



Veterinary Pharmacovigilance in Algeria: Situation and Prospects

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RESEARCH ARTICLE

Abstract


An investigation was carried out to assess the real situation of veterinary pharmacovigilance, as well as the role and/or involvement of this medico-legal system in the surveillance and control of the use of veterinary medicines. A total of 150 veterinary doctors were surveyed to obtain information on the subject, our study revealed that the prescription of antibacterials with 85.5%, antiparasitic drugs with 75% and vaccination, immunological products 70.1%; Also showed an average consumption of other drug families, including drugs for the respiratory system with 66.7%, production drugs and vitamins 66.7% and digestive drugs with a prescription rate is 58.3%; Further a 62.5% of reports were made by veterinary practitioners, who are considered to be the main actors of the pharmacovigilance system in the region, with owners and farmers actively contributing to the functioning of the system with a reporting rate of 33.3. Findings show a several initiatives and actions have been taken, such as continuing training for veterinarians 41.7% through training courses and participation in seminars, initial training for veterinary students 37.5% in schools and university training institutes, the establishment and activation of committees for specific expertise in veterinary drug 37.5%, press releases 25%, through actions aimed at marketing authorization holders 20.8% and industrial subsidiaries of veterinary medicinal products, these results remain non-exhaustive but contribute strongly to determine the status of pharmacovigilance in the veterinary field and the region of study.

Keywords: investigation; pharmacovigilance; veterinary.

INTRODUCTION

Received: 30 October 2020
Accepted: 07 December 2020
Published: 14 May 2021

DOI:
10.15835/buasvmcn-vm:2020.0043

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The use of medicines in animals has been historically related to their use in humans since the late 1930s (Alves and Alves, 2011). Animal health, as the first term understood in animal husbandry, seeks to ensure better qualitative and quantitative productivity, while at the same time preserving animals in the optimal possible level of health (Kauppinen et al., 2010). Various traditional medicines are available to improve the well-being of these producer animals, including anti-infectious, anti-inflammatory drugs and medicines for different digestive, respiratory, immune and reproductive functions, etc (Damian and Damian, 1995; Songisepp et al., 2005; Demain and Sanchez, 2009). The ephemeral nature of the efficacy of certain synthetic pharmaceuticals is becoming increasingly apparent (Gambardella, 1995; Prakash, 2015). Rationalising the use of these products is a threefold concern, first and foremost, for public and animal health, environmental but also economic; Furthermore, the uncontrolled use of conventional medicines in general and chemically produced medicines in particular can lead to the formation of residues in food products derived from animals. Human health is directly linked to its environment and in particular to the nature and quality of its food (Tilman and Clark, 2014). Practitioners are gradually

becoming aware of the importance of their participation through the publications and training available to them. However, veterinarians should become more familiar with this tool for collecting and transmitting information, so that national and international bodies have a more realistic picture of the incidence of adverse reactions related to the use of veterinary medicinal products (Giguère et al., 2013; Thrusfield, 2018). The involvement of veterinarians will become even more important in the area of "suspicion of lack of efficacy compared to expected efficacy" and any finding of non-compliance or quality defects so that the necessary measures can be taken (World Health Organization, 2007). They thus play a key role in the surveillance system for veterinary medicinal products (Anthony et al., 2001).

The objectives of veterinary pharmacovigilance are to ensure: the safety of veterinary medicinal products in animals; the safety of foodstuffs of animal origin (derived from treated animals); the safety of persons in contact with veterinary medicinal products; the protection of the environment (Woodward, 2005).

Today, it is responsible for the various stages that range from the feedback of field observations by health professionals, in practice mainly veterinarians and the pharmacovigilance managers of veterinary pharmaceutical laboratories, to the evaluation of the cause and effect relationship by the Veterinary Pharmacovigilance Centres (Mahmood et al., 2011).

The development of reporting will lead to a better use of medicines, allow a better understanding of the real incidence of adverse reactions (Olson et al., 2000), establish a relationship of trust with the owners and on the balance sheet, strengthen our image as a health professional.

The objective of our survey is even an idea about the real situation of veterinary pharmacovigilance at the national level and precisely at the regional level, as well as the role and/or involvement of this medico-legal system in the surveillance and control of the use of veterinary medicines (by guaranteeing the safety of these products in the target (productive) animals, on public and environmental health) based on information and/or data collected from private practitioners in the East Algerian region.

MATERIALS AND METHODS

The pharmacovigilance mission is based on a set of players working in a coordinated manner: from the reporting of adverse reactions and the collection of information on them, through the recording, evaluation and use of this information to produce a report on the benefit/risk ratio of the medicine.

The situation of veterinary pharmacovigilance and the role in the field of control and surveillance of the use of veterinary medicinal products in the East of Algeria, as in the whole national territory, is not precise and ambiguous. Is there a really functional regional veterinary pharmacovigilance system? What is the degree of knowledge, vision and conviction of animal health professionals towards this forensic profession, which guarantees good practices in the use of veterinary medicine.

This is the question that we will try to answer through a survey, based mainly on a questionnaire, formulated and distributed to private veterinary practitioners and those belonging to the public sector in various communes and institutions of the East of Algeria.

Elaboration of the questionnaire

On the basis of all the information gathered during the preliminary interviews and surveys, a questionnaire was developed. The questionnaire proposed to private and state veterinarians was entitled "Veterinary pharmacovigilance, actual situation and perspectives".

The elements of the questionnaire « Pharmacovigilance and good practice in the use of medicinal products in veterinary medicine» include the following sections:

- 1- The use of veterinary medicines: the criteria for choosing the drugs prescribed, their provenance and methods of its administration.
- 2- The veterinarians' knowledge of pharmacovigilance: Missions and actors in Algeria, Circuits and frequency of information statements.
- 3- Nature and type of information communicated, distribution of undesirable effects and residual problems of the administration of the drugs.

Survey

The main survey lasted about a year (from January 2019 to January 2020), two types of surveys were carried out: an exploratory survey and a land survey through a questionnaire.

A. Exploratory survey (pre-survey):

This preliminary survey consisted of a bibliographical research: Data on veterinary pharmacovigilance in Algeria, on the use (management, operation and surveillance of the operation) of pharmaceutical products for veterinary purposes in Algeria were collected through the documentation in the university library and on the Internet from several search engines and journals such as GOOGLE Scholar, the FAO website, private veterinary practices, public services and structures.

A census of private veterinarians practising in the different study regions (interviews were conducted to discuss and/or collect information on the pharmacovigilance function and good practices in the use of veterinary medicines.

B. Field survey (the survey as such):

This is a formal, questionnaire survey based on the results of the exploratory survey.

The survey affects and/or covers part (several communes) of the territory of the Wilaya of Souk Ahras. One hundred and fifty (150) questionnaires were distributed to (mainly) private and state veterinarians working in the different common institutions explored.

The data collection was done by direct interview (at the level of the practice and or service) with the veterinarian concerned, the results obtained are processed by the statistical software Sigma plot 1.25 and the analysis is purely descriptive.

RESULTS AND DISCUSSIONS

Criteria for the choice, nature and method of administration of the veterinary medicinal product.

The present results (**Figure 1**) show that the majority of prescribing doctors' favour and/or choose their medicines according to the nature of the product by favouring originator medicines (75% of favourable responses), as well as the origin of the medicine. The manufacturing laboratory is one of the criteria favoured by most prescribing doctors in the region, with a favourable response rate of around 67. Other professional clinicians (45.8% of the responding doctors) prefer the use of medicines because of their availability and their often stable and constant supply at local and national level. Depending on the values obtained, few doctors (around 25%) use the rightly priced and/or less expensive pharmaceuticals and even fewer use generic drugs.

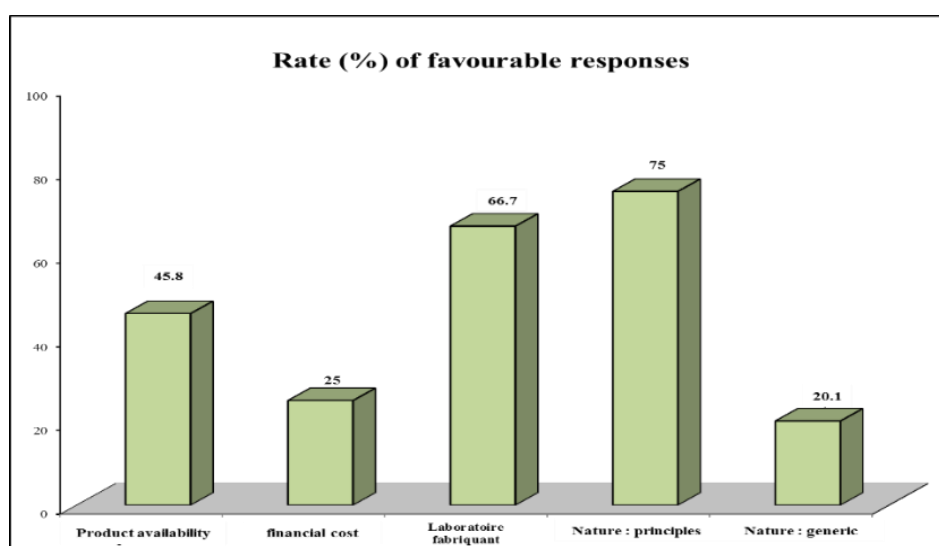


Figure 1. Criteria for the choice of veterinary drug.

According to the predictive statements, veterinarians choose the use of safer drugs (according to most stakeholders) i.e. originator products and products derived and/or manufactured in better known pharmaceutical laboratories, with a focus on the quality (and good manufacturing practices), safety and/or security of these pharmaceutical products which are often used and better known in veterinary medicine.

The results obtained (**Figure 2**) illustrate the rate and/or frequency (calculated in %) of use and/or prescription of the different drug families (all species in the regions explored) indicating a relatively high prescription of anti-infectious and immunological drugs; antibacterials (antibiotics: with a favourable response rate of 85.5%) and antiparasitic drugs (75%) and vaccination and immunological products (70.1%). This can be explained by the nature and frequency of dominant pathologies in the different target species. (Berrahal and Eulmi, 2017).

The importance of antibiotics is crucial in the fight against infectious diseases (Lopez-Romero et al., 2015; De Waele et al., 2018). These molecules are used in many fields as the main means of infection control, also used as prophylactic and/or preventive treatment, as well as in the field of animal production, as a medicated pre-mix in medicated feeds. They are used in veterinary medicine, whether in production animal husbandry or for the care of pets (Collignon and McEwen, 2019).

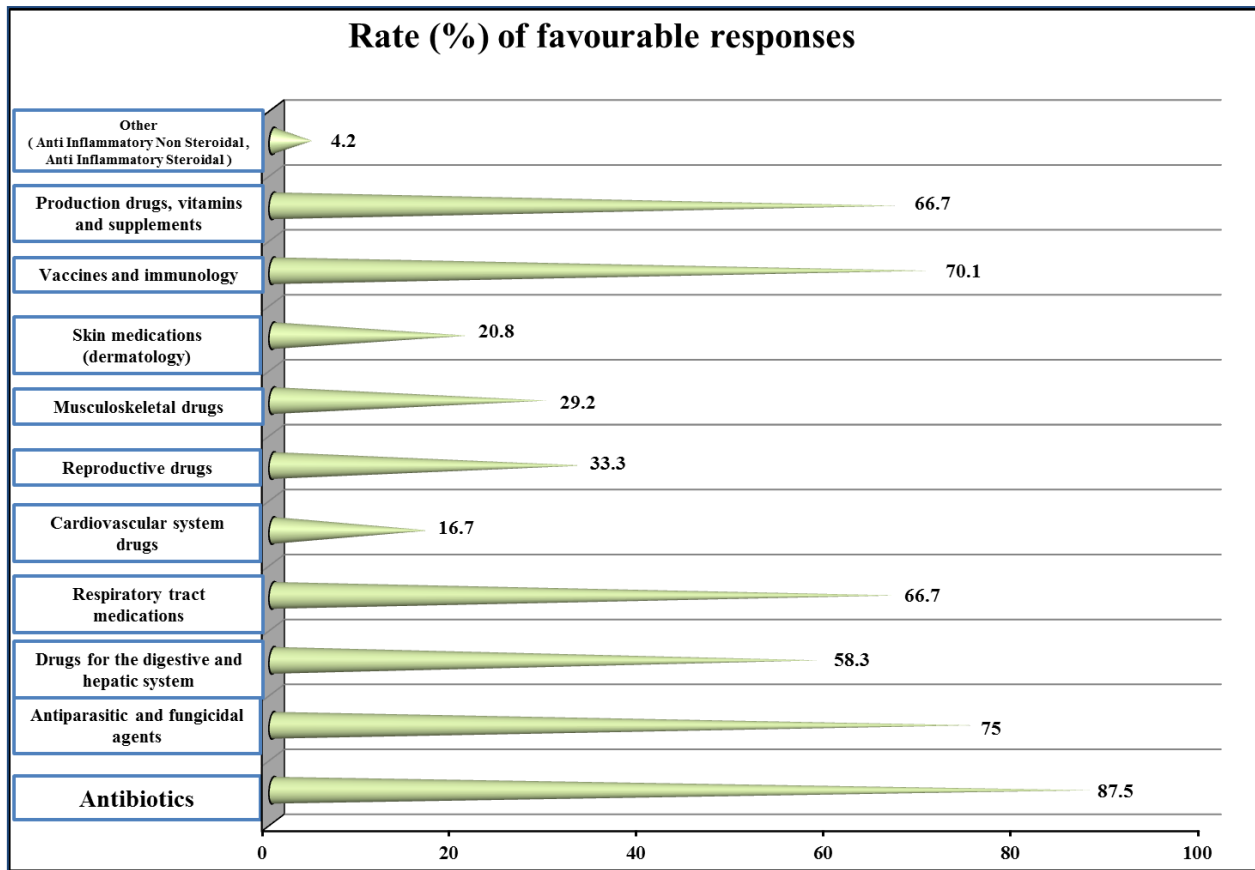


Figure 2. The most commonly used drug classes (families) (all species)

The results also show an average consumption of other drug families, including drugs for the respiratory system (66.7% favourable responses), production drugs and vitamins (66.7%) and digestive drugs with a prescription rate of 58.3%. The results obtained indicate also a relatively low and/or lower use of other classes of veterinary drugs with a prescription frequency ranging from 33% (concerning reproductive drugs) to 4.2% for anti-inflammatory drugs, used in symptomatic treatment in combination with targeted drugs.

Use (acquisition, origin and method of administration) of the veterinary medicinal product

According to the statements obtained (**Figure 3**) from veterinary clinicians, most prescriptions and/or dispensing of medicines (83.3%) are carried out following and/or after clinical examinations of sick animals. A medical examination of the farms and the assistance of the veterinary doctor is therefore essential and often compulsory in some cases on a regular basis and/or in the face of certain severe (so-called dangerous) pathologies and/or acute symptoms.

The present results show that approximately 29.2% of the medicines consumed are used for clinical examinations of sick animals, often proposed (by the doctor) after a simple interview and/or listening to the farmers or owners concerned.

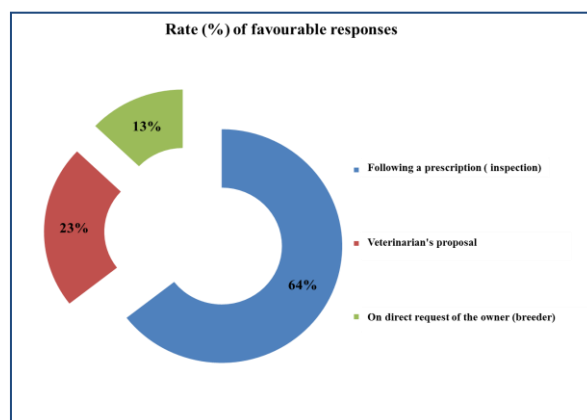


Figure 3. Issuance and/or procurement of veterinary medicines

According to these results, a relatively small number of the surveyed veterinarians (16.7%) state that they have dispensed (and/or given) medicines following a direct request from the owners. A situation often encountered with certain medicines (vitamins, minerals, etc.), medicines intended for so-called less severe conditions, including certain metabolic diseases and those used in dermatology, etc., which are not used for the treatment of these diseases.

The results shown in Figure 4a illustrate the responses of veterinary clinicians on good practice and recommendations for the use of pharmaceuticals used. Approximately 58.3% know the origin, routes and storage conditions of the drug up to its administration. On the other hand, and paradoxically, a third (33.3% of favourable responses) of the practising clinicians surveyed stated that they had no idea about these methods of use.

Acquiring and/or requesting information on the criteria and methods of use of pharmaceutical products is sometimes abandoned and/or disinterested, and this behaviour may be justified by the success and achievement of the desired results and/or therapeutic effects (product efficacy), as well as by the assurance and guarantee (of product quality) provided by approved suppliers and/or by the pharmaceutical laboratories themselves.

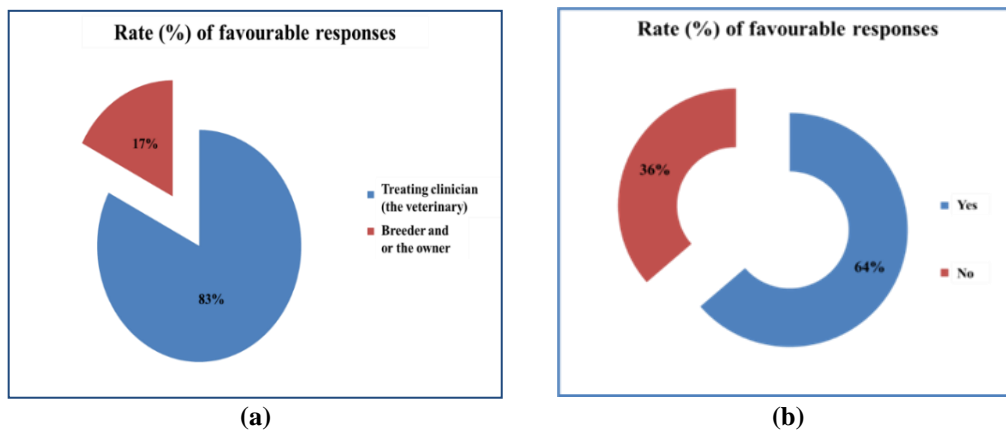


Figure 4. Use of the veterinary medicinal product: Origin (a) and Methods of administration (b).

Concerning the modalities of administration of veterinary medicines, the results indicate that about 79.2% of the administrations are performed by the attending physician himself. Only 16.7% of the medicines consumed are handled by the farmers and/or owners themselves. These statements are consistent with the data presented in Figure 4 (B) on the methods of drug acquisition, of which 16.7% of veterinary drugs are dispensed at the direct request of the owners, using clinical examinations of sick animals.

Reporting pathways and the nature of information declared in veterinary pharmacovigilance

The results shown in Figures 5 and 6 illustrate the reporting channels and the nature of information reported in the veterinary pharmacovigilance system. Preliminary results indicate that approximately 50% of veterinary practitioners have previously reported information to the competent services at the level of the study region.

The present results show that 62.5% of reports were made by veterinary practitioners, who are considered to be the main actors of the pharmacovigilance system in the region, with owners and farmers actively contributing to the functioning of the system with a reporting rate of 33.3%. Other contributors include pharmacies and suppliers with a reporting rate of 25% and public training institutions, such as schools and institutes with a participation rate of 16.7%.

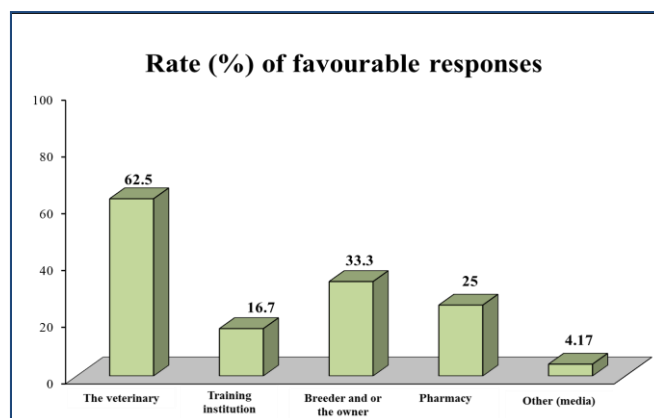


Figure 5. Veterinary pharmacovigilance information declaration circuits

Concerning the nature of the information declared to the pharmacovigilance services of the regions, the data obtained indicate that more than 62% of declarations are suspicions of lack of efficacy of the product administered. This type of information is mainly carried out by clinicians who are the main actors in this system of monitoring and control of drug use.

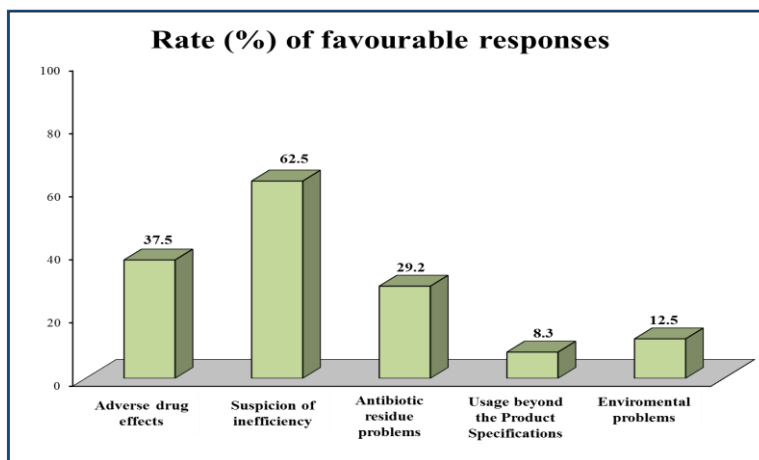


Figure 6. The nature (type) of information declared in veterinary pharmacovigilance

Undesirable effects (as information) are statically ranked second with a rate of 37.5 % of reported information. Several parameters may justify this observation, including the rarity of side effects produced, probably due to better diagnosis, dosage and/or better adapted medication, as well as the use of pharmaceutical products of good quality, both originator drugs and those from better known pharmaceutical laboratories.

According to the results obtained, almost a third of the information reported (29.2%) is related to residue problems, the rates of which have increased due to the excessive, systematic and inappropriate use of certain classes of drugs such as anti-infectives (antibiotics and anti-parasites) and production and reproduction drugs.

Numerous research works have alerted the scientific community and the public authorities to the dangers and risks caused by drug residues (especially residues in foodstuffs of animal origin) in target animals, on public health (consumers) and on other environmental compartments, including the development of bacterial antibiotic resistance. Other types of information are reported to the veterinary pharmacovigilance system, such as environmental problems (12.5%) and the off-label use of certain veterinary medicines.

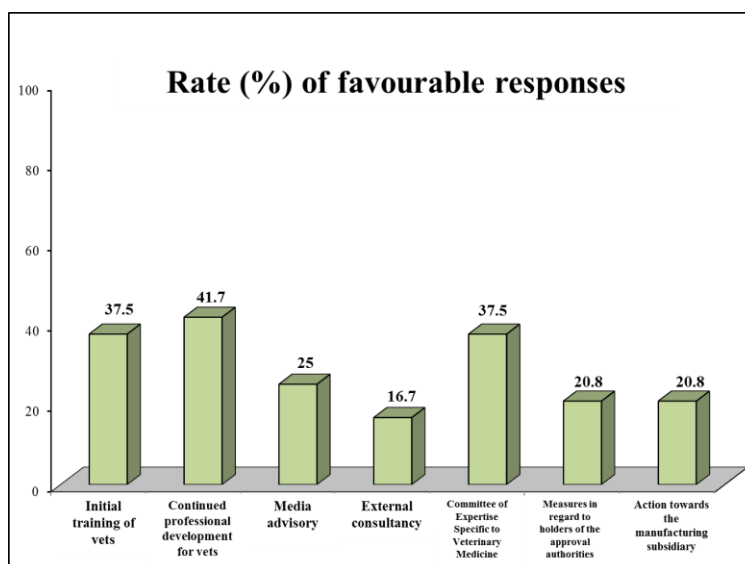


Figure 7. Actions required (reducing the risks associated with the drug)

The results shown in Figure 7 show the actions to be taken to eliminate and reduce the risks associated with the use of the veterinary medicinal product (McEwen and Fedorka-Cray, 2002). According to the responses of the various clinical practitioners involved, several initiatives and actions have been taken, such as continuing training for veterinarians (41.7%) through training courses and participation in seminars and scientific speciality days, initial training for veterinary students (37.5%) in schools and university training institutes, the establishment and/or activation of committees for specific

expertise in veterinary medicinal products (37.5%), press releases (25%), through actions aimed at marketing authorisation holders (20.8%) and industrial subsidiaries of veterinary medicinal products, etc.

Pharmacovigilance has additional objectives, always in relation to the specific characteristics of the veterinary medicinal product: search for lack of efficacy (possibly correlated with the appearance of adverse effects), monitoring of resistance, search for possible environmental impact of physical or chemical origin of the medicinal products and/or their metabolites, non-compliance with maximum residue limits (MRLs).

The development of reports will lead to better use of medicines, will enable a better understanding of the real incidence of adverse effects, will establish a relationship of trust with the owners, and will strengthen our image as health professionals.

The involvement of veterinarians will become even more widespread in the area of "suspicion of lack of efficacy compared to expected efficacy",

A wide field of action is opening up for veterinary pharmacovigilance and all those involved, providing veterinarians with the opportunity to apply their insatiable curiosity, their naturalist culture, their concern for the preservation of animal health, public health and respect for the environment, in coordination with other health professionals.

The need for increased communication between notifies, which can be achieved through continuous training and by improving knowledge of both the pharmacovigilance organisation and the missions of each person, as well as by

Practitioners' awareness of the importance of their participation is gradually growing through the publications and training courses made available to them.

CONCLUSIONS

The realization of one health project at this time should be an obligation, where human health is linked with animal health as well as with environmental health.

Veterinary pharmacovigilance is a field that considers in its importance as that of humans, and its establishment in developed countries is a challenge for the coming decade.

The results of our survey show a positive feature in the application of veterinary pharmacovigilance measures in Algeria.

Author Contributions: D.C. Conceived and designed the analysis; Collected the data; Contributed data or analysis tools; Performed the analysis; B.N; D.C & B.N: Wrote the paper.

Acknowledgments

The authors are thankful to the Laboratory of Science and Technique of Living, Institute of Agronomic and Veterinarian Sciences, University of Mohamed Cherif Messaâdia, Souk Ahras, Algeria.

Funding Source: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflicts of Interest

There is no conflict of interest.

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