Legislation of Veterinary Medical Products in Albania

TECHNICAL REPORT

Under action A2.1 of the Egyptian Vulture New LIFE project

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Protection and Preservation of Natural Environment in Albania

EGYPTIAN VULTURE NewLIFE

Contents

Summary

This report represents the results of a desk-based study on the legislation and information publicly found about the veterinary medical products (VMPs) from the vulture conservation point of view, in the republic of Albania. This research was conducted in 2020 to obtain information and the legal implementation of legislation over the regulation of use, trade and control during transport of VMPs in the country.

In Albania there is only one general law that regulates all the veterinary activities in the country. Adjacent to that, in the recent years, there has been one regulation to clarify several articles better. The particular law in Albanian constitution is conducted according to several directives and regulations carried out in the EU. As it appears in the law a lot of the legal acts allow activities that could lead to harms in the vulture population in the country.

The procedures of VMPs using in Albania are very strict and regulated by a whole chapter in the voluminous law. Also a very strict management towards livestock upbringing has made vulture approaching to food from livestock farms, nearly impossible. There are several articles in the Albanian legislation that define the ways of depositing of wastes-both of animal or chemical origin- in order to avoid pollution of water, soil or air and the spreading of diseases. This is related directly to the prevention of environment rather than an attempt to balance the whole biodiversity.

As far as it relates the VMPs, there is a state commission that licenses every single VMP traded in the country. VMPs that have been licensed in an EU country can be automatically registered and licensed in the country. This means that substances such as paracetamol, carprofen, ketoprofen etc that are harmful for the vulture population of the country, are registered, licensed and allowed to be traded and administered by veterinarians or farmers in the country. Most of the anti-inflammatory drugs dangerous to the vulture population in the country are listed as permitted substance both in the VMPs list aswell as in the human medical products one. Unfortunately, in difference from the other countries of the region, there is no public official list for the VMPs that are approved or not approved in the country. Thus, there is no official “maximal allowed residues” criteria, for anti-inflammatory or drugs of such nature.

The organization and control use, trade, import and production of VMPs is centralized at the hands of the commission and the Executive Director of, what in the time of conducting this report is the by law required “competent authority”, National Food Authority. The next level of control consist of the Regional Agencies of Veterinary and Plant Protection. Despite the fact that only veterinarians are allowed to administer some drugs, their distribution in the veterinary pharmacist can be also done to simple farmers. The state laboratories, authorize the registration of drugs, if

the samples sent are of good result. Each importing or producing company of VMPs must be able to present samples at any time it may be asked by the authorities. However this information is not publicly available online.

Subject and Purpose of the Report

This report was developed under the frames of action A2 of the LIFE+ project "Egyptian vulture New LIFE" funded by the European Commission and co-funded by the "A.G. Leventis Foundation" and implemented by different partners of Birdlife International. Subcontracting partners for the implementation of actions A1 are the Macedonian Ecololgical Society (MES) and the Association of the Preservation and Protection of the Natural Environment in Albania (PPNEA).

The widespread use of anti-inflammatory drugs (NSAIDs) and antibiotics in a routine base in livestock farming poses a serious life hazard to the population of vultures in the republic of Albania. These activities can have serious bad effects such as kidney failure in birds that are fed on a medicated livestock corpse.

The objectives of action A2 were to:

- ✓ Explore the use of VMPs with a proven negative effect on vultures with emphasis on NSAIDs aceclofenac, ketoprofen, carprofen, flunixin, diclofenac and nimesulide. I addition all medications containing the ending "fenac" as well as metamizole, ibuprofen, mefenamic acid, tolfenamic acid, paracetamol, phenylbutazone, carprofen and piroxicam would be studied with higher priority, because their impact on vultures was expected to be similar as the VMPs mentioned above.
- ✓ Investigate and identify potential alternatives to the dangerous drugs and advocate for their implementation.

This report was compiled thanks to the information gathered from the conducting of desk-based study on national legislation and publically available information.

Targeted desk research was carried out in the winter of 2020 in order to obtain publically available information about regulations of use, trade and transboundary control of VMPs as well as the implementation of the legislation. After preliminary analysis of the publically available information, a letter for access to public information was send to the BFSA, in order to obtain further official information about the substances targeted under action A2.

List of the legal acts

In the republic of Albania, one general law and one regulation, regulate all the activities related to animal treating, livestock farming, veterinary control, veterinary professionals work, production, use and trade of VMPs and productions and trade of animal products. The Law nr 10 465 For the Veterinary Service in the Republic of Albania is the main law in this field and the Four Regional Agencies of Veterinary and Plant Protection supervised by a competent authority

(which at the time this report is written is the National Authority of Food) are the competent authorities governing the system in Albania. The national legislation was developed in accordance to relevant European (EU) legislation. This law was conducted according to fourteen directives and ten regulations of the European Commission.
In the national legislation of Albania there are several laws that contain articles that regulate the sell of VMPs and Nsaids in the country. Such laws are: Law nr 105/2014 for Medicines and the Pharmaceutical Service; Law nr 113/2015 for the Professional Chamber of Veterinarians and the Law nr 10 006/2008 For the Protection of Wild Fauna.

Laws

Law nr 10 465, date 29/09/2011 For the Veterinary Service in the Republic of Albania

The Law nr 10 465, date 29/09/2011, for Veterinary Service in the Republic of Albania is the law that has to be obeyed by all the veterinarians that are active, overview or control veterinary activities both in the State Veterinary Service, various public entities or in private practice. It is also a law that regulates the activities of owners and operators of animal breeding stations. It is established to protect and improve the health of animals while also determining the procedures of prevention, monitoring, diagnostification, treatment and extermination of diseases in animals. This particular law also protects the public health from zoonotic diseases transmittable by animals , aswell as from hazardous waste substances, that are found in public consumption products. It ensures the implementation of veterinary health measures for products with animal origin, produced in farms, non-processed substances, pastures, water and the places that the animals drink. For what concerns us it is a law that regulates the measures in order to protect the environment from infections, poisons, animal wastes and pollution whether it is of a chemical, biological, chemical or radiobiological nature and to also to protect animals from torture and to ensure their wellbeing and also protect wild animals in general. It is a law that ensures the correct extermination of dead animals, carcasses, animal wastes and the animal products that are not destined for human consumption.
The main subject of this law is:

1. Determine the basic principles of the health protection and wellbeing of animals according to the international standards of the World Organization of Animal Health (OiE) and the European Union.
2. To regulate, organize, finance the veterinary service, determine the obligations, regulations and procedures of the veterinary service over the protection of the animal health and wellbeing of the animals.
3. The protection of the public health of the Republic of Albania from zoonotic diseases transmitted from animals, according to the EU law.

This law was partially approximated and adapted according to these directives:

- 82/894/KEE; 86/609/KEE; 90/425/KEE; 91/496/KEE; 92/119/KEE; 93/119/KE; 96/23/KE; 97/78/KE; 98/58/KE; 2001/82/KE; 2002/32/KE; 2002/99/KE; 2003/99/KE; 2006/88/KE

and according to the following regulations:

- 999/2001/KE; 178/2002/KE; 1831/2003/KE; 21/2004/KE; 854/2004/KE; 882/2004/KE; 1/2005/KE; 1198/2006/KE; 834/2007/KE; 1099/2009/KE

Terminology:
In this law the following terms have these meanings:

1. "Antimicrobials" are substances produced in a synthetic or natural way and are used to kill or prevent the growth of microorganisms, including bacterias, viruses, fungus and protozoas.
2. "Competent Authority" is the general directory of the ministry that is responsible after the health of the animals all over the territory of the country.
3. "Competent Authority for BIP" is the authority responsible for the administration and control of the border inspection points.
4. "Beta-agonists" are substances that counteract with beta-adrenoreceptors.
5. "Disinfectation" is the application of methods that aim to extinguish the infective agent of the diseases of animals, including zoonosis aswell.
6. "Elimination" is the procedure that causes the forced death of the animal.
7. "Enforced elimination" is the elimination or slaughtering by a veterinary order, because of an accident, serious physiological or functional malfunction.
8. "Veterinary Pharmacopeia" it's a collection that includes instructions to prepare VMP-s, published by a state authority of a country or a medical or pharmaceutical society.
9. "Animal" are the mammals, birds, amphibians, reptiles, fish, mollusks, crustaceans, vertebrates or invertebrates that are bred for trade or nontrade purposes or that live freely in nature.
10. "Exotic Animals" are animals that are kept for non-trade purposes but that they are not considered companion animals
11. "Carcasses" is the body of an animal after the slaughtering and preparing of the meat for trading and/or usage.
12. "Suspension time" is the required time, in-between the last usage of a VMP in living animals and the production of foods from those animals, in a way that the level of VMP wastes in this food to be below the maximal permitted levels.

13. "Coccidiostatics and histomonostatics" are VMPs that are used to exterminate or stop the reproduction of protozoas.
14. "National Laboratory of Reference" is the laboratory that monitors the other laboratories in the country for the application of the standards and methods of the lab control, briefing of the standard reference samples and it is known as a competent authority to do specific analyses.
15. "Waste" are the waste of materials that have metabolites with pharmacological effect, that pass to the products with animal origin and might have a bad effect on humans.
16. "Hormonal products" are products that contain hormonal substances (directly or indirectly) with estrogenic, androgenic and gestagenic effects.
17. "Veterinary Medical Products/VMP" is every substance or mixture of substances that:
    a. Is used for the treatment and prevention of diseases in animals.
    b. that can be administered to animals to retrieve, regulate or change their physiological functions in animals, applying a pharmacological, immunological or metabolic action.
18. "Specifically Dangerous Animal Products" are organs and tissues of ruminants where there is a collection of the Transmissible Spongiform Encephalopathy (TSE)
19. "Hazard" is it's a biological, chemical or physical agent or a state of the animal or product with animal origin with the ability to a counter effect to health.
20. "Thyrostatics" are substances that limit the thyroid gland functions, stimulating the growth effect.
21. "Vector" is any animal, vertebrate or invertebrate, that in a mechanical or biological way transmits or spreads the cause of a disease.
22. "Zoonosis" is any disease or infection that, in a natural way, it is transmitted directly or indirectly, from animals to humans.

Competent Authorities:

The veterinary service in the Republic of Albania is organized in a unified system that acts according to the directives of this law. The system integrates structures that, have veterinary functions in other public institutions, apart from the ones regulated by the Ministry of Agriculture and regulates them aswell.
The veterinary service of the country is part of a the regional and international network, cooperating with OiE, the institutions of the European Union and other countries. All the representatives of the veterinary service in regional or international organizations are chosen by

the Minister of Agriculture.
The competent authorities for the regulation of the veterinary authority in Albania are:

- The Competent Authority that directs the veterinary service and fulfils the needs of the service in the whole territory of the Republic of Albania.
- The Four Regional Agencies of Veterinary Service and Plant Protection that monitor every farm, private veterinarian and point of veterinary medical product sale in the country.

National Regulations:

The following national regulations provide a detailed description of the requirements and procedures undr certain provisions of law:

- Ordinance Nr.370 date 29/07/2014 for the approval of the regulations "over veterinary medical products"
- Directive of the Council of Ministers (DCM) Nr. 146/2018 for the creation, organization and functionality of the regional agencies of the veterinary service and plant protection.

Law nr 105/2014 for Medicines and the Pharmaceutical Service

This law regulates the function of the pharmaceutical service in Albania and as it cites in cites in Articles 2(2.ç) one of its fields of application is for Veterinary Medical Products. As far as the trading of veterinary medical products is concerned under Article 61(2.e) this competent agency overviews the trading of veterinary medical products aswell, also citing under Article 63(1.n) a certain fine if these substances are sold by someone not certified as a veterinary pharmacist.

Law nr 113/2015 for the Professional Chamber of Veterinarians

This law, re-organised with a directive from the DCM nr 43/2019 regulates the structure of the professional chamber of veterinarians in the Republic of Albania and. The chamber using its comitte among other stuff to certifies, educates and monitors the activity of veterinary pharmacist in the country. According to the internal law of the Chamber citied in Article 4(2) the veterinary pharmacist in order to be licenced, has to have been graduated from the Faculty of Veterinary Medicine as a veterinarian and has to have completed a 4 week course organised by the Professional Chamber of Veterinarians.

Law nr 10 006/2008 For the Protection of Wild Fauna

This law, re-organised by the Parliamentary Directive nr 46/2019, regulates the life of wild fauna in the territory of Albania with the purpose to preserve the species and the habitats where they live. The wild fauna of the Republic of Albania is a national property that is administered by several state agencies. To avoid the negative effects and the overall genetics damage over the wild fauna the usage of agricultural chemical substances and VMP is regulated under certain law desposits(Art.10). It is prohibited by law in Albania to use baits with poison for the extermination of wild fauna individuals (Art.19) and there is also a certain amount of fine in case of any attempt

to breach this law(Art.43.12). All the individuals that are confiscated or seized should be handed over to rescue centers.

Procedures

There are several procedures described under the Law for Veterinary Service and also in the national directive about the Regulation over VMPs, which are directly or indirectly connected to production, use, storage, trade or import of VMPs. These are described below.

Veterinary Medical Practice

According to the Article 76(e,f), it is prohibited by law to treat and to administer VMP-s to animals by anauthorised personnel. It is also prohibited to administer anesthetics or another types of substances that effect negatively the health of the animal if it is not justified by a medical reason or by a medical procedural experiment approved by the competent authorities. As of Article 110(c.i,ii,ç,e,f) the Veterinarian when he is treating a farm animal is obliged to register the date of treatment, to clarify the name, expiring date and suspension time of an administered VMP. The veterinarian should also notify the owner about the suspension time and side effects of the VMP over the animal. In case of an unexpected severe reaction of the animal or people from the VMP, the veterinarian is obliged to notify the regional authorities. The veterinarian should respect the dosage of beta-agonists and thyroidstatics of VMP with hormonal compounds.

Measures of animal health control

It is the responsibility of the component authority of the veterinary service to control the general health of the animal population in the country, segregate sick animals from the healthy ones and to limit the exposure and transport of any sick animals (Art.15). The owner or caretaker of any animal is forced by law to inform the authorities for the death of an animal and to take care of the transportation of the animal wastes to the nearest place of collection and processing of wastes(Art.79.1,2). In case of animal imports they should be subject to quarantine not less than 21 days to go through a list of several examinations(Art.41.2). There is a list of controls done on living animals to verify that they are healthy before slaughtering and to distinguish any chemical waste(Art.30). These types of controls shall be done without a prior notice and should identify any possible breach of standards (Art.30.2).

Border veterinary control

During import, export or transit of living animals, VMPs, embryonic animal products, products with animal origin etc need to be a controlled by the veterinary service of the border. These veterinary border points are to be placed in every border crossing in the Republic of Albania. As for the VMP there are several directives about loading and storage of any imported VMP. During any attempt to import or export a certain amount of VMP-s there has to be a certain control by the veterinary authorities in the border, where at any time there ought to be a veterinarian at any time (Art.34.3). The Border point must always notify the veterinary authorities for any cargo that arrives in the border. It is allowed for VMPs to be imported or exported only after they have been

certified according to the legislation (Art.38.2). The importer is responsible to notify the authorities prior to the arrival of the cargo, present the cargo for control and for the tariff of the border clearance to be payed by the owner (Art.35).

Wholesale of VMPs

According to Article 94 the wholesale trading of VMP-s in the country is done according to the legislation in power for general import of medicines in Albania. The wholesale trader can sell their products to veterinary pharmacies, veterinarians and farm owners according to prescription. They should also have a detailed register of all the details that compose the VMP they trade. The trader has to have at least once a year a report sent to the competent authorities of the overall VMP-s bought,sold and in stock. These registers should be kept intact for at least three years. In addition to that according to the Article 95 of the same law, if a batch of VMP has reached its expiring date, its quality parameters have changed because of bad storage or transport, the wholesale trader is obliged by law to eliminate this batch. In the presence of a state veterinarian the wholesale trader has to with-hold a record of elimination where the type, quantity, batch number and the reason of elimination of this VMP are written and are offered to the competent authority if asked to do so. In the case that the wholesale trader refuses to eliminate a batch, then the expenses of elimination of the batch by the competent authorities, are covered by the wholesale trader.

Licensing for production, import and export of VMPs

The VMPs, disinfectants and veterinary disinfectants can be traded in the Republic of Albania only after they have been approved by the Stae Commission of VMPs (Art85). The Commission recognizes certificates of VMPs from the European Medication Agency or from one of the EU countries. Its is strictly prohibited to trade or use VMP that have not been certified by the Commission (Art.92.9), with the only exception if the veterinarian with his own responsibility chooses to medicate a non-farm animal with unregistered VMP in order to seize its suffering or when there are no drugs registered in the country that can give a positive effect towards a specific disease or when this drug is prepared by a pharmacist or a veterinary pharmacist that is certified in the country(Art.92.9).In the case of farm animals the same conditions of exception take also part in this (Art.92.10).As far as it concerns the homeopathic VMPs they have a different way of obtaining a license. If a homeopathic VMP is licensed in EU then it can automatically be certified in Albania aswell (Art.92.18). If the homeopathic VMP are destined for companion animals and non-farm animals it can be certified using a simplified procedure, if and only if the drugs usage is included in the European Pharmacopeia and it is guaranteed enough not to leave any VMP wastes (Art.92.19). Nevertheless, as it is implied in the Albanian law, all the certified products have to be registered in the state register of VMPs (Art.93).

The license to produce VMPs in the country is given to the units that do simultaneously: sectioning, tablet pressing, packaging, mixing or production of active substances. These units should have the adequate infrastructure and cited the pharmaceutical forms that the VMP will be available in (Art.92.34). All the procedures of producing of VMPs are approved by the Minister of Agriculture (Art. 92). The producer is obliged to have detailed documentation of the VMPs produced by him, including some samples of the VMP. The producer is also obliged to show at

any requested time, the registers and other documentations related to the drug. On the other hand , the producer is not obliged to show results of security tests, to the competent authorities, if and only if, he can verify that the VMP is a derivative of a medical product that has been certified in EU for more than 8 years (Art 93.41.12). If it is the case of the production of an active substance the production unit has to deal with the whole process of partition, packaging and branding of the VMP (Art.93.41). A producer should always hire someone with a degree in Veterinary Medicine, Chemistry or Pharmaceutical Technology (Art.93.42.4&5)

Retail sale of VMPs

Retail sale of VMP is only available in veterinary pharmacies by people that are authorized to do so by the legislation in act (Art.96). The pharmacist in this pharmacy has to be a veterinarian that has been given a certificate by the Veterinary Pharmacy Course. If the pharmacies have not been given a trading certificate then they cannot sell VMPs(Art.97). Also, in veterinary pharmacies it is prohibited to sell VMP with immunologic effect over diseases that have been included in the National Programme of Prophylaxis. The veterinary pharmacies have to maintain a daily register where the date and the quantity of the sales, naming and number, the details of expiry of the VMP are stated (Art.98). Also, in order to protect the public health there are certain categories of VMPs that can only be sold with a veterinarians prescription (Art.99). These are:

I. VMP that have an enforced limitation from convents of OSCE about psychotropic and narcotic substances, or by limitations from EU laws.

II. VMP that are used in farm animals and have a suspension time.

Control of VMP-s and Pharmacovigilance

It's the duty of the competent authority to build a system of pharmacovigilance and to ensure that any counter indication of the drug over the animals will be notified (Art.102). If such a problem arises it has to be analyzed by the competent laboratory and if it is judged to be of a severe importance, then the certificate can me suspended and furthermore the authority has to notify the European Agency of Drugs and other agencies for the consequences of this VMP (Art.102.1,2,5). Also as measure of state control of VMPs the competent authority is obliged to overview the production, sale and usage of any VMP traded in the country (Art.103). Any controls over a related product is carried out by the competent authority and in case that there is any breach of actions outside the competence given in the competence given in the certificate, the suspension of the VMP trading is declared. The importer or producer of an VMP , or the owner of a farm, is obliged to notify, in written form, the competent authorities , in case of any counter indication of an VMP on animals(Art.103.67). The pharmacovigilance is a responsibility of the regional veterinarian. The general system of pharmacovigilance is controlled by the Regional Veterinary Agency which reports regularly to the competent laboratory and the competent authorities (Art.103.67).

Analysis of the Procedures for use, import, storage and treatment of VMPs/NSAIDs

Albania has a very strict legislation on livestock farming , in VMPs use, production, trade and import. Presumably the legislation was designed to ensure an efficient food safety and human and animal health. This on the other hand has limited drastically the available food for the vulture population in the country. As far as the environment is concerned, the laws have been created to protect it but from a livestock point of view. There is no proper Biodiversity Protection Law in the country so everything that is directly related to wildlife and thus to the vulture population in the country, seems to be regulated by different articles of the laws described in this report. Among others, recently, it has been illegal to poison wildlife in the country, but on the other hand, there is strict control on VMPs that are able to indirectly or directly do so.

Despite the strict procedures of registering of VMPs in the country, the whole process is simplified if a drug is certified in the EU, making it very difficult to report different substances used by farmers and veterinary pharmacists in the country. A lack of a public state register about VMPs in the country is also a setback for the prevention of excessive usage of VMPs and NSAIDs. Furthermore while some substances are not registered as VMPs in the country, such as diclofenac for example, they are registered in the human pharmacy sector and are pretty easy to be bought. Adjusting to that there are a lot of diclofenac-containing VMPs in the European Union that can easily be introduced in the VMPs trade in Albania.

The structure of the institutions that are authorized to organize, coordinate and control the use, trade, production or import of VMPs in the country is very fragile as the definition in the law is given in a very broad meaning. Also the commission of VMPs is conducted by a very small group of specialists but the decision is centralized at the hands of the director of the National Food Authority. The lack of transparency of the implementation of the law seems to be a major weakness of the whole jurisdictional network for this matter. The role of implementation of the law is allocated to the official veterinarian who are based in one of the four Regional Agencies of Veterinary and Plant Protection. Veterinarians are also supposed to participate in border point controls.

The legislation related to VMPs was based mainly on license and control mechanisms of the whole procedure of VMPs. There were several levels of control which were related to the use, trade and production of VMPs. At local level the control is carried by local official veterinarians that are responsible for the control of VMP usage by farmers as well as with the border veterinary control, accompanied by a detailed documentation. The highest control level laboratory wise is the laboratory of the Institute of the Food and Veterinary Safety, which should have the necessary kits to test for residues of VMPs and generally NSAIDs in animals.

Other VMPs that can lead to poisoning.

The main focus remains on NSAIDs. While for sure the majority of the poisoning cases in vultures are caused by this class of VMPs there are other substances that can be easily part of the poisonous baits.

- **Tetramethrin**

Tetramethrin is a pyrethroid antiparasitic substance, that is commonly used by veterinarians to heal ectoparasites in farm and domestic animals. Normally a vile of 5ml is diluted with 1 liter of water and the animals are sprinkled. As it is understood, it is a highly toxic substances and it is very easy for anyone in Albania to get hold of a vile. Also is among the cheapest and most used treatments against ectoparasites in the VMPs market.

- **Diazepam**

Diazepam is a commonly used VMP convulsant. It is mainly used for sedation and mild anesthetic induction. It is generally toxic in certain dosages for the liver. As it is fairly available in most of the human and veterinary pharmacies, having a low price (less than 1 euro for a 5mg/mL solution) it is of a high risk towards the vulture population.

- **Bisopropol fumarate**

It is a antiarrhythmic, beta blocker used to reduce the heart rate and conductivity. In high dosages it can turn into a beta $_2$ blocker and do the contrary action by increasing the heart rate and eventually cause immediate heart arrest and death. It's high toxicity is also adjusted by the fact that it is commonly used in large animals in the country but generally it doesn't have an indicated minimal residue dosage.

- **Praziquantel**

It is a substance that is commonly used as a deworming and internal anti-parasitic treatment substance. Often it is found in a combination with other substance, of which, fenbendazole, making the combination highly toxic in certain amounts. Mixtures with high content of praziquantel can easily obtain in veterinary pharmacies but also in pet shops across the country.

- **Rifampin/Rifampicin**

It is an antibiotic that is commonly used to fight tuberculosis avium infections. Mostly metabolized in the liver and with a low half –life elimination time, it is a substance that acts fast in organisms with high metabolism. It is reported to be hepatoxic in certain dosages in animals with low body weight.

- **Selamectin**

It is a topical parasiticide and anthelminthic commonly used in dogs and cats to prevent heartworms,fleas, mites and different types of mange. If used in excessive dosages it can cause neuroparalisis as it is highly toxic and it has a complex mechanism that can also cause apnea. It is a very common drug in the VMP market of the country.

- **Ivermectin**

It is one of the most used antiparasitic substances used in farm and domestic animals. Generally it is administered in small doses, but, there is no specific dosing for all the species. Thus resulting into residues found in cadavers of animals in slaughterhouses, pretty often.It is highly neurotoxic that can cause a central nervous system depression and muscular ataxia. It can be found in any veterinary pharmacy in the country and it can be obtained in a cheap price.

Obstacles of successful implementation of law

While conducting this report and reading the different laws that regulate the VMPs and NSAIDs in the country, I was faced with a lot of written lines that exist only in paper but where never implemented properly. I will hereby list the main obstacles, of implementation of the law on VMPs in Albania, that I have found through private practice:

- **High Registering Prices:**

For every new VMP registered in the country, whether it is registered by a company or by a private veterinarian, the price of registration and tests is pretty high. In order to register a new drug the fee could reach 700000 lek (approximately 5.5 thousand euros). The cost becomes bigger taking in consideration the tests and samples that ought to be done by the importer. Faced with these high prices the veterinarians tend to turn their interest to cheaper alternatives or even buying in the black market. These cheaper or illegally bought substances are pretty dangerous for the vulture population in the country, they have not been tested and there is no residue limit guidance, thus making them a general threat.

- **Lack of Veterinarians in Border Control Points**

Although in the Laws analyzed in this report, it is legally required, for at least a veterinarian to be always present at all border control points in the country. Interestingly so, as many veterinarians in the country are aware, there is no veterinarian in the Qafe Thane-Kjafasan Border Point (Between Albania and Nothern Macedonia), Kapshtice-Krystallopigi Border Point and Kakavia-Ktismata Border Point (Both between Albania and Greece). The above mentioned borders are among the most important borders in the country with most of the imports and exports in the country occurring there. Also, in the Mother Theresa International Airport in Tirana and the Durres Harbor the veterinarian is present only a few days a week. These facts proves the lack of implementation of several articles or even chapters of the Albanian Legislation about VMPs and generally for the Veterinary Service in the country.

Suggestions for better implementation

Throughout the conduct of this report, I found several gaps in the legislation procedures that, if filled would make the implied laws more durable and more applicable.

- Immediate need for a publication of a list of VMP active in the country, meaning that every registered VMP details could be easily accessed by any veterinarian in the country. Making these registers public will help build a better tracking system on the drugs that can badly affect the vulture population in the country. Also, if it is possible, by knowing the used substances in designated parts of the country, one could suggest the substitution of a severly hazardous drug with one that would have less effect over the health of the animals.

- Lack of veterinary officers in most of the border points makes the implementation of the regulation of VMP in the country, fairly, impossible. Having a better control from a specialized personel would make the flow of VMP in and out of the country more

accountable, making able to track down any mis-usage of the drugs, hence minimizing the poisoning risks.

- Provide the state veterinary laboratory with the necessary kits to detect and analyze poisoned birds in order to evaluate the risks of a certain NSAIDs used on a specified region or during a specific time. As I am conducting this report the state laboratory has no capacity to analyze cadavers of animals that appear to have been poisoned.

Conclusions

Albania has a pretty solid legislation on VMPs use, production, trade and import as well as on livestock welfare and breeding. The legislation was also designed to ensure animal and human food safety and health, resulting in a limitation on food for the vulture population in the country.

Although the legislation is approximated to the European Union directives and regulations, it seems to be very distant to the actual requirements. Furthermore, despite the fact that there is an article that sanctions the poisoning of wildlife in the country, licensing of NSAIDs or other VMPs with the same potential or chemical proximity, are very easily able to be imported and licensed in the country. This weakness in the legislation is quite risky especially for the vulture conservation issue. This, adjacent with the fact that the country still doesn't have a public national register for VMPs or some other type of register to be accessible by veterinarians and farmers simultaneously, makes the implementation of the law very difficult.

The only positive thing about the law that seems to work properly is the fact that the licensing of drugs in the country goes through a State Commission, but the fact that the commission doesn'thold a public register, overshadows the credibility of the whole process.

Sources of information

Law nr 10 465, date 29/09/2011 For the Veterinary Service in the Republic of Albania
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https://www.parlament.al/Files/Integrimi/ligj_nr_105_dt_31_7_2014_18582_12.pdf

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