANCE

#### Degree of Knowledge of the Concept of Veterinary Pharmacovigilance

Among the actors questioned, only 36.17% (Figure 1) were able to give a correct definition of pharmacovigilance, in other words who ticked answer No. 4 proposed by the questionnaire.

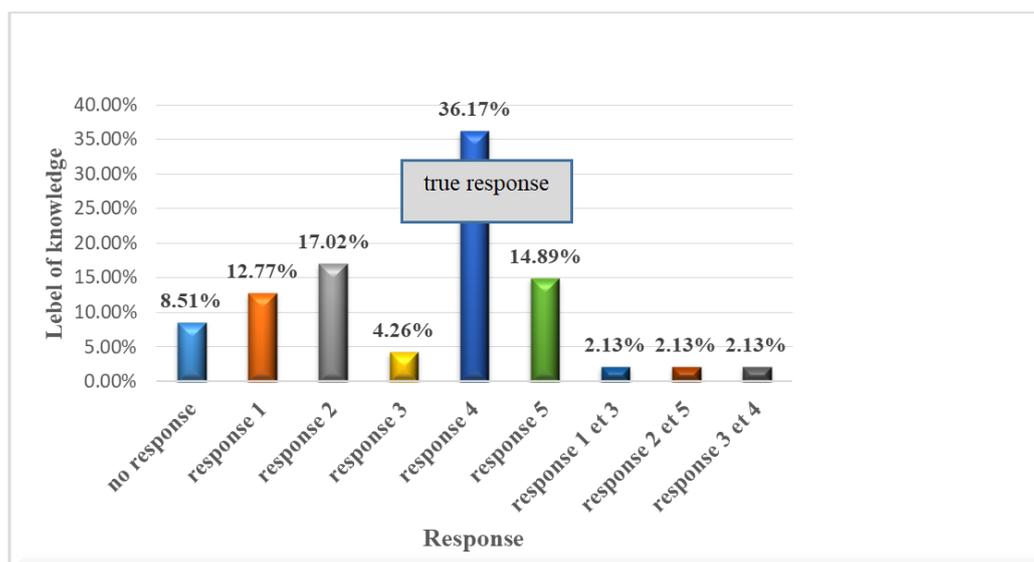


Figure 1: Distribution of the degree of knowledge of the concept of pharmacovigilance by the actors

**Answer 1:** Vigilance with respect to veterinary pharmaceutical products.

**Answer 2:** All of the effects attributable to a veterinary medicinal product after administration in animals and/or in humans.

**Answer 3:** All the effects attributable to a veterinary medicinal product occurring in the animal and/or in the people who handle the medicinal product or who are in contact with the treated animal.

**Answer 4:** Monitoring of effects attributable to a veterinary medicinal product occurring in the animal and/or in persons handling the medicinal product or who are in contact with the treated animal.

**Answer 5:** Vigilance with regard to all veterinary medicinal products used in animals and/or in humans.

#### Degree of Knowledge of Legal Texts

Among the users questioned, 69.2% do not know the national texts relating to veterinary pharmacy,

in particular Law No. 96-561 relating to veterinary pharmacy of July 25, 1996. More specifically, 41% affirmed that this law makes mention of the declaration by health professionals of presumed adverse effects of veterinary medicinal products, when this is not the case. In addition, 44% believe that this law has an application text from the Ministry of Animal Production encouraging the reporting of adverse effects and/or lack of efficacy of a veterinary drug when this is also not the case. Furthermore, 62.5% do not know whether Regulation No. 02/2006/CM/UEMOA of March 23, 2006 encourages the reporting of suspected adverse effects of veterinary drugs by health professionals. Some users are unaware of the existence of community texts.

### Need for Information and Training on Pharmacovigilance

Ninety-seven percent (97%) of actors say they need training and information on veterinary pharmacovigilance.

## DISCUSSION

Veterinary pharmacovigilance in Côte d'Ivoire is essentially based on WAEMU community texts. Indeed, apart from Order No. 35 of August 9, 2007 that defines pharmacovigilance, no national regulatory text exists to date on veterinary pharmacovigilance. The Community veterinary pharmaceutical regulations make injunctions in terms of veterinary pharmacovigilance but they are not very explicit. Indeed, it certainly urges the Member States to encourage health professionals to notify the presumed adverse effects of veterinary medicinal products and asks the veterinary authorities to transmit the information collected to WAEMU. Nevertheless, it does not describe how healthcare professionals should make the declarations. Furthermore, the roles of the players concerned are not clearly defined, nor are the organization of veterinary pharmacovigilance. Assoumy (2010) and Sidibé (2010) also made these findings. WAEMU should review its texts in order to better define the tasks of the actors, as well as the organization of veterinary pharmacovigilance. It could be based on the regulation, organization and functioning of the veterinary pharmacovigilance systems of the European Union or countries such as France or Morocco (Enriquez, 2008; Ministère de l'agriculture, du développement rural et des pêches maritimes, 2004; Ibrahim and Keck, 2001).

The DSV is one of the structures that carries out activities relating to veterinary pharmacovigilance. Indeed, this study revealed that the SDMPV of the DSV occasionally receives telephone reports of adverse effects and/or presumed lack of efficacy of veterinary medicinal products. After receiving these declarations, the agents of the SDPMV often go to the scene to make the report; but most of these declarations remained unanswered. These actions of the SDPMV in terms of pharmacovigilance, compared to those carried out in France or Morocco, are insufficient. Indeed, they are

limited only to the observation of adverse effects and no corrective action is taken by the competent veterinary authorities. This could be explained by the absence of national regulations on veterinary pharmacovigilance but also by the lack of appropriate means. However, the actions of the SDPMV are to be encouraged despite the legal void existing at the national level. It should nevertheless be emphasized that the competent Ivorian authorities could have relied on the provisions of Regulation No. 02/2006/CM/UEMOA which has applied to all UEMOA Member States since its date of signature. However, this Regulation is also not very explicit in terms of veterinary pharmacovigilance.

In addition to the DSV, the ecotoxicology center could have a mission to monitor the adverse effects of drugs. Indeed, this center is responsible, among other things, for preventing poisoning caused by xenobiotics (in particular health products, pesticides, household products, industrial products and plants), improving their management and monitoring their effects on health (animal and public). However, only the control of pesticides is currently carried out by this center. During this investigation, the absence of registration of cases of human or animal poisoning attributable to a veterinary medicinal product is undoubtedly due to the lack of functioning of this centre. The managers of this laboratory have in mind the creation of a pharmacovigilance unit and a Toxicological Information Center (CIT). Given the importance of monitoring the adverse effects of veterinary medicinal products, this idea of creating a pharmacovigilance unit is commendable and it would be interesting for it to be implemented as soon as possible.

The LNSP carries out veterinary pharmacovigilance activities through its toxicology unit, since it is responsible for participating in the establishment of a system for detecting, evaluating and preventing the adverse effects of any dangerous health product, occurring in the population. For this, it has several units including a toxicology center. During our investigation, he had not recorded any cases of suspected human or animal poisoning due to a veterinary drug, but he did record a few cases of suspected human poisoning due to a human drug. This could be explained by a lack of collaboration with the veterinary services. Thanks to its toxicology center, the national public health laboratory could play an important role in a veterinary pharmacovigilance system in Côte d'Ivoire. All the missions and activities of these different structures show the willingness of the Ivorian authorities to monitor the adverse effects of veterinary drugs. However, these veterinary pharmacovigilance activities compared to those of France, Morocco or Belgium are insufficient and should be reinforced (Enriquez, 2008; Ministère de l'agriculture, du développement rural et des pêches maritimes, 2004; Ibrahim and Keck, 2001). This study also revealed that Côte d'Ivoire has neither a poison control center nor a drug information center. Given that

it has in view the establishment of a veterinary pharmacovigilance system (Ministère de la production animale et des ressources halieutiques, 2010) it should think about creating one because close collaboration between the poison control center, the pharmacovigilance centers and the centers of drug information is necessary for a better efficiency of a veterinary pharmacovigilance system (Uppsala Monitoring Centre, 2010).

Only 36.17% of the players in the sector questioned ticked the correct definition of veterinary pharmacovigilance, which shows that veterinary pharmacovigilance is a new concept for the majority of these players. This is why they would have said almost unanimously (97%) that they needed information and training on this new discipline for them. This is understandable, given that pharmacovigilance is not mentioned in Law No. 96-561 of July 25, 1996, relating to veterinary pharmacy in Côte d'Ivoire. In addition, all the actors questioned unanimously considered that it is essential to declare adverse effects because this would allow, among other things, the protection of animal health, public health and the environment, the fight against chemoresistance and drug residues in foodstuffs of animal origin. These reasons are in line with the objectives of veterinary pharmacovigilance, which are to ensure the safety of veterinary medicinal products in animals, the safety of persons in contact with the veterinary medicinal product, the safety of foodstuffs of animal origin, the protection of the environment, the search for lack of efficacy and the monitoring of resistance. From this observation, it emerges that only the terminology "pharmacovigilance" is unknown to the players in the sector, but the objectives of this concept are well known. National texts are unknown by 69.2% of users. These figures clearly show that the users of veterinary medicinal products (clinicians included) have not appropriated the law organizing veterinary pharmacy, probably due to a lack of interest. A provision of Regulation No. 02/2006/CM/UEMOA encourages the reporting of suspected adverse effects of veterinary medicinal products by health professionals. It is, however, unknown by 62.5% of the users questioned, although the Community Regulations apply to all the countries of the WAEMU area without any prior transposition. This lack of knowledge could be justified, on the one hand, by a lack of awareness among Union nationals of the new Community regulations relating to veterinary pharmacy. This insufficiency would be at the level of the Member States, but also of the WAEMU. On the other hand, the ignorance of the content of the Law relating to veterinary pharmacy in Côte d'Ivoire by certain actors would be enough to understand their indifference with regard to community texts.

## CONCLUSION

Veterinary pharmacovigilance is an interactive tool for monitoring and harmonization, useful for

deciding on the persistence and terms of keeping veterinary medicinal products on the market, useful for protecting animal health and public health. Given the importance of veterinary drugs in improving the productivity of Ivorian livestock and also given the economic stakes represented by these drugs and a pharmacovigilance system in a country, we urge the State of Côte d'Ivoire, to establishment of a veterinary pharmacovigilance system based on solid national and Community legal bases. This implementation must go through the awareness of the actors of the sector, particularly veterinarians. It must be established gradually through information and training sessions.

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