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VETMEDICRIME SURVEY REPORT
Survey on falsification of medical products for veterinary use

State replies

prepared by

Dr. José María ESTEBAN FERNÁNDEZ,
Spanish National Health Pharmaceutical S.

Dr. Sigitas SIRIUKAITIS,
Veterinary of the Republic of Lithuania

Criminal Law Co-operation Unit Secretariat
Directorate General I – Human Rights and Rule of Law

1. INTRODUCTION:

The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter, "the MEDICRIME Convention" or "the Convention") aims to prevent and combat threats to public health. Article 4 of the Convention defines as follows: "*the term "medicinal product" shall mean medicines for human and veterinary use… (sic)"*.

The lack of information of the real situation on veterinary counterfeit[1] medicines and the threat that they mean not only to animal health but also to human health, imposed the need for the MEDICRIME Committee of the Parties (hereinafter, "the MEDICRIME Committee" or "the CoP") to start an evaluation on the situation among its Parties and associated countries with the aim of seeing, following an evaluation, if there is a real need of acting, as it has been the case with human medicines and medical devices, with such a success.

As described in the preamble of the survey sent to Parties, counterfeit veterinary medicines are a big threat to human health, knowing that animal-derivate products are an important part of our food. It is through daily consumption that such veterinary medicine used to cure or prevent an animal disease could enter into the human food chain. Many zoonotic diseases, if not properly treated in the animal origin, can be transferred to humans and be a real threat. They can also become resistant to available treatments if the medicine is counterfeit. The same may happen if the medicines used to treat pets' diseases are counterfeit, thus putting pet owners at risk. This can also create antimicrobial and antiparasitic resistance.

Counterfeit veterinary medicines not only pose a health threat, but their trade has a real economic impact and is a source of illegal funds for criminals.

Both the continuing rapid growth of buying and selling products online (*e-commerce*) and a parallel growth in international trade, especially of small packages, have created new opportunities for the trade in counterfeit veterinary medicines. It is necessary to know if countries and authorities are appropriately responding to this situation.

In case of the European Union countries, and those who follow the same criteria, it should be considered the entry into force on 28th of January 2022 on Regulation 2019/6 (Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC). It establishes new measures aimed at tackling antibiotic resistance, given the need to ensure rational use of antimicrobials in the veterinary sector under ONE Health approach. It also aims at modernising the legal framework applying to veterinary medicines, including in connection with the retail and dispensing of such medicines, control of

[1] The term "counterfeit", as defined in Article 4.j, of the MEDICRIME Convention and used in this report is intended to have the same meaning as the term "falsified" has in relation to medical products by the World Health Organization (WHO) and the United Nations Office on Drugs and Crime (UNODC).

counterfeit. Finally, it also intends to give incentives to stimulate innovation and increase the availability of quality and trustable veterinary medicines within the European Union.

The Regulation develops further principles set out originally in the Patients' Rights Directive and the Falsified Medicines Directive, with respect to the recognition of veterinary prescriptions and the Common Logo for Internet sites selling veterinary medicines. Indeed, the Regulation provides that internet sale of veterinary non-prescription medicines must be authorised in all EU member States under conditions which mirror the provisions introduced by the Falsified Medicines Directive for the Internet sale of human non-prescription medicines (i.e. provide certain information, display a common logo, etc.). This makes the Veterinary Medicines Regulation consistent with the rules applying to human medicines which are welcome. The new rules apply as from 28 January 2022. So, following the survey, many EU countries that joined the MEDICRIME convention are already implementing that Regulation. This mean that they will have to implement in their legislation (if not already) actions against counterfeit and/or substandard veterinary medicines by Including in that regulation the obligation to the holders of a manufacturing authorisation, distributors and authorities' actions in this field of counterfeit and substandard.

In a recent study[1], authors conducted searches in Embase, PubMed, MEDLINE, Global Health, Web of Science, CAB Abstracts, Scopus, Google Scholar, Google and websites with interest in veterinary medicines quality up to 28 February 2021. Articles in English and French were screened for eligibility. They found that 52% of the 1246 veterinary medicine samples collected in Asia and Africa tested for quality were substandard or counterfeit. The most common reason for sample failure was out-of-specification active ingredient(s) content (46.6%, 481/1032), and 4.2% of all samples contained incorrect active ingredient(s). As many veterinary API and medicines come from Asian origin (mainly China, India, or even South Korea), we are facing a real global problem.

Perhaps, as happened with counterfeit medicines and medical devices for human use, complementary actions and, overall, awareness to the authorities (health and others), politicians, security forces, veterinaries, judicial bodies, customs and general population, must be considered.

Against this background, and for doing so, a group of experts, ruled by the Executive Secretary of the CoP, Mr. Oscar Alarcón, create a simple short survey that was sent to all Parties and some signatory countries. Once the survey will be replied by all Parties, it will be possible to evaluate the situation, shortcomings, needs, actions and proposals that could be issued within the framework of the MEDICRIME Convention.

The survey was sent to all Parties and signatories on 21/10/2021. Countries were requested to provide their answers. Up to now (October 2023) 14 countries replied to the survey. The accession of new countries to the Committee of the Parties brings new replies in a different timing.

The survey aims to obtain a clearer picture of the control of counterfeit veterinary medicines in those countries which are Parties to the MEDICRIME Convention. This survey is conceived as a first approach to the topic, covering the basic elements of potential legal and regulatory practices.

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[1] *The quality of veterinary medicines and their implications for One Health,* Vayouly Vidhamaly, Konnie Bellingham, Paul N Newton and Céline Caille. BMJ Glob Health: first published as 10.1136/bmjgh-2022008564 on 2 August 2022.

The experts are aware that is a limited snapshot of the situation. Those countries who already answered the survey show different situations and this can show an preliminary overview.

In addition, in the EU countries, the implementation of the above-mentioned quoted Regulation is going to be a great change in the approach of the counterfeit veterinary medicines control.

2. SURVEY DESCRIPTION AND EVALUATION CRITERIA

As an annex to this report, the received surveys are included. So can be seen what has been questioned in the survey.

The terms used in the survey are:

- *Counterfeit veterinary medicine*to refer to products that deliberately/fraudulently misrepresent their identity, composition or source, which include: medicines developed to resemble the original ones (unregistered/unlicensed, packaging, labelling, etc.), including vaccines.
- "API" to refer to *active pharmaceutical ingredients.*

The questions could be grouped in three main different aspects:

- If the country has a regulation and a specific administrative authority/ies that are acting in the field of counterfeit veterinary medicines. Including judicial and criminal offences
- If there is an strategy and actions to control (and also evaluate, in a routinely basis) the counterfeit veterinary medicines
- If have information on how it is affecting their countries and people/specialists' awareness

3. SURVEY RESULTS :

Thirteen countries have already answered: Belarus, Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Lithuania, Portugal, Russian Federation, Spain, Switzerland, Turkey, Ukraine. Republic of Armenia has recently (August 2023) sent its survey answer, when the final report was already done and sent. So this is an update that includes that country too.

We do thank again to all of them for their support, efforts and answers.

3.1. Questions results:

3.1.1. ***Does your country have a specific regulation for veterinary use medicines?***

100% of them have a specific regulation.

Those who belong to the EU must comply with Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC. Others have their own national regulations. Some of them included into the general medicines one or a specific one for veterinary medicines.

3.1.2. ***Do veterinary medicines follow equivalent criteria to medicines for human use (i.e. authorised manufacturers, controlled distributors, need for a veterinary prescription, distribution and/or sales under pharmaceutical control, etc.) in your country?***

100% of them follow the equivalent criteria.

The regulation controls, in general, in the same way medicines for human use and for veterinary use.
It is interesting to point out that in some countries the Authorities in this field are those also related with medicines for human use (mainly Medicines Agencies). Meanwhile others have specific veterinary medicines administrative organism not directly related with medicines for human use.

3.1.3. ***Does your country have specific regulations and/or control the use of bulk API (in food or water for pigs, poultry, fish, etc.) in veterinary medicine?***

84.6% of them have

Those who belong to the EU must comply with Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.
In most of the countries, API in bulk may not be used if it is not in the form of the authorized veterinary medicinal product. It is important not to forget that in some cases bulks API in veterinary medicines have an important role as could be directly used for the treatment in farms and fishery. So, lack of proper control could be a problem.

3.1.4. ***Does your country have specific border control (customs control) for veterinary medicines and APIs for veterinary use?***

100% of them have

Here will be important to know in future if the protocols are general or specific. And how the customs authorities and personnel are formed regarding counterfeit veterinary medicines. All countries have specific border control for VMP, however in some cases there are no specific border control for API.

3.1.5. ***Are the offers and sales of veterinary medicines through the Internet regulated in your country (including e-commerce platforms)?***

50% of them have

This issue is very important as internet (e-commerce) have a geometrical increase on selling veterinary medicines. And, as it happens with medicines for human use, usually could become the main source of illegal products.

From 28/01/2022 with the implementation of the new regulation on veterinary medicines Regulation 6/2019, the online sale of non-prescription veterinary medicinal products is possible throughout EU. It is not known if some countries have the system of the sale of prescription veterinary medicinal products through Internet. Could be very interesting to know how that regulation and control are made in the countries they have.

3.1.6. ***Does your country have any regulation about counterfeit medicines for veterinary use?***

85.7% of them have

Very important issue and to get to know how that regulation is updated to face the new challenges in the field of counterfeit veterinary medicines

3.1.7. ***Does your country have an effective strategy for the control of counterfeit veterinary medicines?***

50% have

It is interesting that if around 91.1% of the countries have a regulation on counterfeit veterinary medicines, they assume that they do not have an effective strategy. Moreover, those countries which answered, that have an effective strategy, emphasized, that It is difficult to estimate the effectiveness of existing monitoring and control measures to prevent the entry of counterfeit veterinary products.
It resembles the situation that when MEDICRIME started faced years ago. There could be some regulation, but the strategies were not so effective.
This resul shows the importance that could mean to create a VETMEDICRIME strategy and support. Based in the experience of years in the field of counterfeit medicines for human use, but with the specificity for veterinary medicines.

3.1.8. ***Does your country have an industry-wide/distributors' database of incidents involving counterfeit veterinary medicines?***

21.4% have

Here we have also an important indicative parameter on the situation.
In the EU the cited regulation 2019/6; request information and that distributors and manufacturing authorization holders be active in informing on incidents on counterfeit. Not having a database of incidents in this field, means a lack of information and control.

3.1.9. ***In your experience, which are the main distribution channels/suppliers of veterinary medicines currently existing in your country (rate from 1, less important, to 5, most important; or N/A – not applicable):***

Licensed wholesalers	5
Approved physical retailers (pharmacies, merchants)	4
Veterinarians (direct supply from them, if legal in your country)	3
Approved internet retailer/supplier/pharmacy	2
Other *e-commerce,* if legal, for veterinary medicines (e.g., eBay, Amazon, Alibaba)	0
Social media, if legal, for veterinary medicines (e.g., Facebook, Twitter)	0
Unapproved physical retailer/ merchants	1
Unapproved internet pharmacies	0
Other unapproved internet sources	1
Others (please describe):	

In each country is a different model of distribution model. After results of this survey, it could be concluded, that the main distribution channels/suppliers of veterinary medicines currently existing in countries (78.5 % of countries with answer 5) are licensed wholesalers. Approved physical retailers (pharmacies, merchants) are also one of the most important suppliers of veterinary medicines (42.8% of countries with answer 5), but not like wholesalers. Interesting that in

some countries are unapproved physical or internet retailers, which must be regulated and controlled.

It is said that there is no other *e-commerce* offers. But should be made a deeper study if in different legal platforms could be offering veterinary medicines.

In some countries there are specific groups of specialists (for example breeders) which are not in the survey list, however they are allowed retailing of VMP.

3.1.10. ***Has your country included in their criminal justice regulations any specific subject on counterfeit veterinary medicines?***

71.4% have

Most of the regulations are administrative based as a health problem. Since the spreading of crimes related with counterfeit medicines and medical devices for human use, many countries now include in their criminal regulation this subject. Some with the same criteria for human and veterinary, the regulations apply for medicinal products in general, and VMP are included.

Perhaps should be necessary to evaluate if the penalties in those regulations are updated related with the threats that counterfeit veterinary medicines mean also for human health.

3.1.11. ***Is there any regulated and routine control on counterfeit veterinary medicines and counterfeit veterinary APIs by:***

Customs / Border control authorities at entry ports/airports/terrestrial frontiers alone or in conjunction with other agencies e.g. Interpol/Europol/World Customs Organization, national enforcement or veterinary medicines/pharmaceutical control agencies	71.4%
Regulators/Veterinary medicines agency (or equivalent)	85.7%
National enforcement officers at destination market	50%
Approved internet retailer/supplier/pharmacy controllers	35.7 %
Combined operations, including against counterfeit websites	35.7 %
Regulators and enforcement agencies together (federal and state, in case)	64.3 %
Others (please describe):	

Counterfeit veterinary medicines and counterfeit veterinary APIs are *regulated and routine controlled by* Regulators/Veterinary medicines agency (or equivalent) in all countries. More regulation and control is necessary in retailers sector and there are very low percentages of combined operations against counterfeit websites. Communication and collaboration between governmental agencies/competent authorities etc. should be increased.

3.1.12. ***Is there national cooperation and information exchange between veterinary medicines agency (or equivalent), law enforcement, and other competent authorities?***

100% answered yes

Could be interesting to get to know the system.
The SPOC structure has demonstrated to be very effective and useful in the case ofMEDICRIME, perhaps that approach could be recommended and applied in veterinary too, if not already done.

3.1.13. ***Does your country have regulations regarding corporate liability (legal person liable under conditions) for the offenses related to counterfeit veterinary medicines?***

85.7 % answered yes

That liability is not implemented in all countries. There are cases, that administrative offenses established, by law decree, for veterinary medicines that do not comply with the requirements of the legislation. Counterfeit veterinary medicines do not comply with the requirements for a marketing authorization and, in this way, these entities are penalized.

3.1.14. ***If your country has regulated sanctions for offences related to counterfeit veterinary medicines, please specify the type (choose all that apply):***

Administrative 85.7%
Civil 7.1 %
Criminal/penal
71.4 % Others
(please describe):

In majority of countries which have regulated sanctions for offences related to counterfeit veterinary medicines, iIn *85.7% are administration sanctions. 71.4 % Of countries have their own criminal/penal sanctions and only 1 country has civil sanctions.*

Due to the threat for animal and human health that counterfeit veterinary medicines mean, should be implemented a specific criminal/penal regulation.

3.1.15. ***Do the following actors have access to regular training in the field of counterfeit veterinary medicines for (check those that apply)?***

Veterinary regulatory Agency	57.14 %	**Veterinary professional**	28.5 %
Pharmacists	14.2 %	**Manufacturers**	28.5%
Providers	14.2 %	**Distributors**	28.5 %
Police/Enforcement agencies	21.4 %	**Custom/border control**	21.4 %
Judges	0	**Prosecutors**	0
Veterinary/pharmacist Associations	21.4 %		
Relevant Authorities (politicians).	7.7 %		
Civil society	0		
Others (please describe):			

It is very important to emphasize that in 35.7 % of countries there is no any regular training in the field of counterfeit veterinary medicines.

The majority of Veterinary regulatory Agencies (57.14 %) have *access to regular training in the field of counterfeit veterinary medicines;* however, it must be in all countries. The lack of such trainings in veterinary pharmacy industry, judicial and prosecutors has been shown and the needs of these trainings are essential.

3.1.16. ***Does your country have policies or strategies implemented to promote or conduct awareness-raising campaigns targeted at the general public on counterfeit veterinary medicines?***

35.7% of them have

Here we find another situation of risk. As not having a complete strategy for public awareness mean that population do not have the sensation of being at risk in this issue. Public awareness is mandatory to minimize the impact of counterfeit veterinary medicines in human and animal health, apart from the impact in economic.
Much more in some specific population, like farmers.
Doing such campaigns is very important

No other commentary to the survey has been presented by the countries.

4. CONCLUSIONS

In general, those countries who answer the survey demonstrate that they are aware about the problem on counterfeit veterinary medicines.

Most of them have a regulation even in the criminal area.

The new regulation that in the EU that comes into force in the 2022 mean that all EU Countries must implement not only the control, but the strategies on the field of counterfeit veterinary medicines. Being expected that they will follow the same criteria that with medicines and medical devices for human use.

From the survey, that was made before the actions taken under that Regulation, we can also realize that there is a lack on some strategies also policies, to promote general population awareness. In addition, perhaps, judicial and police authorities.

So, as a summary the main conclusions could be considered the following:

1. In general, there is a specific regulation that includes counterfeit veterinary medicines. Those EU countries are implementing the EU Regulation.

2. Many have not specific regulations and/or control the use of bulk API. It could be included in the general regulation or not. In veterinary medicine these types of products have a great impact as are widely used, even by the farmers.

3. There are different models of distribution model. The main distribution channels/suppliers of veterinary medicines currently existing in countries are licensed wholesalers; but there are others that need a specific control, as in the survey pointed out the existence of not well controlled source.

4. Control of *e-commerce* (Internet offering) is a weakness in many countries. Nowadays Internet is becoming an important source of products. Regulation and control of it is very important and must be implemented.

5. Some countries have not regulated and routine control on counterfeit veterinary in some areas. Even at the end of the supply chain and/or not even in the internet. Although seems that official Veterinary control Agencies and Custom authorities usually act, from the results of the survey some problems are also detected in this area, mainly in combined operations too.

6. Most of the countries assume they have not a proper and right strategy against counterfeit veterinary medicines. We do thank for being sincere on that issue. In many of them there is a Regulation but seems that must step on to a better strategy.

7. Same it happens with the database of incidents involving counterfeit veterinary medicines. Not yet implemented in many countries. In fact, it means a lack of information that affects to the whole system.

8. Considering the criminal aspect of counterfeit veterinary medicines is also very important. From the preliminary survey results seems that still not enough formative actions for the judicial authorities to be aware of the real risk and threat that counterfeit mean.

9. Regular training in the field of counterfeit veterinary medicines is a real problematic issue. Even in 35.7 % of countries there is no any regular training in the field of counterfeit veterinary medicines. But is a real problem that in most of the different actors implied in the veterinary medicines control and crime fight lack updated formative actions.

10. The low percentage of regular training of counterfeit veterinary medicines in the veterinary pharmacy industry field has been shown and the need of it is essential in order to raise the aware about the risks on these types of counterfeit products.

11. Another important issue found in this preliminary report is the lack of public awareness on the threat of counterfeit veterinary medicines. Many countries have not a specific program/s to aware the population about the risks on these types of counterfeit products.

Some recommendations may be the following:

- Even having regulations in many countries, there is a lack in some key issues as is shown in the survey conclusions. Perhaps the inclusion as a criminal act, in those countries where still is not included, should be mandatory.

- Veterinary API are widely used, and some countries should implement a control and/or deeper control of them.

- Internet is becoming an important source of veterinary medicines and veterinary APIs. So, countries must develop a stronger strategy to know which is the real situation and, if needed, increase controls against counterfeit.

- Co-operation between national competent authorities, law enforcement agencies, customs services and the judiciary on the national and international scale must be reinforced and communication encouraged as well as the exchange of information and data.

- Training reinforcement and periodic and updated one is needed to all those who are into fighting the counterfeit veterinary medicines.

- General population awareness on the risks that counterfeit veterinary medicines mean must be increased. Not only for those who have pets, but also to farmers and any person that should face a counterfeit veterinary medicine acquisition.

- The National platform system worked really well in the fight against counterfeit medicines and medical devices. So, apply that systematics could be very useful to veterinary counterfeit medicines, too.

- Include the counterfeit veterinary medicines into the Pangea Campaign.

- Regular national or international training courses and actions on the MEDICRIME Convention is essential.

MEDICRIME convention has shown to be a great tool to combat and prevent the crimes in the field of counterfeit medical products. In veterinary medicine, the experience acquired in human counterfeit medicines can be of real help and support.

ANNEX I.
SURVEY ANSWER FROM THE COUNTRIES

ANNEXE I.
RÉPONSES DES PAYS À L'ENQUÊTE

5. INTRODUCTION:

The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter, MEDICRIME Convention) aims to prevent and combat threats to public health. This Convention concerns medical products, including medicinal products and medical devices. Article 4 of the Convention defines as follows: "*the term "medicinal product" shall mean medicines for human and veterinary use… (sic)"*.

Strong efforts have been made in the fight against counterfeit medicinal products for human use and also counterfeit medical devices. Efforts remain insufficient in the field of veterinary medicines. Veterinary medicines are needed to treat farm animal diseases (including in fish farming, hunting preys for human consumption and wildlife) as well as domestic pets 'pathologies.

Counterfeit veterinary medicines are a big threat to human health, knowing that animal-derivated products are an important part of our food. It is through daily consumption that such veterinary medicine used to cure or prevent an animal disease could enter into the human food chain. Many zoonotic diseases, if not properly treated in the animal origin, can transfer to humans and be a real threat. They can also become resistant to available treatments if the medicine is counterfeit. The same may happen if the medicines used to treat pets' diseases are counterfeit, thus putting pet owners at risk. This can also create antimicrobial and antiparasitic resistance.

In 2012, the treatment of *nagana* (a type of animal African trypanosomiasis) using counterfeit medicines led to the loss of more than 4.500 million dollars. In this light, the FAO (Food and Agriculture Organization of the United Nations) and the IFAH (International Federation for Animal Health) collaborated in the development of the first pharmaceutical protocols to fight against counterfeit veterinary medicines.

A recent report from the Health for Animals Association (2018) estimates that counterfeit veterinary medicines (which includes Unregistered/Unlicensed and Counterfeit) grossed a US$1-2 billion annual market. Both vaccines and pharmaceutical products are affected by the trade in counterfeit veterinary medicines.

The continuing rapid growth in online buying and selling of products (*e-commerce*) and a parallel growth in international trade especially of small packages has created new opportunities for trade in counterfeit veterinary medicines.

In conclusion, we must admit that counterfeit, counterfeit and unregistered products harm animals and decrease food safety and security, while increasing the risk of zoonotics and antimicrobial/antiparasitic resistance.

Considering the foregoing, this survey aims to get a clearer image on the control of counterfeit veterinary medicines in Parties to the MEDICRIME Convention. It is envisaged as a first approach to the topic, covering the basic elements of potential legal

and regulatory practices. No details on judicial interpretation (case-law analysis) or law enforcement practices are therefore required.

The responses to this survey will be compiled and analysed, with a view to drafting a horizontal assessment of the global situation. The latter willidentify both threats and needs, making proposals for improvement in line with the MEDICRIME Convention. Parties to the MEDICRIME Convention will be invited to submit observations to the draft of this report before its adoption and publication.

6. SURVEY

We will use in this survey the terms:

- *counterfeit veterinary medicine*to refer to products that deliberately/fraudulently misrepresent their identity, composition or source, which include: medicines developed to resemble the original ones (unregistered/unlicensed, packaging, labelling, etc.), including vaccines.
- "API" to refer to*active pharmaceutical ingredients.*

Please inform the following:

Name of Country:

- **Main Government Authority in your country directly involved with veterinary medicines regulation:**
  - **The Scientific Center of Drug and Medical Technology Expertise after academician Emil Gabrielyan of the Ministry of Health of the Republic of Armenia, ○ The Ministry of Health of the Republic of Armenia, ○ The Ministry of Economy of the Republic of Armenia,**
  - **Health and Labour Inspectorate of the Government of the Republic of Armenia**
- **Main National Administrative body/institution/agency that controls veterinary medicines (evaluation, authorisation, market control, etc.). If more than one, please specify:**
  - **Health and Labour Inspectorate of the Government of the Republic of Armenia**
- **Person/s (name, position, address, phone, e-mail) to get in touch with,about this survey:**
  - admin@pharm.am, ○ info@moh.am ○ secretariat@minecon omy.am ○ info@hlib.am

6.1. Questions:

6.1.1. Doesyour country has a specific regulation for veterinary use medicines?

□ Yes

6.1.2. Do veterinary medicines follow equivalent criteria to medicines for human use (i.e. authorised manufacturers, controlled distributors, need for a veterinary prescription, distribution and/orsales under pharmaceutical control, etc.) in your country?

□ Yes

2.1.3. Does your country have specific regulations and/or control the use of bulk API (in food or water for pigs, poultry, fish, etc.) in veterinary medicine?

□ Yes

2.1.4. Doesyour country have specific border control (customs control) for veterinary medicines and APIs for veterinary use?

□ Yes

2.1.5. Arethe offers and salesof veterinary medicines through the Internet regulated in your country (including*e-commerce* platforms)?

□ No

2.1.6 Does your country have any regulation about falsified medicines for veterinary use?

□ Yes

2.1.7.Does your country have an effective strategy for the control of falsified veterinary medicines?

□ Yes

2.1.8. Doesyour country have an industry-wide/distributors' database of incidents involving falsified veterinary medicines?

□ No

2.1.9.In your experience, which are the main distribution channels/suppliers of veterinary medicines currently existingin your country (rate from 1, less important, to 5, most important; or N/A –not applicable):

Licensed wholesalers	Yes
Approved physical retailers (pharmacies, merchants)	Yes
Veterinarians (direct supply from them, if legal in your country)	Yes
Approved internet retailer/supplier/pharmacy	No
Other *e-commerce,* if legal, for veterinary medicines (e.g. eBay, Amazon, Alibaba)	No
Social media, if legal, for veterinary medicines (e.g. Facebook, Twitter)	No

Unapproved physical retailer/ merchants	No
Unapproved internet pharmacies	No
Other unapproved internet sources	No
Others (please describe):	N/A

2.1.10. Has your country included in their criminal justice regulations any specific subject on falsified veterinary medicines?

□ Yes

2.1.11. Is there any regulated and routine control on falsified veterinary medicines and falsifiedveterinary APIs by:

Customs / Border control authorities at entry ports/airports/terrestrial frontiers alone or in conjunction with other agencies e.g. Interpol/Europol/World Customs Organization, national enforcement or veterinary medicines/pharmaceutical control agencies	□ Yes
Regulators/Veterinary medicines agency (or equivalent)	□ Yes
National enforcement officers at destination market	□ Yes
Approved internet retailer/supplier/pharmacy controllers	□ No
Combined operations, including against falsified websites	□ Yes
Regulators and enforcement agencies together (federal and state, in case)	□ Yes
Others (please describe):	N/A

2.1.12. Is there national cooperation and information exchange between veterinary medicines agency (or equivalent), law enforcement, and other competent authorities?

□ Yes

2.1.13. Does your country have regulations regarding corporate liability (legal person liable under conditions) for the offenses related tofalsified veterinary medicines?

□ Yes

2.1.14. If your country has regulated sanctionsfor offences related tofalsified veterinary medicines, please specify thetype (choose all that apply):

Administrative □ Yes
Civil □ No
Criminal/penal□
Yes Others
(please
describe):

2.1.15. Do the following actors have access to regular training in the field of falsified veterinary medicines for (check those that apply)?

Veterinary regulatory Agency	□ Yes	Veterinary professional	□ Yes
Pharmacists	□ Yes	Manufacturers	□ Yes
Providers	□ Yes	Distributors	□ Yes
Police/Enforcement agencies	□ Yes	Custom/border control	□ Yes
Judges	□	Prosecutors	□
Veterinary/pharmacist Associations	□ Yes	Relevant Authorities (politicians)	□
Civil society	□ No		

Others (please describe):

2.1.16. Does your country havepolicies or strategies implemented to promote or conduct awareness-raising campaigns targeted at the general public on falsified veterinary medicines?

□ No

Please share any other consideration, comments or aspects that could be noted for this survey:

The legislative status of the veterinary medicines regulations is following: according to Law on Medicines of the Republic of Armenia it has been established that the marketing authorization, import authorization and other regulatory actions under the Ministry of Health, and only, the serum and vaccines used in veterinary practice is authorized by the Ministry of Economy of the Republic of Armenia. The market control of the veterinary medicines are placed under the Health and Labour Inspectorate of the Government of the Republic of Armenia.

VETERINARY SURVEY

7. INTRODUCTION:

The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter, MEDICRIME Convention) aims to prevent and combat threats to public health. This Convention concerns medical products, including medicinal products and medical devices. Article 4 of the Convention defines as follows: "*the term "medicinal product" shall mean medicines for human and veterinary use… (sic)"*.

Strong efforts have been made in the fight against falsified medicinal products for human use and also falsified medical devices. Efforts remain insufficient in the field of veterinary medicines. Veterinary medicines are needed to treat farm animal diseases (including in fish farming, hunting preys for human consumption and wildlife) as well as domestic pets' pathologies.

Falsified veterinary medicines are a big threat to human health, knowing that animal-derivated products are an important part of our food. It is through daily consumption that such veterinary medicine used to cure or prevent an animal disease could enter into the human food chain. Many zoonotic diseases, if not properly treated in the animal origin, can transfer to humans and be a real threat. They can also become resistant to available treatments if the medicine is falsified. The same may happen if the medicines used to treat pets' diseases are falsified, thus putting pet owners at risk. This can also create antimicrobial and antiparasitic resistance.

In 2012, the treatment of *nagana* (a type of animal African trypanosomiasis) using falsified medicines led to the loss of more than 4.500 million dollars. In this light, the FAO (Food and Agriculture Organization of the United Nations) and the IFAH (International Federation for Animal Health) collaborated in the development of the first pharmaceutical protocols to fight against falsified veterinary medicines.

A recent report from the Health for Animals Association (2018) estimates that falsified veterinary medicines (which includes Unregistered/Unlicensed and Falsified) grossed a US$1-2 billion annual market. Both vaccines and pharmaceutical products are affected by the trade in falsified veterinary medicines.

The continuing rapid growth in online buying and selling of products (*e-commerce*) and a parallel growth in international trade especially of small packages has created new opportunities for trade in falsified veterinary medicines.

In conclusion, we must admit that counterfeit, falsified and unregistered products harm animals and decrease food safety and security, while increasing the risk of zoonotics and antimicrobial/antiparasitic resistance.

Considering the foregoing, this survey aims to get a clearer image on the control of falsified veterinary medicines in Parties to the MEDICRIME Convention. It is envisaged as a first approach to the topic, covering the basic elements of potential legal and

regulatory practices. No details on judicial interpretation (case-law analysis) or law enforcement practices are therefore required.

The responses to this survey will be compiled and analysed, with a view to drafting a horizontal assessment of the global situation. The latter will identify both threats and needs, making proposals for improvement in line with the MEDICRIME Convention. Parties to the MEDICRIME Convention will be invited to submit observations to the draft of this report before its adoption and publication.

8. SURVEY

We will use in this survey the terms:

- *falsified veterinary medicine* to refer to products that deliberately/fraudulently misrepresent their identity, composition or source, which include: medicines developed to resemble the original ones (unregistered/unlicensed, packaging, labelling, etc.), including vaccines.
- "API" to refer to *active pharmaceutical ingredients.*

Please inform the following:

Name of Country:

- **Main Government Authority in your country directly involved with veterinary medicines regulation:**the Department of Veterinary and Food Supervision of the Ministry of Agriculture and Food of the Republic of Belarus

- **Main National Administrative body/institution/agency that controls veterinary medicines (evaluation, authorisation, market control, etc.). If more than one, please specify:**

- **Person/s (name, position, address, phone, e-mail) to get in touch with, about this survey:** Protas Irina A.,consultant of the Department of Veterinary and Food Supervision of the Ministry of Agriculture and Food of the Republic of Belarus, tel: +37517 328 59 95, address: Kirova street, 15, 220030, Minsk, The Republic of Belarus, e-mail:
  dvpnvp@dvpn.gov.by/

8.1. Questions:

8.1.1. Does your country have a specific regulation for veterinary use medicines?

X Yes □ No

8.1.2. Do veterinary medicines follow equivalent criteria to medicines for human use (i.e. authorised manufacturers, controlled distributors, need for a veterinary prescription, distribution and/or sales under pharmaceutical control, etc.) in your country?

X Yes □ No

2.1.3. Does your country have specific regulations and/or control the use of bulk API (in food or water for pigs, poultry, fish, etc.) in veterinary medicine?

X Yes □ No

2.1.4. Doesyour country have specific border control (customs control) for veterinary medicines and APIs for veterinary use?

X Yes □ No

2.1.5. Are the offers and sales of veterinary medicines through the Internet regulated in your country (including *e-commerce* platforms)?

□ Yes X No

2.1.6 Does your country have any regulation about falsified medicines for veterinary use?

X Yes □ No

2.1.7. Does your country have an effective strategy for the control of falsified veterinary medicines?

X Yes □ No

2.1.8. Doesyour country have an industry-wide/distributors' database of incidents involving falsified veterinary medicines?

X Yes □ No

2.1.9. In your experience, which are the main distribution channels/suppliers of veterinary medicines currently existing in your country (rate from 1, less important, to 5, most important; or N/A –not applicable):

Licensed wholesalers	5
Approved physical retailers (pharmacies, merchants)	N/A
Veterinarians (direct supply from them, if legal in your country)	N/A
Approved internet retailer/supplier/pharmacy	N/A
Other *e-commerce,* if legal, for veterinary medicines (e.g. eBay, Amazon, Alibaba)	N/A
Social media, if legal, for veterinary medicines (e.g. Facebook, Twitter)	N/A
Unapproved physical retailer/ merchants	N/A
Unapproved internet pharmacies	N/A
Other unapproved internet sources	N/A

Others (please describe):	

2.1.10. Has your country included in their criminal justice regulations any specific subject on falsified veterinary medicines?

X Yes □ No

2.1.11. Is there any regulated and routine control on falsified veterinary medicines and falsified veterinary APIs by:

Customs / Border control authorities at entry ports/airports/terrestrial frontiers alone or in conjunction with other agencies e.g. Interpol/Europol/World Customs Organization, national enforcement or veterinary medicines/pharmaceutical control agencies	□ Yes X No
Regulators/Veterinary medicines agency (or equivalent)	□ Yes X No
National enforcement officers at destination market	□ Yes X No
Approved internet retailer/supplier/pharmacy controllers	□ Yes X No
Combined operations, including against falsified websites	□ Yes X No
Regulators and enforcement agencies together (federal and state, in case)	□ Yes X No
Others (please describe):	

2.1.12. Is there national cooperation and information exchange between veterinary medicines agency (or equivalent), law enforcement, and other competent authorities?

X Yes □ No

2.1.13. Does your country have regulations regarding corporate liability (legal person liable under conditions) for the offenses related to falsified veterinary medicines?

X Yes □ No

2.1.14. If your country has regulated sanctionsfor offences related to falsified veterinary medicines, please specify the type (choose all that apply):

Administrative	X
Civil	□
Criminal/penal	
X Others (please describe):	

2.1.15. Do the following actors have access to regular training in the field of falsified veterinary medicines for (check those that apply)?

Veterinary regulatory Agency	X	Veterinary professional	X
Pharmacists	□	Manufacturers	X
Providers	□	Distributors	□
Police/Enforcement agencies	□	Custom/border control	□
Judges	□	Prosecutors	□
Veterinary/pharmacist Associations	□	Relevant Authorities (politicians)	□
Civil society	□		
Others (please describe):			

2.1.16. Does your country have policies or strategies implemented to promote or conduct awareness-raising campaigns targeted at the general public on falsified veterinary medicines?

X Yes □ No

Please share any other consideration, comments or aspects that could be noted for this survey:

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

T-MEDICRIME(2021)12_Rev_EN

VETERINARY SURVEY

1. INTRODUCTION:

The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter, MEDICRIME Convention) aims to prevent and combat threats to public health. This Convention concerns medical products, including medicinal products and medical devices. Article 4 of the Convention defines as follows: "*the term "medicinal product" shall mean medicines for human and veterinary use… (sic)"*.

Strong efforts have been made in the fight against falsified medicinal products for human use and also falsified medical devices. Efforts remain insufficient in the field of veterinary medicines. Veterinary medicines are needed to treat farm animal diseases (including in fish farming, hunting preys for human consumption and wildlife) as well as domestic pets' pathologies.

Falsified veterinary medicines are a big threat to human health, knowing that animalderivated products are an important part of our food. It is through daily consumption that such veterinary medicine used to cure or prevent an animal disease could enter into the human food chain. Many zoonotic diseases, if not properly treated in the animal origin, can transfer to humans and be a real threat. They can also become resistant to available treatments if the medicine is falsified. The same may happen if the medicines used to treat pets' diseases are falsified, thus putting pet owners at risk. This can also create antimicrobial and antiparasitic resistance.

In 2012, the treatment of *nagana* (a type of animal African trypanosomiasis) using falsified medicines led to the loss of more than 4.500 million dollars. In this light, the FAO (Food and Agriculture Organization of the United Nations) and the IFAH (International Federation for Animal Health) collaborated in the development of the first pharmaceutical protocols to fight against falsified veterinary medicines.

A recent report from the Health for Animals Association (2018) estimates that falsified veterinary medicines (which includes Unregistered/Unlicensed and Falsified) grossed a US$1-2 billion annual market. Both vaccines and pharmaceutical products are affected by the trade in falsified veterinary medicines.

The continuing rapid growth in online buying and selling of products (*e-commerce*) and a parallel growth in international trade especially of small packages has created new opportunities for trade in falsified veterinary medicines.

In conclusion, we must admit that counterfeit, falsified and unregistered products harm animals and decrease food safety and security, while increasing the risk of zoonotics and antimicrobial/antiparasitic resistance.

Considering the foregoing, this survey aims to get a clearer image on the control of falsified veterinary medicines in Parties to the MEDICRIME Convention. It is envisaged as a first approach to the topic, covering the basic elements of potential legal and regulatory practices. No details on judicial interpretation (case-law analysis) or law enforcement practices are therefore required.

The responses to this survey will be compiled and analysed, with a view to drafting a horizontal assessment of the global situation. The latter will identify both threats and needs, making proposals for improvement in line with the MEDICRIME Convention. Parties to the MEDICRIME Convention will be invited to submit observations to the draft of this report before its adoption and publication.

2. SURVEY

We will use in this survey the terms:

- *falsified veterinary medicine* to refer to products that deliberately/fraudulently misrepresent their identity, composition or source, which include: medicines developed to resemble the original ones (unregistered/unlicensed, packaging, labelling, etc.), including vaccines.
- "API" to refer to *active pharmaceutical ingredients.*

Please inform the following:

Name of Country: Belgium

- **Main Government Authority in your country directly involved with veterinary medicines regulation: Federal Agency for Medicines and Health Products**

- **Main National Administrative body/institution/agency that controls veterinary medicines (evaluation, authorisation, market control, etc.). If more than one, please specify: Federal Agency for Medicines and Health Products**

- **Person/s (name, position, address, phone, e-mail) to get in touch with, about this survey: Anja Ebraert, GDP inspector, Galileelaan 5/03, 1210 Brussel**

2.1. Questions:

2.1.1. Does your country have a specific regulation for veterinary use medicines?

□ Yes (the same as for human medicines, but this will change on the 28th of January 2022 when the Regulation 2019/6 will come into force)

2.1.2. Do veterinary medicines follow equivalent criteria to medicines for human use (i.e. authorised manufacturers, controlled distributors, need for a veterinary prescription, distribution and/or sales under pharmaceutical control, etc.) in your country?

□ Yes

2.1.3. Does your country have specific regulations and/or control the use of bulk API (in food or water for pigs, poultry, fish, etc.) in veterinary medicine?

□ No (but this will change starting the coming into force of the Regulation 2019/6)

2.1.4. Does your country have specific border control (customs control) for veterinary medicines and APIs for veterinary use?

□ Yes (the same as for human medicines)

2.1.5. Are the offers and sales of veterinary medicines through the Internet regulated in your country (including *e-commerce* platforms)?

□ Yes

2.1.6. Does your country have any regulation about falsified medicines for veterinary use?

□ Yes

2.1.7. Does your country have an effective strategy for the control of falsified veterinary medicines?

□ No

2.1.8. Does your country have an industry-wide/distributors' database of incidents involving falsified veterinary medicines?

□ No

2.1.9. In your experience, which are the main distribution channels/suppliers of veterinary medicines currently existing in your country (rate from 1, less important, to 5, most important; or N/A – not applicable):

Licensed wholesalers	5

Approved physical retailers (pharmacies, merchants)	5
Veterinarians (direct supply from them, if legal in your country)	5
Approved internet retailer/supplier/pharmacy	1
Other *e-commerce,* if legal, for veterinary medicines (e.g. eBay, Amazon, Alibaba)	N/A
Social media, if legal, for veterinary medicines (e.g. Facebook, Twitter)	N/A
Unapproved physical retailer/ merchants	?
Unapproved internet pharmacies	?
Other unapproved internet sources	?
Others (please describe):	

2.1.10. Has your country included in their criminal justice regulations any specific subject on falsified veterinary medicines?

□ Yes (the same as for human medicines)

2.1.11. Is there any regulated and routine control on falsified veterinary medicines and falsified veterinary APIs by:

Customs / Border control authorities at entry ports/airports/terrestrial frontiers alone or in conjunction with other agencies e.g. Interpol/Europol/World Customs Organization, national enforcement or veterinary medicines/pharmaceutical control agencies	□ Yes
Regulators/Veterinary medicines agency (or equivalent)	□ Yes
National enforcement officers at destination market	□ Yes
Approved internet retailer/supplier/pharmacy controllers	□ Yes
Combined operations, including against falsified websites	□ No
Regulators and enforcement agencies together (federal and state, in case)	□ Yes
Others (please describe):	

2.1.12. Is there national cooperation and information exchange between veterinary medicines agency (or equivalent), law enforcement, and other competent authorities?

□ Yes

2.1.13. Does your country have regulations regarding corporate liability (legal person liable under conditions) for the offenses related to falsified veterinary medicines?

□ Yes

2.1.14. If your country has regulated sanctions for offences related to falsified veterinary medicines, please specify the type (choose all that apply):

Administrative	x
Civil	□
Criminal/penal	x Others (please describe):

2.1.15. Do the following actors have access to regular training in the field of falsified veterinary medicines for (check those that apply)?

Veterinary regulatory Agency	□	Veterinary professional	□
Pharmacists	□	Manufacturers	□
Providers	□	Distributors	□
Police/Enforcement agencies	□	Custom/border control	□
Judges	□	Prosecutors	□
Veterinary/pharmacist Associations	□	Relevant Authorities (politicians)	□
Civil society	□		

Others (please describe):

2.1.16. Does your country have policies or strategies implemented to promote or conduct awareness-raising campaigns targeted at the general public on falsified veterinary medicines?

□ No

Please share any other consideration, comments or aspects that could be noted for this survey:

T-MEDICRIME(2021)12_Rev_FR

ENQUÊTE SUR LA CRIMINALITÉ VÉTÉRINAIRE

9. INTRODUCTION :

La convention du Conseil de l'Europe sur la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique (ci-après, convention MEDICRIME) a pour objet de prévenir et de combattre les menaces pour la santé publique. Cette convention concerne les produits médicaux qui comprennent les médicaments et les dispositifs médicaux. L'article 4 de la convention stipule que : "*le terme "médicament" désigne les médicaments à usage humain et vétérinaire...*
(sic)".

De gros efforts ont été faits dans la lutte contre les médicaments falsifiés à usage humain et dans les dispositifs médicaux. Encore trop peu d'efforts ont été faits dans le domaine des médicaments vétérinaires.

Les médicaments vétérinaires sont nécessaires pour traiter les maladies des animaux d'élevage (également dans la pisciculture, la chasse aux proies destinées à la consommation humaine et certains animaux sauvages), ainsi que les pathologies des animaux domestiques.

Les médicaments vétérinaires falsifiés constituent une grande menace pour la santé des êtres humainsétant donné que les produits dérivés des animaux constituent une part importante de notre alimentation.C'est dans notre consommation quotidienne que de tels médicaments vétérinaires utilisés pour guérir ou prévenir une maladie animale peuvent entrer dans la chaîne alimentaire. De nombreuses zoonoses, si elles ne sont pas traitées correctement chez l'animal, peuvent se transmettre à l'homme et constituer une véritable menace,ou encore, devenir résistantes aux traitements disponibles si le médicament est falsifié. Il en va de même si les médicaments utilisés pour traiter les maladies des animaux de compagnie sont falsifiés, ce qui peut constituer une autre menace pour le propriétaire de l'animal. Cela peut également créer une résistance aux antimicrobiens et aux antiparasites.

En 2012, le traitement de la maladie du *nagana* (un type de trypanosomiase africaine animale), par des médicaments falsifiés, a entraîné une perte de plus de 4500 millions de dollars. A la lumière de ces informations, la FAO (Organisation des Nations unies pour l'alimentation et l'agriculture) et l'IFAH (Fédération internationale pour la santé animale) ont collaboré à l'élaboration des premiers protocoles pharmaceutiques pour lutter contre les médicaments vétérinaires falsifiés.

Un rapport récent de l'association Health for Animals (année 2018), estime que les médicaments vétérinaires falsifiés (qui comprennent les médicaments non enregistrés/non homologués et falsifiés) représentent un marché annuel de 1 à 2 milliards de dollars US. Tant les vaccins que les produits pharmaceutiques, sont affectés par le commerce de médicaments vétérinaires falsifiés.
La croissance rapide et continue de l'achat et de la vente de produits en ligne (*e-commerce)* et la croissance parallèle du commerce international, notamment des petits

colis, ont créé de nouvelles opportunités pour le commerce de médicaments vétérinaires falsifiés.

Pour conclure, nous devons admettre que les produits contrefaits, falsifiés et non homologués nuisent aux animaux et diminuent la sécurité alimentaire, tout en augmentant le risque de zoonoses et de résistance aux antimicrobiens/antiparasites.

Compte tenu de ce qui précède, cette enquête vise à obtenir une image plus claire du contrôle des médicaments vétérinaires falsifiés au sein des Parties à la convention MEDICRIME. Elle est envisagée comme une première approche du sujet, couvrant les éléments de base des pratiques légales et réglementaires potentielles. Aucun détail sur l'interprétation judiciaire (analyse de la jurisprudence) ou les pratiques d'application de la loi n'est donc requis.

Les réponses à cette enquête seront compilées et analysées, en vue de rédiger une évaluation horizontale de la situation globale. Cette dernière identifiera à la fois les menaces et les besoins, en faisant des propositions d'amélioration en accord avec la convention MEDICRIME. Les Parties à la convention MEDICRIME seront invitées à soumettre leurs observations sur ce projet de rapport avant son adoption et sa publication.

10. ENQUÊTE

Nous utiliserons dans cette enquête les termes :

- *Médicament vétérinaire falsifié :* se réfère à des produits dont l'identité, la composition ou la source sont délibérément/frauduleusement faussées, ce qui inclut : des médicaments développés pour ressembler aux originaux (non enregistrés/non homologués, emballage, étiquetage, etc.
- "API" pour désigner les *principes pharmaceutiques actifs*

Merci de renseigner les questions suivantes:

Nom du pays : BOSNIE-HERZEGOVINE

- **Principale autorité gouvernementale de votre pays directement impliquée dans la réglementation des médicaments vétérinaires :**

  BUREAU VÉTÉRINAIRE DE LA BOSNIE-HERZEGOVINE (IMPORTATION / EXPORTATION, INSPECTION AUX FRONTIÈRES)

- **Principal organisme/institution/agence administrative nationale qui contrôle les médicaments vétérinaires (évaluation, autorisation, contrôle du marché, etc.). Si plus d'un organisme, veuillez préciser :**

MINISTÈRE FÉDÉRAL DE L'AGRICULTURE, DES EAUX ET DES FORÊTS (AUTORISATION / ÉVALUATION) ET ADMINISTRATIONS FÉDÉRALES ET CANTONALES POUR LES AFFAIRES DE CONTRÔLE (CONTRÔLE DU MARCHÉ)

MINISTERE DE L'AGRICULTURE, DES EAUX ET DES FORETS DE LA REPUBLIQUE SRPSKA, BOSNIE-HERZEGOVINE

- **Personne(s) (nom, fonction, adresse, téléphone, e-mail) à contacter au sujet de cette enquête :**

10.1. Questions :

10.1.1. Votre pays dispose-t-il d'une réglementation spécifique pour les médicaments à usage vétérinaire ?

X Oui □ Non

2.1.2. Dans votre pays, les médicaments vétérinaires suivent-ils des critères équivalents à ceux des médicaments à usage humain (fabricants autorisés, distributeurs contrôlés, nécessitant une prescription vétérinaire, distribués et/ou vendus sous contrôle pharmaceutique, etc.)

X Oui □ Non

10.1.2. Votre pays dispose-t-il d'une réglementation et/ou d'un contrôle spécifique sur l'utilisation des IPA en vrac (dans les aliments ou l'eau pour les porcs, les volailles, les poissons, etc.) en médecine vétérinaire ?

X Oui □ Non

2.1.4. Votre pays dispose-t-il d'un contrôle frontalier (contrôle douanier) spécifique pour les médicaments vétérinaires et les IPA à usage vétérinaire ?

X Oui □ Non

2.1.5. L'offre et la vente de médicaments vétérinaires par Internet sont-elles réglementées dans votre pays (y compris les plateformes de *commerce électronique*) ?

□ Oui X Non

2.1.6 Votre pays dispose-t-il d'une réglementation sur les médicaments falsifiés à usage vétérinaire ?

□ Oui X Non

2.1.7. Votre pays dispose-t-il d'une stratégie efficace pour le contrôle des médicaments vétérinaires falsifiés ?

□ Oui X Non

2.1.8. Votre pays dispose-t-il d'une base de données à l'échelle de l'industrie/distributeurs sur les incidents impliquant des médicaments vétérinaires falsifiés ?

□ Oui X Non

2.1.9. D'après votre expérience, quels sont les principaux canaux de distribution/fournisseurs de médicaments vétérinaires dans votre pays (évaluez de 1, moins important, à 5, principal ; ou N/A non applicable-) :

Grossistes sous licence	5
Détaillants physiques agréés (pharmacies, commerçants)	3

Vétérinaires (approvisionnement direct auprès d'eux, si légal dans votre pays)	3
Détaillant internet agréé fournisseur/pharmacie	N/A
Autre *commerce électronique,* si légal, pour les médicaments vétérinaires (par exemple, eBay, Amazon, Alibaba)	N/A
Médias sociaux, si légaux, pour les médicaments vétérinaires (par exemple, Facebook, Twitter)	N/A
Détaillants/marchands physiques non agrees	1
Pharmacies en ligne non approuvées	N/A
Autres sources Internet non approuvées	1
Autres (veuillez décrire):	

2.1.10. Votre pays a-t-il inclus dans sa réglementation en matière de justice pénale un sujet spécifique sur les médicaments vétérinaires falsifiés ?

□ Oui □ Non

EN COURS

2.1.11. Existe-t-il un contrôle réglementé et systématique des médicaments vétérinaires falsifiés et des API vétérinaires falsifiés par :

Les autorités de contrôle des douanes et des frontières dans les ports d'entrée, les aéroports et les frontières terrestres, seules ou en collaboration avec d'autres organismes, telles qu'Interpol, Europol, l'OMD, les organismes nationaux chargés de l'application des lois ou du contrôle des médicaments vétérinaires et des produits pharmaceutiques	X Oui □ Non
Régulateurs/Agence des médicaments vétérinaires (ou équivalent)	X Oui □ Non
Agents nationaux de contrôle sur le marché de destination	□ Oui □ Non
Contrôleurs agréés des détaillants sur Internet, des fournisseurs et des pharmacies	□ Oui □ Non
Opérations combinées, notamment contre les sites web falsifiés	□ Oui □ Non
Les régulateurs et les agences d'exécution ensemble (fédéraux et étatiques, au cas où)	□ Oui □ Non

Autres (veuillez décrire):	

2.1.12. Existe-t-il une coopération nationale et un échange d'informations entre l'Agence des médicaments vétérinaires (ou son équivalent), les services répressifs et les autres autorités compétentes ?

XOui □ Non

2.1.13. La réglementation de votre pays prévoit-elle une responsabilité de l'entreprise (personne morale responsable sous conditions) pour les délits liés aux médicaments vétérinaires falsifiés ?

X Oui □ Non

2.1.14. Si votre pays dispose de sanctions réglementées pour les infractions liées aux médicaments vétérinaires falsifiés, de quel type pourraient-elles être (choisissez toutes les réponses applicables) ?

Administratif □
Civil □
Criminel/pénal □
Autres (veuillez décrire) :

PROCEDURE EN COURS

2.1.15. Les acteurs suivants ont-ils accès à des formations régulières dans le domaine des médicaments vétérinaires falsifiés (cochez les cases correspondantes) ?

Agence de régulation vétérinaire	□	Professionnels vétérinaires	□
Pharmaciens	□	Fabricants	□
Fournisseurs	□	Distributeurs	□
Police/agences de contrôle	□	Douane/contrôle des frontières	□
Juges	□	Procureurs	□
Associations de vétérinaires/pharmaciens			□
Autorités compétentes (politiciens)	□	Société civile	□

Autres (veuillez décrire) :

Une formation est necessaire en vue de mettre en place les meilleures pratiques

2.1.16. Votre pays a-t-il mis en œuvre des politiques ou des stratégies pour promouvoir ou mener des campagnes de sensibilisation destinées au grand public sur les médicaments vétérinaires falsifiés ?

□ Oui □ Non

En cours

Veuillez nous faire part de toute autre considération, commentaire ou aspect qui pourrait être noté pour cette enquête :

Étant donné que nous n'avons pas d'industrie pharmaceutique pour la production de des produits veterinaires en BiH, ces produits sont importés.

Les grossistes agréés qui ont un permis decerne par les Ministèrescompetents des entites de la Bosnie-Herzegovine achètent les produits mentionnés par l'intermédiaire de fournisseurs et de fabricants enregistrés et les importe par des passages frontaliers agréés, soumis aune inspection vétérinaire aux frontières et a 'un contrôle douanier.

L'Office vétérinaire de Bosnie-Herzégovine est chargé de decerner les permis relatives à l'importation de médicaments vétérinaires agréés, de tenir les registres des fabricants, des fournisseurs, des utilisateurs de marchandises et des importateurs, ainsi que le registre des médicaments agréés pouvant être commercialisés sur le territoire de la BiH,

CROATIA

1. INTRODUCTION:

The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter, MEDICRIME Convention) aims to prevent and combat threats to public health. This Convention concerns medical products, including medicinal products and medical devices. Article 4 of the Convention defines as follows: "*the term "medicinal product" shall mean medicines for human and veterinary use… (sic)"*.

Strong efforts have been made in the fight against falsified medicinal products for human use and also falsified medical devices. Efforts remain insufficient in the field of veterinary medicines. Veterinary medicines are needed to treat farm animal diseases (including in fish farming, hunting preys for human consumption and wildlife) as well as domestic pets' pathologies.

Falsified veterinary medicines are a big threat to human health, knowing that animalderivated products are an important part of our food. It is through daily consumption that such veterinary medicine used to cure or prevent an animal disease could enter into the human food chain. Many zoonotic diseases, if not properly treated in the animal origin, can transfer to humans and be a real threat. They can also become resistant to available treatments if the medicine is falsified. The same may happen if the medicines used to treat pets' diseases are falsified, thus putting pet owners at risk. This can also create antimicrobial and antiparasitic resistance.

In 2012, the treatment of *nagana* (a type of animal African trypanosomiasis) using falsified medicines led to the loss of more than 4.500 million dollars. In this light, the FAO (Food and Agriculture Organization of the United Nations) and the IFAH (International Federation for Animal Health) collaborated in the development of the first pharmaceutical protocols to fight against falsified veterinary medicines.

A recent report from the Health for Animals Association (2018) estimates that falsified veterinary medicines (which includes Unregistered/Unlicensed and Falsified) grossed a

US$1-2 billion annual market. Both vaccines and pharmaceutical products are affected by the trade in falsified veterinary medicines.

The continuing rapid growth in online buying and selling of products (*e-commerce*) and a parallel growth in international trade especially of small packages has created new opportunities for trade in falsified veterinary medicines.

In conclusion, we must admit that counterfeit, falsified and unregistered products harm animals and decrease food safety and security, while increasing the risk of zoonotics and antimicrobial/antiparasitic resistance.

Considering the foregoing, this survey aims to get a clearer image on the control of falsified veterinary medicines in Parties to the MEDICRIME Convention. It is envisaged as a first approach to the topic, covering the basic elements of potential legal and regulatory practices. No details on judicial interpretation (case-law analysis) or law enforcement practices are therefore required.

The responses to this survey will be compiled and analysed, with a view to drafting a horizontal assessment of the global situation. The latter will identify both threats and needs, making proposals for improvement in line with the MEDICRIME Convention. Parties to the MEDICRIME Convention will be invited to submit observations to the draft of this report before its adoption and publication.

2. SURVEY

We will use in this survey the terms:

- *falsified veterinary medicine* to refer to products that deliberately/fraudulently misrepresent their identity, composition or source, which include: medicines developed to resemble the original ones (unregistered/unlicensed, packaging, labelling, etc.), including vaccines.
- "API" to refer to *active pharmaceutical ingredients.*

Please inform the following:

Name of Country:

- **Main Government Authority in your country directly involved with veterinary medicines regulation:** *Ministry of Agriculture, Veterinary and Food Safety Directorate*

- **Main National Administrative body/institution/agency that controls veterinary medicines (evaluation, authorisation, market control, etc.). If more than one, please specify:**
  Croatian Veterinary Institute in Zagreb is the main institution for controls of veterinary medicines.

  COMMENT:

By the end of 2022, with implementation of 'VMP regulation' into national legislation (with the new Law for veterinary medicines), "The Agency for Medicinal Products and Medical Devices" - HALMED will become main agency for controls of veterinary medicines.

- **Person/s (name, position, address, phone, e-mail) to get in touch with, about this survey:** *Tomislav Kiš,*
  Head of Food Safety and Veterinary Public Health Sector,Veterinary and Food Safety Directorate,Ministry of Agriculture,Planinska 2a, 10000 Zagreb,Croatia, phone: +385 1 6443 554 and e-mail:tomislav.kis@mps.hr

2.1. Questions:

2.1.1. Does your country have a specific regulation for veterinary use medicines?

√ **Yes** □ No

2.1.2. Do veterinary medicines follow equivalent criteria to medicines for human use (i.e. authorised manufacturers, controlled distributors, need for a veterinary prescription, distribution and/or sales under pharmaceutical control, etc.) in your country?

√ **Yes** □ No

2.1.3. Does your country have specific regulations and/or control the use of bulk API (in food or water for pigs, poultry, fish, etc.) in veterinary medicine?

√ **Yes** □ No

2.1.4. Does your country have specific border control (customs control) for veterinary medicines and APIs for veterinary use?

√ **Yes** □ No

2.1.5. Are the offers and sales of veterinary medicines through the Internet regulated in your country (including *e-commerce* platforms)?

□ Yes √ **No**

2.1.6. Does your country have any regulation about falsified medicines for veterinary use?

√ **Yes** □ No

2.1.7. Does your country have an effective strategy for the control of falsified veterinary medicines?

□ Yes √ **No**

2.1.8. Does your country have an industry-wide/distributors' database of incidents involving falsified veterinary medicines?

√ **Yes** □ No

2.1.9. In your experience, which are the main distribution channels/suppliers of veterinary medicines currently existing in your country (rate from 1, less important, to 5, most important; or N/A – not applicable):

Licensed wholesalers	5
Approved physical retailers (pharmacies, merchants)	5
Veterinarians (direct supply from them, if legal in your country)	5
Approved internet retailer/supplier/pharmacy	N/A
Other *e-commerce,* if legal, for veterinary medicines (e.g. eBay, Amazon, Alibaba)	N/A
Social media, if legal, for veterinary medicines (e.g. Facebook, Twitter)	N/A
Unapproved physical retailer/ merchants	2
Unapproved internet pharmacies	1
Other unapproved internet sources	1
Others (please describe):	

2.1.10. Has your country included in their criminal justice regulations any specific subject on falsified veterinary medicines?

□ Yes √ **No**

2.1.11. Is there any regulated and routine control on falsified veterinary medicines and falsified veterinary APIs by:

Customs / Border control authorities at entry ports/airports/terrestrial frontiers alone or in conjunction with other agencies e.g. Interpol/Europol/World Customs Organization, national enforcement or veterinary medicines/pharmaceutical control agencies	√ **Yes** □ No
Regulators/Veterinary medicines agency (or equivalent)	√ **Yes** □ No
National enforcement officers at destination market	□ Yes √ **No**
Approved internet retailer/supplier/pharmacy controllers	□ Yes √ **No**
Combined operations, including against falsified websites	□ Yes √ **No**
Regulators and enforcement agencies together (federal and state, in case)	□ Yes √ **No**

Others (please describe):	

2.1.12. Is there national cooperation and information exchange between veterinary medicines agency (or equivalent), law enforcement, and other competent authorities?

√ **Yes** □ No

2.1.13. Does your country have regulations regarding corporate liability (legal person liable under conditions) for the offenses related to falsified veterinary medicines?

√ **Yes** □ No

2.1.14. If your country has regulated sanctions for offences related to falsified veterinary medicines, please specify the type (choose all that apply):

Administrative **x**
Civil **x**
Criminal/penal □ Others
(please describe):

2.1.15. Do the following actors have access to regular training in the field of falsified veterinary medicines for (check those that apply)?

Veterinary regulatory Agency	□	Veterinary professional	□
Pharmacists	□	Manufacturers	□
Providers	□	Distributors	□
Police/Enforcement agencies	□	Custom/border control	□
Judges	□	Prosecutors	□
Veterinary/pharmacist Associations	□	Relevant Authorities (politicians)	□
Civil society	□		

Others (please describe):

There is no any regular training in the field of falsified veterinary medicines.
We only occasionally organize one-day trainings, in cooperation with the Faculty of Veterinary Medicine, when there is a change in the law or regulations.

2.1.16. Does your country have policies or strategies implemented to promote or conduct awareness-raising campaigns targeted at the general public on falsified veterinary medicines?

□ Yes √ **No**

Please share any other consideration, comments or aspects that could be noted for this survey:

FRANCE

ENQUÊTE SUR LA CRIMINALITÉ VÉTÉRINAIRE

3. INTRODUCTION :

La convention du Conseil de l'Europe sur la contrefaçon des produits médicaux et les infractions similaires menaçant la santé publique (ci-après, convention MEDICRIME) a pour objet de prévenir et de combattre les menaces pour la santé publique. Cette convention concerne les produits médicaux qui comprennent les médicaments et les dispositifs médicaux. L'article 4 de la convention stipule que : "*le terme "médicament" désigne les médicaments à usage humain et vétérinaire... (sic)"*.

De gros efforts ont été faits dans la lutte contre les médicaments falsifiés à usage humain et dans les dispositifs médicaux. Encore trop peu d'efforts ont été faits dans le domaine des médicaments vétérinaires.

Les médicaments vétérinaires sont nécessaires pour traiter les maladies des animaux d'élevage (également dans la pisciculture, la chasse aux proies destinées à la consommation humaine et certains animaux sauvages), ainsi que les pathologies des animaux domestiques.

Les médicaments vétérinaires falsifiés constituent une grande menace pour la santé des êtres humainsétant donné que les produits dérivés des animaux constituent une part importante de notre alimentation.C'est dans notre consommation quotidienne que de tels médicaments vétérinaires utilisés pour guérir ou prévenir une maladie animale peuvent entrer dans la chaîne alimentaire. De nombreuses zoonoses, si elles ne sont pas traitées correctement chez l'animal, peuvent se transmettre à l'homme et constituer une véritable menace,ou encore, devenir résistantes aux traitements disponibles si le médicament est falsifié. Il en va de même si les médicaments utilisés pour traiter les maladies des animaux de compagnie sont falsifiés, ce qui peut constituer une autre menace pour le propriétaire de l'animal. Cela peut également créer une résistance aux antimicrobiens et aux antiparasites.

En 2012, le traitement de la maladie du *nagana* (un type de trypanosomiase africaine animale), par des médicaments falsifiés, a entraîné une perte de plus de 4500 millions de dollars. A la lumière de ces informations, la FAO (Organisation des Nations unies pour l'alimentation et l'agriculture) et l'IFAH (Fédération internationale pour la santé animale) ont collaboré à l'élaboration des premiers protocoles pharmaceutiques pour lutter contre les médicaments vétérinaires falsifiés.

Un rapport récent de l'association Health for Animals (année 2018), estime que les médicaments vétérinaires falsifiés (qui comprennent les médicaments non enregistrés/non homologués et falsifiés) représentent un marché annuel de 1 à 2 milliards de dollars US. Tant les vaccins que les produits pharmaceutiques, sont affectés par le commerce de médicaments vétérinaires falsifiés.
La croissance rapide et continue de l'achat et de la vente de produits en ligne (*ecommerce)* et la croissance parallèle du commerce international, notamment des

petits colis, ont créé de nouvelles opportunités pour le commerce de médicaments vétérinaires falsifiés.

Pour conclure, nous devons admettre que les produits contrefaits, falsifiés et non homologués nuisent aux animaux et diminuent la sécurité alimentaire, tout en augmentant le risque de zoonoses et de résistance aux antimicrobiens/antiparasites.

Compte tenu de ce qui précède, cette enquête vise à obtenir une image plus claire du contrôle des médicaments vétérinaires falsifiés au sein des Parties à la convention MEDICRIME. Elle est envisagée comme une première approche du sujet, couvrant les éléments de base des pratiques légales et réglementaires potentielles. Aucun détail sur l'interprétation judiciaire (analyse de la jurisprudence) ou les pratiques d'application de la loi n'est donc requis.

Les réponses à cette enquête seront compilées et analysées, en vue de rédiger une évaluation horizontale de la situation globale. Cette dernière identifiera à la fois les menaces et les besoins, en faisant des propositions d'amélioration en accord avec la convention MEDICRIME. Les Parties à la convention MEDICRIME seront invitées à soumettre leurs observations sur ce projet de rapport avant son adoption et sa publication.

4. ENQUÊTE

Nous utiliserons dans cette enquête les termes :

- *Médicament vétérinaire falsifié :* se réfère à des produits dont l'identité, la composition ou la source sont délibérément/frauduleusement faussées, ce qui inclut : des médicaments développés pour ressembler aux originaux (non enregistrés/non homologués, emballage, étiquetage, etc.
- "API" pour désigner les *principes pharmaceutiques actifs*

Merci de renseigner les questions suivantes:

Nom du pays : FRANCE

- **Principale autorité gouvernementale de votre pays directement impliquée dans la réglementation des médicaments vétérinaires : Ministère de la Santé et Ministère de l'Agriculture**

- **Principal organisme/institution/agence administrative nationale qui contrôle les médicaments vétérinaires (évaluation, autorisation, contrôle du marché, etc.). Si plus d'un organisme, veuillez préciser : ANMV au sein de l'ANSES**

- **Personne(s) (nom, fonction, adresse, téléphone, e-mail) à contacter au sujet de cette enquête :**

Hervé SEVESTRE, enquêteur à la BNEVP (Direction Générale de l'Alimentation/MAA), 10 rue du séminaire 94016 RUNGIS, 07 64 26 09 21, herve.sevestre@agriculture.gouv.fr / Florence PRUD'HON, enquêtrice à la BNEVP , florence.prud'hon@agriculture.gouv.fr, 06 73 67 09 29

4.1. Questions :

4.1.1. Votre pays dispose-t-il d'une réglementation spécifique pour les médicaments à usage vétérinaire ?

X Oui □ Non

2.1.2. Dans votre pays, les médicaments vétérinaires suivent-ils des critères équivalents à ceux des médicaments à usage humain (fabricants autorisés, distributeurs contrôlés, nécessitant une prescription vétérinaire, distribués et/ou vendus sous contrôle pharmaceutique, etc.)

X Oui □ Non

4.1.2. Votre pays dispose-t-il d'une réglementation et/ou d'un contrôle spécifique sur l'utilisation des IPA en vrac (dans les aliments ou l'eau pour les porcs, les volailles, les poissons, etc.) en médecine vétérinaire ?

X Oui □ Non

2.1.4. Votre pays dispose-t-il d'un contrôle frontalier (contrôle douanier) spécifique pour les médicaments vétérinaires et les IPA à usage vétérinaire ?

X Oui □ Non

2.1.5. L'offre et la vente de médicaments vétérinaires par Internet sont-elles réglementées dans votre pays (y compris les plateformes de *commerce électronique*) ?

X Oui □ Non

2.1.6 Votre pays dispose-t-il d'une réglementation sur les médicaments falsifiés à usage vétérinaire ?

X Oui □ Non

2.1.7. Votre pays dispose-t-il d'une stratégie efficace pour le contrôle des médicaments vétérinaires falsifiés ?

X Oui □ Non

2.1.8. Votre pays dispose-t-il d'une base de données à l'échelle de l'industrie/distributeurs sur les incidents impliquant des médicaments vétérinaires falsifiés ?

□ Oui X Non

2.1.9. D'après votre expérience, quels sont les principaux canaux de distribution/fournisseurs de médicaments vétérinaires dans votre pays (évaluez de 1, moins important, à 5, principal ; ou N/A -non applicable-) :

Grossistes sous licence	N/A
Détaillants physiques agréés (pharmacies, commerçants)	4
Vétérinaires (approvisionnement direct auprès d'eux, si légal dans votre pays)	5
Détaillant internet agréé fournisseur/pharmacie	3

Détaillants/marchands physiques non agréés	N/A
Pharmacies en ligne non approuvées	N/A
Autres sources Internet non approuvées	N/A
Autres (veuillez décrire): groupement d'éleveurs agrees 20% du marché du detail selon le SIMV 2020	4
Autre *commerce électronique,* si légal, pour les médicaments vétérinaires (par exemple, eBay, Amazon, Alibaba)	N/A
Médias sociaux, si légaux, pour les médicaments vétérinaires (par exemple, Facebook, Twitter)	N/A

2.1.10. Votre pays a-t-il inclus dans sa réglementation en matière de justice pénale un sujet spécifique sur les médicaments vétérinaires falsifiés ?

X Oui □ Non

2.1.11. Existe-t-il un contrôle réglementé et systématique des médicaments vétérinaires falsifiés et des API vétérinaires falsifiés par :

Les autorités de contrôle des douanes et des frontières dans les ports d'entrée, les aéroports et les frontières terrestres, seules ou en collaboration avec d'autres organismes, telles qu'Interpol, Europol, l'OMD, les organismes nationaux chargés de l'application des lois ou du contrôle des médicaments vétérinaires et des produits pharmaceutiques	X Oui □ Non
Régulateurs/Agence des médicaments vétérinaires (ou équivalent)	X Oui □ Non
Agents nationaux de contrôle sur le marché de destination	□ Oui X Non
Contrôleurs agréés des détaillants sur Internet, des fournisseurs et des pharmacies	X Oui □ Non
Opérations combinées, notamment contre les sites web falsifiés	X Oui □ Non
Les régulateurs et les agences d'exécution ensemble (fédéraux et étatiques, au cas où)	□ Oui □ Non
Autres (veuillez décrire):	

2.1.12. Existe-t-il une coopération nationale et un échange d'informations entre l'Agence des médicaments vétérinaires (ou son équivalent), les services répressifs et les autres autorités compétentes ?

X Oui □ Non

2.1.13. La réglementation de votre pays prévoit-elle une responsabilité de l'entreprise (personne morale responsable sous conditions) pour les délits liés aux médicaments vétérinaires falsifiés ?

X Oui □ Non

2.1.14. Si votre pays dispose de sanctions réglementées pour les infractions liées aux médicaments vétérinaires falsifiés, de quel type pourraient-elles être (choisissez toutes les réponses applicables) ?

Administratif □
Civil □ Criminel/pénal X
Autres (veuillez décrire) :

2.1.15. Les acteurs suivants ont-ils accès à des formations régulières dans le domaine des médicaments vétérinaires falsifiés (cochez les cases correspondantes) ?

Agence de régulation vétérinaire	X	Professionnels vétérinaires	□
Pharmaciens	□	Fabricants	□
Fournisseurs	□	Distributeurs	□
Police/agences de contrôle	□	Douane/contrôle des frontières	□
Juges	□	Procureurs	□

Associations de vétérinaires/pharmaciens □ Autorités compétentes (politiciens) □ Société civile □
Autres (veuillez décrire) :

2.1.16. Votre pays a-t-il mis en œuvre des politiques ou des stratégies pour promouvoir ou mener des campagnes de sensibilisation destinées au grand public sur les médicaments vétérinaires falsifiés ?

□ Oui X Non

Veuillez nous faire part de toute autre considération, commentaire ou aspect qui pourrait être noté pour cette enquête :

Réponse au 2.1.9 : source Syndicat de l'Industrie du Médicament Vétérinaire, uniquement le marché du détail, pas de donnée sur les achats des médicaments vétérinaires en dehors des réseaux de distribution connus ; selon une étude de Pfizer de 2010, 14% des français achètent des médicaments humains sur prescription sur internet.

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

T-MEDICRIME(2021)12_Rev_EN

VETERINARY SURVEY

1. INTRODUCTION:

The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter, MEDICRIME Convention) aims to prevent and combat threats to public health. This Convention concerns medical products, including medicinal products and medical devices. Article 4 of the Convention defines as follows: "*the term "medicinal product" shall mean medicines for human and veterinary use… (sic)"*.

Strong efforts have been made in the fight against falsified medicinal products for human use and also falsified medical devices. Efforts remain insufficient in the field of veterinary medicines. Veterinary medicines are needed to treat farm animal diseases (including in fish farming, hunting preys for human consumption and wildlife) as well as domestic pets' pathologies.

Falsified veterinary medicines are a big threat to human health, knowing that animalderivated products are an important part of our food. It is through daily consumption that such veterinary medicine used to cure or prevent an animal disease could enter into the human food chain. Many zoonotic diseases, if not properly treated in the animal origin, can transfer to humans and be a real threat. They can also become resistant to available treatments if the medicine is falsified. The same may happen if the medicines used to treat pets' diseases are falsified, thus putting pet owners at risk. This can also create antimicrobial and antiparasitic resistance.

In 2012, the treatment of *nagana* (a type of animal African trypanosomiasis) using falsified medicines led to the loss of more than 4.500 million dollars. In this light, the FAO (Food and Agriculture Organization of the United Nations) and the IFAH (International Federation for Animal Health) collaborated in the development of the first pharmaceutical protocols to fight against falsified veterinary medicines.

A recent report from the Health for Animals Association (2018) estimates that falsified veterinary medicines (which includes Unregistered/Unlicensed and Falsified) grossed a US$1-2 billion annual market. Both vaccines and pharmaceutical products are affected by the trade in falsified veterinary medicines.

The continuing rapid growth in online buying and selling of products (*e-commerce*) and a parallel growth in international trade especially of small packages has created new opportunities for trade in falsified veterinary medicines.

In conclusion, we must admit that counterfeit, falsified and unregistered products harm animals and decrease food safety and security, while increasing the risk of zoonotics and antimicrobial/antiparasitic resistance.

Considering the foregoing, this survey aims to get a clearer image on the control of falsified veterinary medicines in Parties to the MEDICRIME Convention. It is envisaged as a first approach to the topic, covering the basic elements of potential legal and regulatory practices. No details on judicial interpretation (case-law analysis) or law enforcement practices are therefore required.

The responses to this survey will be compiled and analysed, with a view to drafting a horizontal assessment of the global situation. The latter will identify both threats and needs, making proposals for improvement in line with the MEDICRIME Convention. Parties to the MEDICRIME Convention will be invited to submit observations to the draft of this report before its adoption and publication.

2. SURVEY

We will use in this survey the terms:

- *falsified veterinary medicine* to refer to products that deliberately/fraudulently misrepresent their identity, composition or source, which include: medicines developed to resemble the original ones (unregistered/unlicensed, packaging, labelling, etc.), including vaccines.
- "API" to refer to *active pharmaceutical ingredients.*

Please inform the following:

Name of Country: HUNGARY

- **Main Government Authority in your country directly involved with veterinary medicines regulation: Ministry of Agriculture**

- **Main National Administrative body/institution/agency that controls veterinary medicines (evaluation, authorisation, market control, etc.). If more than one, please specify: National Food Chain Safety Office**

- **Person/s (name, position, address, phone, e-mail) to get in touch with, about this survey:**

-

Dr Eszter Kollár-Nagy, veterinary officer, Ministry of Agriculture – Department of Food Chain Control, +36-1-8967303, eszter.kollar@am.gov.hu

2.1. Questions:

2.1.1. Does your country have a specific regulation for veterinary use medicines?

x □ Yes □ No

2.1.2. Do veterinary medicines follow equivalent criteria to medicines for human use (i.e. authorised manufacturers, controlled distributors, need for a veterinary prescription, distribution and/or sales under pharmaceutical control, etc.) in your country?

x □ Yes □ No

2.1.3. Does your country have specific regulations and/or control the use of bulk API (in food or water for pigs, poultry, fish, etc.) in veterinary medicine?

x □ Yes □ No

2.1.4. Does your country have specific border control (customs control) for veterinary medicines and APIs for veterinary use?

x □ Yes □ No

2.1.5. Are the offers and sales of veterinary medicines through the Internet regulated in your country (including *e-commerce* platforms)?

x □ Yes □ No

2.1.6. Does your country have any regulation about falsified medicines for veterinary use?

x □ Yes □ No

2.1.7. Does your country have an effective strategy for the control of falsified veterinary medicines?

□ Yes **x□ No**

2.1.8. Does your country have an industry-wide/distributors' database of incidents involving falsified veterinary medicines?

□ Yes **x□ No**

2.1.9. In your experience, which are the main distribution channels/suppliers of veterinary medicines currently existing in your country (rate from 1, less important, to 5, most important; or N/A – not applicable):

Licensed wholesalers	5
Approved physical retailers (pharmacies, merchants)	5
Veterinarians (direct supply from them, if legal in your country)	4

Approved internet retailer/supplier/pharmacy	1
Other *e-commerce,* if legal, for veterinary medicines (e.g. eBay, Amazon, Alibaba)	1
Social media, if legal, for veterinary medicines (e.g. Facebook, Twitter)	1
Unapproved physical retailer/ merchants	1
Unapproved internet pharmacies	1
Other unapproved internet sources	1
Others (please describe):	-

2.1.10. Has your country included in their criminal justice regulations any specific subject on falsified veterinary medicines?

x □ Yes □ No

2.1.11. Is there any regulated and routine control on falsified veterinary medicines and falsified veterinary APIs by:

Customs / Border control authorities at entry ports/airports/terrestrial frontiers alone or in conjunction with other agencies e.g. Interpol/Europol/World Customs Organization, national enforcement or veterinary medicines/pharmaceutical control agencies	**x □ Yes** □ No
Regulators/Veterinary medicines agency (or equivalent)	**x □ Yes** □ No
National enforcement officers at destination market	**x □ Yes** □ No
Approved internet retailer/supplier/pharmacy controllers	**x □ Yes** □ No
Combined operations, including against falsified websites	**x □ Yes** □ No
Regulators and enforcement agencies together (federal and state, in case)	**x □ Yes** □ No
Others (please describe):	

2.1.12. Is there national cooperation and information exchange between veterinary medicines agency (or equivalent), law enforcement, and other competent authorities?

x □ Yes □ No

2.1.13. Does your country have regulations regarding corporate liability (legal person liable under conditions) for the offenses related to falsified veterinary medicines?

x □ Yes □ No

2.1.14. If your country has regulated sanctions for offences related to falsified veterinary medicines, please specify the type (choose all that apply):

Administrative □ **x**
Civil □
Criminal/penal □ **x** Others (please describe):

2.1.15. Do the following actors have access to regular training in the field of falsified veterinary medicines for (check those that apply)?

Veterinary regulatory Agency	**□x**	**Veterinary professional**	**□x**
Pharmacists	□	Manufacturers	□
Providers	□	Distributors	□
Police/Enforcement agencies	□	Custom/border control	□
Judges	□	Prosecutors	□
Veterinary/pharmacist Associations	□	Relevant Authorities (politicians)	□
Civil society	□		

Others (please describe):

2.1.16. Does your country have policies or strategies implemented to promote or conduct awareness-raising campaigns targeted at the general public on falsified veterinary medicines?

x□ Yes □ No

Please share any other consideration, comments or aspects that could be noted for this survey:

LITHUANIA

VETERINARY SURVEY

5. INTRODUCTION:

The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter, MEDICRIME Convention) aims to prevent and combat threats to public health. This Convention concerns medical products, including medicinal products and medical devices. Article 4 of the Convention defines as follows: "*the term "medicinal product" shall mean medicines for human and veterinary use… (sic)"*.

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Falsified veterinary medicines are a big threat to human health, knowing that animalderivated products are an important part of our food. It is through daily consumption that such veterinary medicine used to cure or prevent an animal disease could enter into the human food chain. Many zoonotic diseases, if not properly treated in the animal origin, can transfer to humans and be a real threat. They can also become resistant to available treatments if the medicine is falsified. The same may happen if the medicines used to treat pets' diseases are falsified, thus putting pet owners at risk. This can also create antimicrobial and antiparasitic resistance.

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A recent report from the Health for Animals Association (2018) estimates that falsified veterinary medicines (which includes Unregistered/Unlicensed and Falsified) grossed a US$1-2 billion annual market. Both vaccines and pharmaceutical products are affected by the trade in falsified veterinary medicines.

The continuing rapid growth in online buying and selling of products (*e-commerce*) and a parallel growth in international trade especially of small packages has created new opportunities for trade in falsified veterinary medicines.

In conclusion, we must admit that counterfeit, falsified and unregistered products harm animals and decrease food safety and security, while increasing the risk of zoonotics and antimicrobial/antiparasitic resistance.

Considering the foregoing, this survey aims to get a clearer image on the control of falsified veterinary medicines in Parties to the MEDICRIME Convention. It is envisaged as a first approach to the topic, covering the basic elements of potential legal and regulatory practices. No details on judicial interpretation (case-law analysis) or law enforcement practices are therefore required.

The responses to this survey will be compiled and analysed, with a view to drafting a horizontal assessment of the global situation. The latter will identify both threats and needs, making proposals for improvement in line with the MEDICRIME Convention. Parties to the MEDICRIME Convention will be invited to submit observations to the draft of this report before its adoption and publication.

6. SURVEY

We will use in this survey the terms:

- *falsified veterinary medicine* to refer to products that deliberately/fraudulently misrepresent their identity, composition or source, which include: medicines developed to resemble the original ones (unregistered/unlicensed, packaging, labelling, etc.), including vaccines.
- "API" to refer to *active pharmaceutical ingredients.*

Please inform the following:

Name of Country: …LITHUANIA……

- **Main Government Authority in your country directly involved with veterinary medicines regulation:**
- **Main National Administrative body/institution/agency that controls veterinary medicines (evaluation, authorisation, market control, etc.). If more than one, please specify:**
- **Person/s (name, position, address, phone, e-mail) to get in touch with, about this survey:**

6.1. Questions:

6.1.1. Does your country have a specific regulation for veterinary use medicines?

X Yes □ No

6.1.2. Do veterinary medicines follow equivalent criteria to medicines for human use (i.e. authorised manufacturers, controlled distributors, need for a veterinary prescription, distribution and/or sales under pharmaceutical control, etc.) in your country?

X Yes □ No

2.1.3. Does your country have specific regulations and/or control the use of bulk API (in food or water for pigs, poultry, fish, etc.) in veterinary medicine?

□ Yes X No

2.1.4. Does your country have specific border control (customs control) for veterinary medicines and APIs for veterinary use?

X Yes □ No

2.1.5. Are the offers and sales of veterinary medicines through the Internet regulated in your country (including *e-commerce* platforms)?

X Yes □ No

2.1.6 Does your country have any regulation about falsified medicines for veterinary use?

X Yes □ No

2.1.7. Does your country have an effective strategy for the control of falsified veterinary medicines?

□ Yes X No

2.1.8. Doesyour country have an industry-wide/distributors' database of incidents involving falsified veterinary medicines?

□ Yes X No

2.1.9. In your experience, which are the main distribution channels/suppliers of veterinary medicines currently existing in your country (rate from 1, less important, to 5, most important; or N/A –not applicable):

Licensed wholesalers	5
Approved physical retailers (pharmacies, merchants)	4
Veterinarians (direct supply from them, if legal in your country)	3
Approved internet retailer/supplier/pharmacy	1
Other *e-commerce,* if legal, for veterinary medicines (e.g. eBay, Amazon, Alibaba)	N/A
Social media, if legal, for veterinary medicines (e.g. Facebook, Twitter)	N/A
Unapproved physical retailer/ merchants	N/A
Unapproved internet pharmacies	N/A
Other unapproved internet sources	N/A
Others (please describe):	N/A

Regulators/Veterinary medicines agency (or equivalent)	X Yes □ No
National enforcement officers at destination market	X Yes □ No
Approved internet retailer/supplier/pharmacy controllers	X Yes □No
Combined operations, including against falsified websites	□ Yes X No
Regulators and enforcement agencies together (federal and state, in case)	X Yes □ No
Others (please describe):	

2.1.10. Has your country included in their criminal justice regulations any specific subject on falsified veterinary medicines?

□ Yes X No

2.1.11. Is there any regulated and routine control on falsified veterinary medicines and falsified veterinary APIs by:

Customs / Border control authorities at entry ports/airports/terrestrial frontiers alone or in conjunction with other agencies e.g. Interpol/Europol/World Customs Organization, national enforcement or veterinary medicines/pharmaceutical control agencies	X Yes □ No

2.1.12. Is there national cooperation and information exchange between veterinary medicines agency (or equivalent), law enforcement, and other competent authorities?

X Yes □ No

2.1.13. Does your country have regulations regarding corporate liability (legal person liable under conditions) for the offenses related to falsified veterinary medicines?

X Yes □ No

2.1.14. If your country has regulated sanctionsfor offences related to falsified veterinary medicines, please specify the type (choose all that apply):

Administrative X

Civil □
Criminal/penal X Others
(please describe):

2.1.15. Do the following actors have access to regular training in the field of falsified veterinary medicines for (check those that apply)?

Veterinary regulatory Agency	X	Veterinary professional	□
Pharmacists	□	Manufacturers	X
Providers	□	Distributors	X
Police/Enforcement agencies	□	Custom/border control	□
Judges	□	Prosecutors	□
Veterinary/pharmacist Associations	X	Relevant Authorities (politicians)	□
Civil society	□		

Others (please describe):

2.1.16. Does your country have policies or strategies implemented to promote or conduct awareness-raising campaigns targeted at the general public on falsified veterinary medicines?

□ Yes X No

Please share any other consideration, comments or aspects that could be noted for this survey:

T-MEDICRIME(2021)12_Rev_EN

VETERINARY SURVEY

7. INTRODUCTION:

The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter, MEDICRIME Convention) aims to prevent and combat threats to public health. This Convention concerns medical products, including medicinal products and medical devices. Article 4 of the Convention defines as follows: "*the term "medicinal product" shall mean medicines for human and veterinary use… (sic)"*.

Strong efforts have been made in the fight against falsified medicinal products for human use and also falsified medical devices. Efforts remain insufficient in the field of veterinary medicines. Veterinary medicines are needed to treat farm animal diseases (including in fish farming, hunting preys for human consumption and wildlife) as well as domestic pets' pathologies.

Falsified veterinary medicines are a big threat to human health, knowing that animalderivated products are an important part of our food. It is through daily consumption that such veterinary medicine used to cure or prevent an animal disease could enter into the human food chain. Many zoonotic diseases, if not properly treated in the animal origin, can transfer to humans and be a real threat. They can also become resistant to available treatments if the medicine is falsified. The same may happen if the medicines used to treat pets' diseases are falsified, thus putting pet owners at risk. This can also create antimicrobial and antiparasitic resistance.

In 2012, the treatment of *nagana* (a type of animal African trypanosomiasis) using falsified medicines led to the loss of more than 4.500 million dollars. In this light, the FAO (Food and Agriculture Organization of the United Nations) and the IFAH (International Federation for Animal Health) collaborated in the development of the first pharmaceutical protocols to fight against falsified veterinary medicines.

A recent report from the Health for Animals Association (2018) estimates that falsified veterinary medicines (which includes Unregistered/Unlicensed and Falsified) grossed a US$1-2 billion annual market. Both vaccines and pharmaceutical products are affected by the trade in falsified veterinary medicines.

The continuing rapid growth in online buying and selling of products (*e-commerce*) and a parallel growth in international trade especially of small packages has created new opportunities for trade in falsified veterinary medicines.

In conclusion, we must admit that counterfeit, falsified and unregistered products harm animals and decrease food safety and security, while increasing the risk of zoonotics and antimicrobial/antiparasitic resistance.

Considering the foregoing, this survey aims to get a clearer image on the control of falsified veterinary medicines in Parties to the MEDICRIME Convention. It is envisaged as a first approach to the topic, covering the basic elements of potential legal and regulatory practices. No details on judicial interpretation (case-law analysis) or law enforcement practices are therefore required.

The responses to this survey will be compiled and analysed, with a view to drafting a horizontal assessment of the global situation. The latter will identify both threats and needs, making proposals for improvement in line with the MEDICRIME Convention. Parties to the MEDICRIME Convention will be invited to submit observations to the draft of this report before its adoption and publication.

8. SURVEY

We will use in this survey the terms:

- *falsified veterinary medicine* to refer to products that deliberately/fraudulently misrepresent their identity, composition or source, which include: medicines developed to resemble the original ones (unregistered/unlicensed, packaging, labelling, etc.), including vaccines.
- "API" to refer to *active pharmaceutical ingredients.*

Please inform the following:

Name of Country: Portugal

Main Government Authority in your country directly involved with veterinary medicines regulation: DGAV - General Directorate of Food and Veterinary (Direção Geral de Alimentação e veterinária).

- **Main National Administrative body/institution/agency that controls veterinary medicines (evaluation, authorisation, market control, etc.). If more than one, please specify:** General Directorate of Food and Veterinary - Management and Authorisation of Veterinary Medicinal Products Unit (Direção Geral de Alimentação e veterinária - Divisão de Gestão e Autorização de Medicamentos Veterinários).

- **Person/s (name, position, address, phone, e-mail) to get in touch with, about this survey:** Ines Flor Dias idias@dgav.pt

8.1. Questions:

8.1.1. Does your country have a specific regulation for veterinary use medicines?

☒ Yes ☐ No

8.1.2. Do veterinary medicines follow equivalent criteria to medicines for human use (i.e. authorised manufacturers, controlled distributors, need for a veterinary prescription, distribution and/or sales under pharmaceutical control, etc.) in your country?

☒ Yes ☐ No

2.1.3. Does your country have specific regulations and/or control the use of bulk API (in food or water for pigs, poultry, fish, etc.) in veterinary medicine?

☐ Yes ☒ No

Only authorized medicines are administrated to animals, not the active substance (API).

2.1.4. Does your country have specific border control (customs control) for veterinary medicines and APIs for veterinary use?

☒ Yes ☐ No

2.1.5. Are the offers and sales of veterinary medicines through the Internet regulated in your country (including *e-commerce* platforms)?

☒ Yes X No

Currently, online sales are not possible under the current veterinary medicines legislation. In 28/01/2022 with the implementation of the new regulation on veterinary medicines Regulation 6/2019, the online sale of non-prescription veterinary medicinal products will be possible throughout Europe.

2.1.6 Does your country have any regulation about falsified medicines for veterinary use?

☒ Yes ☐ No

A falsified veterinary medicine is considered an illegal product.

2.1.7. Does your country have an effective strategy for the control of falsified veterinary medicines?

☒ Yes ☐ No

It is included in the quality alerts and defects system. Post-authorisation surveillance is carried out annually and control of good distribution and retail practices is also carried out annually

2.1.8. Does your country have an industry-wide/distributors' database of incidents involving falsified veterinary medicines?

☒ Yes ☐ No

It is included in the database of quality alerts and defects system.

2.1.9. In your experience, which are the main distribution channels/suppliers of veterinary medicines currently existing in your country (rate from 1, less important, to 5, most important; or N/A – not applicable):

Licensed wholesalers	5
Approved physical retailers (pharmacies, merchants)	4

Veterinarians (direct supply from them, if legal in your country)	1
Approved internet retailer/supplier/pharmacy	N/A
Other *e-commerce,* if legal, for veterinary medicines (e.g. eBay, Amazon, Alibaba)	N/A
Social media, if legal, for veterinary medicines (e.g. Facebook, Twitter)	N/A
Unapproved physical retailer/ merchants	N/A
Unapproved internet pharmacies	N/A
Other unapproved internet sources	
Others (please describe): *All these sources that we describe as N/A are entities that are not allowed in Portugal to supply veterinary medicines. However they may be legally supplying mostly Social media, eBay, Amazon, Alibaba) and unapproved internet sites. These illegal sources must be classified with a 2*	2

2.1.10. Has your country included in their criminal justice regulations any specific subject on falsified veterinary medicines?

[X] Yes □ No

Fraud in the penal code.

2.1.11. Is there any regulated and routine control on falsified veterinary medicines and falsified veterinary APIs by:

Customs / Border control authorities at entry ports/airports/terrestrial frontiers alone or in conjunction with other agencies e.g. Interpol/Europol/World Customs Organization, national enforcement or veterinary medicines/pharmaceutical control agencies	□ Yes [X] No
Regulators/Veterinary medicines agency (or equivalent)	[X] Yes □ No
National enforcement officers at destination market	□ Yes [X] No
Approved internet retailer/supplier/pharmacy controllers	□ Yes X No
Combined operations, including against falsified websites	[X] Yes if there is a complaint □ No
	[X]

Others (please describe): *If there is a complaint, DGAV in accordance with ASAE (Security Authority Food and Economic) and the police can, within the scope of the respective competences, ensure the inspection of the compliance with the rules established.*	
Regulators and enforcement agencies together (federal and state, in case)	Yes No

2.1.12. Is there national cooperation and information exchange between veterinary medicines agency (or equivalent), law enforcement, and other competent authorities?

☒ Yes □ No

2.1.13. Does your country have regulations regarding corporate liability (legal person liable under conditions) for the offenses related to falsified veterinary medicines?

☒ Yes □ No

There are administrative offenses established, by law decree, for veterinary medicines that do not comply with the requirements of the legislation, falsified veterinary medicines do not comply with the requirements for a marketing authorization and, in this way, these entities are penalized. But so far there is no direct article for counterfeit medicines.

The Directive 2011/62/ of 8 June 2011, is only for medicinal products for human use, and there isn´t an European Directive or regulation only for falsified veterinary medicines.

With the implementation of the new regulation on veterinary medicines Regulation 6/2019, addresses falsified veterinary medicines, and the distributors shall immediately inform the competent authority and, where applicable, the marketing authorisation holder, of veterinary medicinal products they receive or are offered which they identify as falsified or suspected to be falsified.

2.1.14. If your country has regulated sanctions for offences related to falsified veterinary medicines, please specify the type (choose all that apply):

Administrative ☒

Civil □

Criminal/penal ☒ *could be criminal if the concrete threat to human and animal health is proven*

Others (please describe): *There are administrative offenses established, by law decree, for veterinary medicines that do not comply with the requirements of the legislation,*

2.1.15. Do the following actors have access to regular training in the field of falsified veterinary medicines for (check those that apply)?

Veterinary regulatory Agency	X	Veterinary professional	□
Pharmacists	X	Manufacturers	X
Providers	□	Distributors	X
Police/Enforcement agencies	□	Custom/border control	X
Judges	□	Prosecutors	□
Veterinary/pharmacist Associations	□	Relevant Authorities (politicians)	X
Civil society	□		
Others (please describe):			

2.1.16. Does your country have policies or strategies implemented to promote or conduct awareness-raising campaigns targeted at the general public on falsified veterinary medicines?

□ Yes X No

Please share any other consideration, comments or aspects that could be noted for this survey:

RUSSIAN FEDERATION

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

T-MEDICRIME(2021)12_Rev_EN

VETERINARY SURVEY

1. INTRODUCTION:

The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter, MEDICRIME Convention) aims to prevent and combat threats to public health. This Convention concerns medical products, including medicinal products and medical devices. Article 4 of the Convention defines as follows: *"the term "medicinal product" shall mean medicines for human and veterinary use… (sic)"*.

Strong efforts have been made in the fight against falsified medicinal products for human use and also falsified medical devices. Efforts remain insufficient in the field of veterinary medicines. Veterinary medicines are needed to treat farm animal diseases (including in fish farming, hunting preys for human consumption and wildlife) as well as domestic pets' pathologies.

Falsified veterinary medicines are a big threat to human health, knowing that animal-derivated products are an important part of our food. It is through daily consumption that such veterinary medicine used to cure or prevent an animal disease could enter into the human food chain. Many zoonotic diseases, if not properly treated in the animal origin, can transfer to humans and be a real threat. They can also become resistant to available treatments if the medicine is falsified. The same may happen if the medicines used to treat pets' diseases are falsified, thus putting pet owners at risk. This can also create antimicrobial and antiparasitic resistance.

In 2012, the treatment of *nagana* (a type of animal African trypanosomiasis) using falsified medicines led to the loss of more than 4.500 million dollars. In this light, the FAO (Food and Agriculture Organization of the United Nations) and the IFAH (International Federation for Animal Health) collaborated in the development of the first pharmaceutical protocols to fight against falsified veterinary medicines.

A recent report from the Health for Animals Association (2018) estimates that falsified veterinary medicines (which includes Unregistered/Unlicensed and Falsified) grossed a US$1-2 billion annual market. Both vaccines and pharmaceutical products are affected by the trade in falsified veterinary medicines.

The continuing rapid growth in online buying and selling of products (*e-commerce*) and a parallel growth in international trade especially of small packages has created new opportunities for trade in falsified veterinary medicines.

In conclusion, we must admit that counterfeit, falsified and unregistered products harm animals and decrease food safety and security, while increasing the risk of zoonotics and antimicrobial/antiparasitic resistance.

Considering the foregoing, this survey aims to get a clearer image on the control of falsified veterinary medicines in Parties to the MEDICRIME Convention. It is envisaged as a first approach to the topic, covering the basic elements of potential legal and regulatory practices. No details on judicial interpretation (case-law analysis) or law enforcement practices are therefore required.

The responses to this survey will be compiled and analysed, with a view to drafting a horizontal assessment of the global situation. The latter will identify both threats and needs, making proposals for improvement in line with the MEDICRIME Convention. Parties to the MEDICRIME Convention will be invited to submit observations to the draft of this report before its adoption and publication.

2. SURVEY

We will use in this survey the terms:

- *falsified veterinary medicine* to refer to products that deliberately/fraudulently misrepresent their identity, composition or source, which include: medicines developed to resemble the original ones (unregistered/unlicensed, packaging, labelling, etc.), including vaccines.
- "API" to refer to *active pharmaceutical ingredients*.

Please inform the following:

Name of Country:

- **Main Government Authority in your country directly involved with veterinary medicines regulation:** PCXM
- **Main National Administrative body/institution/agency that controls veterinary medicines (evaluation, authorisation, market control, etc.). If more than one, please specify:** PCXM
- **Person/s (name, position, address, phone, e-mail) to get in touch with, about this survey:**

2.1. Questions:

2.1.1. Does your country have a specific regulation for veterinary use medicines?

☒ Yes ☐ No

2.1.2. Do veterinary medicines follow equivalent criteria to medicines for human use (i.e. authorised manufacturers, controlled distributors, need for a veterinary prescription, distribution and/or sales under pharmaceutical control, etc.) in your country?

☒ Yes ☐ No

2.1.3. Does your country have specific regulations and/or control the use of bulk API (in food or water for pigs, poultry, fish, etc.) in veterinary medicine?

☑ Yes ☐ No

2.1.4. Does your country have specific border control (customs control) for veterinary medicines and APIs for veterinary use?

☑ Yes ☐ No

2.1.5. Are the offers and sales of veterinary medicines through the Internet regulated in your country (including *e-commerce* platforms)?

☐ Yes ☑ No

2.1.6 Does your country have any regulation about falsified medicines for veterinary use?

☑ Yes ☐ No

2.1.7. Does your country have an effective strategy for the control of falsified veterinary medicines?

☑ Yes ☐ No

2.1.8. Does your country have an industry-wide/distributors' database of incidents involving falsified veterinary medicines?

☐ Yes ☑ No

2.1.9. In your experience, which are the main distribution channels/suppliers of veterinary medicines currently existing in your country (rate from 1, less important, to 5, most important; or N/A – not applicable):

Licensed wholesalers	5
Approved physical retailers (pharmacies, merchants)	5
Veterinarians (direct supply from them, if legal in your country)	N/A
Approved internet retailer/supplier/pharmacy	5
Other *e-commerce,* if legal, for veterinary medicines (e.g. eBay, Amazon, Alibaba)	N/A
Social media, if legal, for veterinary medicines (e.g. Facebook, Twitter)	N/A
Unapproved physical retailer/ merchants	N/A
Unapproved internet pharmacies	N/A
Other unapproved internet sources	N/A
Others (please describe):	

2.1.10. Has your country included in their criminal justice regulations any specific subject on falsified veterinary medicines?

☑ Yes ☐ No

2.1.11. Is there any regulated and routine control on falsified veterinary medicines and falsified veterinary APIs by:

Customs / Border control authorities at entry ports/airports/terrestrial frontiers alone or in conjunction with other agencies e.g. Interpol/Europol/World Customs Organization, national enforcement or veterinary medicines/pharmaceutical control agencies	☐ Yes ☑ No
Regulators/Veterinary medicines agency (or equivalent)	☑ Yes ☐ No
National enforcement officers at destination market	☐ Yes ☑ No
Approved internet retailer/supplier/pharmacy controllers	☐ Yes ☑ No
Combined operations, including against falsified websites	☐ Yes ☑ No
Regulators and enforcement agencies together (federal and state, in case)	☑ Yes ☐ No
Others (please describe):	

2.1.12. Is there national cooperation and information exchange between veterinary medicines agency (or equivalent), law enforcement, and other competent authorities?

☑ Yes ☐ No

2.1.13. Does your country have regulations regarding corporate liability (legal person liable under conditions) for the offenses related to falsified veterinary medicines?

☑ Yes ☐ No

2.1.14. If your country has regulated sanctions for offences related to falsified veterinary medicines, please specify the type (choose all that apply):

Administrative ☑
Civil ☐
Criminal/penal ☑
Others (please describe):

2.1.15. Do the following actors have access to regular training in the field of falsified veterinary medicines for (check those that apply)?

Veterinary regulatory Agency	☑	Veterinary professional	☑
Pharmacists	☐	Manufacturers	☐
Providers	☑	Distributors	☑
Police/Enforcement agencies	☐	Custom/border control	☐
Judges	☐	Prosecutors	☐
Veterinary/pharmacist Associations	☑	Relevant Authorities (politicians)	☐
Civil society	☐		

Others (please describe):

2.1.16. Does your country have policies or strategies implemented to promote or conduct awareness-raising campaigns targeted at the general public on falsified veterinary medicines?

☑ Yes ☐ No

Please share any other consideration, comments or aspects that could be noted for this survey:

SPAIN

Please inform the following:

Name of Country: Spain

- **Main Government Authority in your country directly involved with veterinary medicines regulation:**
  Spanish Agency for Medicines and Health Products, Ministry of Health.

- **Main National Administrative body/institution/agency that controls veterinary medicines (evaluation, authorisation, market control, etc.). If more than one, please specify:**
  Spanish Agency of Medicines and Medical Devices (evaluation, authorisation, market control).

- **Person/s (name, position, address, phone, e-mail) to get in touch with, about this survey:**
  Manuel Ibarra Lorente,
  Head of Department of Inspection and Control of Medicinal Products
  mibarra@aemps.es
  + 34 918225201
  Rubio Montejano Consoil,
  Head of Veterinary Medicines Department
  crubio@aemps.es
  + 34 91 822 54 01

8.2. For Questions:

8.2.1. Did your country have a specific regulation for veterinary use medicines?

x Yes □ No

The legislation in force on veterinary medicinal products in Spain is Royal Decree 1246/2008 of 18 July 2006, regulating the procedure for the authorisation, registration and pharmacovigilance of industrially manufactured veterinary medicinal products and Royal Decree 109/1995 of 27 January. Both currently under review; Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, which is directly applicable in all Member States, will enter into force on 28 January 2022.

8.2.2. Do veterinary medicines compound equivalent criteria to medicines for human use (e.g. authorised manufacturers, controlled distributors, need for a veterinary prescription, distribution and/or salts under pharmaceutical control, etc.) in your country?

x Yes □ No

There are some particularities regarding dispensing and authorized centers for the custody of certain veterinary medicinal products, but in generally equivalent criteria are applied.

2.1.3. Do your country have specific regulations and/or control the use of bulk API (in food or water for pigs, poultry, fish, etc.) in veterinary medicine?

x Yes □ No

For these uses (addition to feed, drinking water or fish) only medicinal products evaluated and authorised for that purpose (premixtures, powder or concentrate for solution...) may be used.
Bulk API in bulk may not be used if it is not in the form of the authorised medicinal product.

2.1.4. Do your country have specific border control (customs control) for veterinary medicines and APIs for veterinary use?

x Yes □ No

2.1.5. Are the offers and salts of veterinary medicines through the Internet regulated in your country (including *e-commerce* platforms)?

x Yes □ No

The sale of prescription veterinary medicinal products cannot be made through Internet. In the case of veterinary medicinal products which do not require a prescription, this sale may take place in compliance with the provisions of Royal Decree 544/2016 of 25 November 2009, which regulates the sale at a distance to the public of veterinary medicinal products not subject to veterinary prescription.

2.1.6 Does your country have any regulation about falsified medicines for veterinary use?

x Yes □ No

The definition of counterfeit medicines does not exclude veterinary medicinal products. The manufacture, import, export, intermediation, distribution and sale of counterfeit medicines (including online sales, and regardless of whether they are for human or animal use) is considered a serious offense.

2.1.7. Do your country have an effective strategy for the control of falsified veterinary medicines?

x Yes □ No

It is difficult to estimate the effectiveness of existing monitoring and control measures to prevent the entry of counterfeit veterinary products. The impact of this problem, based on the data we have, is very low.

2.1.8. Do your country have industry-wide/distributors' database of incidents interfering with falsified veterinary medicines?

□ Yes x No

Licensed Wholesalers	
Approved Physical Broilers (Pharmacies, merchants)	Most sales are made by the Retail Commercial Establishments (4), then by the Livestock Entities and finally by Groupings (3) and less by the Pharmacies (2).
Veterinarians (direct supply from them, if legal in your country)	Not allowed
Approved Internet retailer/supplier/pharmacy	Sales channel not very developed (2); Only approved physical establishments can sell online.
Other *e-commerce,* if legal, for veterinary medicines (e.g. eBay, Amazon, Alibaba)	Not allowed
Social media, if legal, for veterinary medicines (e.g. Facebook, Twitter)	Not allowed
Unapproved physical broiler/merchants	Not allowed
Unapproved Internet Pharmacies	There are no exclusive internet pharmacies; Only authorised (physical) pharmacies and only medicines that do not require veterinary prescription may sell online.
Other Unapproved Internet Sources	Not allowed
Others (please describe):	

2.1.9. In your experience, which are the main distribution channels/suppliers of veterinary medicines currently existing in your country (rate from 1, less important, to 5, most important; Or N/A — not applicable):

2.1.10. Has your country included in their criminal justice regulations any specific subject on falsified veterinary medicines?

x Yes □ No

2.1.11. Is there any regulated and routine control on falsified veterinary medicines and falsified veterinary APIs by:

Customs/Border control authorities at entry ports/airports/terrestrial frontiers alone or in conjunction with other agencies e.g. Interpol/Europol/World Customs Organisation, national enforcement or veterinary medicines/pharmaceutical control agencies	□ Yes x Not specifically
Regulators/Veterinary medicines agency	□ Yes x Not specifically
National enforcement officers at destination market	□ Yes X Not specifically
Approved Internet retailer/supplier/pharmacy controllers	□ Yes x Not specifically
Combined operations, including against falsified websites	□ Yes x Not specifically
Regulators and enforcement agencies together (federal and state, in case)	□ Yes x Not specifically
Others (please describe):	

2.1.12. Is there national cooperation and information exchange between veterinary medicines agency (or equivalent), law enforcement, and other competent authorities?

x Yes □ No

There is cooperation between the Spanish Agency for Medicines and Health Products and the State Security Forces. There are specific sections within these Forces specialized in crimes against animal health and public health.

2.1.13. Do your country have regulations regarding corporate liability (legal person liable under conditions) for the reasons related to falsified veterinary medicines?

□ Yes □ No

2.1.14. If your country has regulated sanctions for fences related to falsified veterinary medicines, please specify the type (choose all that applies):

Administrative x
Civil □
Criminal/criminal x
Others (please describe):

2.1.15. Do the following actors have access to regular training in the field of falsified veterinary medicines for (check that it applies)?

Veterinary regulatory Agency	□	Veterinary Professionals	□
Pharmacists	□	Manufacturers	□
Providers	□	Distributors	□
Police/Enforcement agencies	x	Custom/border control	□
Judges	□	Prosecutors	□
Veterinary/pharmacist Associations	□	Relevant Authorities (politicians)	□
Civil society	□		

Others (please describe):

2.1.16. Does your country have policies or strategies implemented to promote or conduct awareness-raising campaign taken to the general public about falsified veterinary medicines?

□ Yes x No

Please share any other consideration, comments or aspects that could have been taken for this survey:

SWITZERLAND

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

T-MEDICRIME(2021)12_Rev_EN

VETERINARY SURVEY

1. INTRODUCTION:

The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter, MEDICRIME Convention) aims to prevent and combat threats to public health. This Convention concerns medical products, including medicinal products and medical devices. Article 4 of the Convention defines as

follows: "*the term "medicinal product" shall mean medicines for human and veterinary use… (sic)"*.

Strong efforts have been made in the fight against falsified medicinal products for human use and also falsified medical devices. Efforts remain insufficient in the field of veterinary medicines. Veterinary medicines are needed to treat farm animal diseases (including in fish farming, hunting preys for human consumption and wildlife) as well as domestic pets' pathologies.

Falsified veterinary medicines are a big threat to human health, knowing that animalderivated products are an important part of our food. It is through daily consumption that such veterinary medicine used to cure or prevent an animal disease could enter into the human food chain. Many zoonotic diseases, if not properly treated in the animal origin, can transfer to humans and be a real threat. They can also become resistant to available treatments if the medicine is falsified. The same may happen if the medicines used to treat pets' diseases are falsified, thus putting pet owners at risk. This can also create antimicrobial and antiparasitic resistance.

In 2012, the treatment of *nagana* (a type of animal African trypanosomiasis) using falsified medicines led to the loss of more than 4.500 million dollars. In this light, the FAO (Food and Agriculture Organization of the United Nations) and the IFAH (International Federation for Animal Health) collaborated in the development of the first pharmaceutical protocols to fight against falsified veterinary medicines.

A recent report from the Health for Animals Association (2018) estimates that falsified veterinary medicines (which includes Unregistered/Unlicensed and Falsified) grossed a US$1-2 billion annual market. Both vaccines and pharmaceutical products are affected by the trade in falsified veterinary medicines.

The continuing rapid growth in online buying and selling of products (*e-commerce*) and a parallel growth in international trade especially of small packages has created new opportunities for trade in falsified veterinary medicines.

In conclusion, we must admit that counterfeit, falsified and unregistered products harm animals and decrease food safety and security, while increasing the risk of zoonotics and antimicrobial/antiparasitic resistance.

Considering the foregoing, this survey aims to get a clearer image on the control of falsified veterinary medicines in Parties to the MEDICRIME Convention. It is envisaged as a first approach to the topic, covering the basic elements of potential legal and regulatory practices. No details on judicial interpretation (case-law analysis) or law enforcement practices are therefore required.

The responses to this survey will be compiled and analysed, with a view to drafting a horizontal assessment of the global situation. The latter will identify both threats and needs, making proposals for improvement in line with the MEDICRIME Convention. Parties to the MEDICRIME Convention will be invited to submit observations to the draft of this report before its adoption and publication.

2. SURVEY

We will use in this survey the terms:

- *falsified veterinary medicine* to refer to products that deliberately/fraudulently misrepresent their identity, composition or source, which include: medicines developed to resemble the original ones (unregistered/unlicensed, packaging, labelling, etc.), including vaccines.
- "API" to refer to *active pharmaceutical ingredients.*

Please inform the following:

Name of Country: Switzerland

- **Main Government Authority in your country directly involved with veterinary medicines regulation: Swissmedic (Swiss Agency for Therapeutic Products;**https://www.swissmedic.ch/swissmedic/en/home.html)

- **Main National Administrative body/institution/agency that controls veterinary medicines (evaluation, authorisation, market control, etc.). If more than one, please specify: Swissmedic, Federal Customs Administration and cantonal authorities** (e.g. the cantonal veterinary offices) **as well as the Federal Food Safety and Veterinary Office** (in relation to the use of antibiotics in veterinary medicine); See Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; SR 812.21; https://www.fedlex.admin.ch/eli/cc/2001/422/en).

- **Person/s (name, position, address, phone, e-mail) to get in touch with, about this survey: Judith S. Voney, Head of Penal Division, Swissmedic, Hallerstrasse 7, 3012 Bern, Switzerland; phone +41 58 484 92 21; judith.voney@swissmedic.ch.**

2.1. Questions:

2.1.1. Does your country have a specific regulation for veterinary use medicines?

x Yes □ No

In Switzerland, the term "medicinal product" includes both human and veterinary medicinal products. If it`s not explicitly mentioned, the provisions of Swiss legislation on therapeutic products therefore always apply to veterinary medicinal products as well. In addition, specific legal requirements for veterinary medicinal products are set out in the Ordinance on Veterinary Medicinal Products (Ordonnance sur les medicaments vétérinaires; OMédV; SR 812.212.27; https://www.fedlex.admin.ch/eli/cc/2004/592/fr).

2.1.2. Do veterinary medicines follow equivalent criteria to medicines for human use (i.e. authorised manufacturers, controlled distributors, need for a veterinary prescription, distribution and/or sales under pharmaceutical control, etc.) in your country?

x Yes □ No

2.1.3. Does your country have specific regulations and/or control the use of bulk API (in food or water for pigs, poultry, fish, etc.) in veterinary medicine?

x Yes □ No

2.1.4. Does your country have specific border control (customs control) for veterinary medicines and APIs for veterinary use?

x Yes □ No

2.1.5. Are the offers and sales of veterinary medicines through the Internet regulated in your country (including *e-commerce* platforms)?

x Yes □ No

2.1.6. Does your country have any regulation about falsified medicines for veterinary use?

x Yes □ No

2.1.7. Does your country have an effective strategy for the control of falsified veterinary medicines?

□ Yes x No

2.1.8. Does your country have an industry-wide/distributors' database of incidents involving falsified veterinary medicines?

□ Yes x No

2.1.9. In your experience, which are the main distribution channels/suppliers of veterinary medicines currently existing in your country (rate from 1, less important, to 5, most important; or N/A – not applicable):

Licensed wholesalers	5
Approved physical retailers (pharmacies, merchants)	3
Veterinarians (direct supply from them, if legal in your country)	5
Approved internet retailer/supplier/pharmacy	2
Other *e-commerce,* if legal, for veterinary medicines (e.g. eBay, Amazon, Alibaba)	1
Social media, if legal, for veterinary medicines (e.g. Facebook, Twitter)	n.a. (not legal)
Unapproved physical retailer/ merchants	1
Unapproved internet pharmacies	1
Other unapproved internet sources	1

Others (please describe):	

2.1.10. Has your country included in their criminal justice regulations any specific subject on falsified veterinary medicines?

xYes □ No

As mentioned above, the regulations apply for medicinal products in general, and VMP are included.
Furthermore, the violation of restrictions applicable to the use of antibiotics is specifically mentioned as a violation of the criminal provision of the Therapeutic Products Act (art. 86 al. 1 lit. b TPA).

2.1.11. Is there any regulated and routine control on falsified veterinary medicines and falsified veterinary APIs by:

Customs / Border control authorities at entry ports/airports/terrestrial frontiers alone or in conjunction with other agencies e.g. Interpol/Europol/World Customs Organization, national enforcement or veterinary medicines/pharmaceutical control agencies	**x**Yes □ No
Regulators/Veterinary medicines agency (or equivalent)	**x**Yes □ No
National enforcement officers at destination market	**x**Yes □ No
Approved internet retailer/supplier/pharmacy controllers	**x**Yes □ No
Combined operations, including against falsified websites	□ Yes **x**No
Regulators and enforcement agencies together (federal and state, in case)	**x**Yes □ No
Others (please describe):	

2.1.12. Is there national cooperation and information exchange between veterinary medicines agency (or equivalent), law enforcement, and other competent authorities?

x Yes □ No

2.1.13. Does your country have regulations regarding corporate liability (legal person liable under conditions) for the offenses related to falsified veterinary medicines?

x Yes □ No

2.1.14. If your country has regulated sanctions for offences related to falsified veterinary medicines, please specify the type (choose all that apply):

Administrative	x
Civil	□
Criminal/penal	x Others (please describe):

2.1.15. Do the following actors have access to regular training in the field of falsified veterinary medicines for (check those that apply)?

Veterinary regulatory Agency	x	Veterinary professional	□
Pharmacists	□	Manufacturers	□
Providers	□	Distributors	□
Police/Enforcement agencies	x	Custom/border control	x
Judges	□	Prosecutors	□
Veterinary/pharmacist Associations	□	Relevant Authorities (politicians)	□
Civil society	□		

Others (please describe):

2.1.16. Does your country have policies or strategies implemented to promote or conduct awareness-raising campaigns targeted at the general public on falsified veterinary medicines?

x Yes □ No

Please share any other consideration, comments or aspects that could be noted for this survey:

TURKEY

T-MEDICRIME(2021)12_Rev_EN

VETERINARY SURVEY

9. INTRODUCTION:

The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter, MEDICRIME Convention) aims to prevent and combat threats to public health. This Convention concerns medical products, including medicinal products and medical devices. Article 4 of the Convention defines as follows: "*the term "medicinal product" shall mean medicines for human and veterinary use… (sic)"*.

Strong efforts have been made in the fight against falsified medicinal products for human use and also falsified medical devices. Efforts remain insufficient in the field of veterinary medicines. Veterinary medicines are needed to treat farm animal diseases (including in fish farming, hunting preys for human consumption and wildlife) as well as domestic pets' pathologies.

Falsified veterinary medicines are a big threat to human health, knowing that animalderivated products are an important part of our food. It is through daily consumption that such veterinary medicine used to cure or prevent an animal disease could enter into the human food chain. Many zoonotic diseases, if not properly treated in the animal origin, can transfer to humans and be a real threat. They can also become resistant to available treatments if the medicine is falsified. The same may happen if the medicines used to treat pets' diseases are falsified, thus putting pet owners at risk. This can also create antimicrobial and antiparasitic resistance.

In 2012, the treatment of *nagana* (a type of animal African trypanosomiasis) using falsified medicines led to the loss of more than 4.500 million dollars. In this light, the FAO (Food and Agriculture Organization of the United Nations) and the IFAH (International Federation for Animal Health) collaborated in the development of the first pharmaceutical protocols to fight against falsified veterinary medicines.

A recent report from the Health for Animals Association (2018) estimates that falsified veterinary medicines (which includes Unregistered/Unlicensed and Falsified) grossed a US$1-2 billion annual market. Both vaccines and pharmaceutical products are affected by the trade in falsified veterinary medicines.

The continuing rapid growth in online buying and selling of products (*e-commerce*) and a parallel growth in international trade especially of small packages has created new opportunities for trade in falsified veterinary medicines.

In conclusion, we must admit that counterfeit, falsified and unregistered products harm animals and decrease food safety and security, while increasing the risk of zoonotics and antimicrobial/antiparasitic resistance.

Considering the foregoing, this survey aims to get a clearer image on the control of falsified veterinary medicines in Parties to the MEDICRIME Convention. It is envisaged as a first approach to the topic, covering the basic elements of potential legal and regulatory practices. No details on judicial interpretation (case-law analysis) or law enforcement practices are therefore required.

The responses to this survey will be compiled and analysed, with a view to drafting a horizontal assessment of the global situation. The latter will identify both threats and needs, making proposals for improvement in line with the MEDICRIME Convention. Parties to the MEDICRIME Convention will be invited to submit observations to the draft of this report before its adoption and publication.

10. SURVEY

We will use in this survey the terms:

- *falsified veterinary medicine* to refer to products that deliberately/fraudulently misrepresent their identity, composition or source, which include: medicines developed to resemble the original ones (unregistered/unlicensed, packaging, labelling, etc.), including vaccines.
- "API" to refer to *active pharmaceutical ingredients.*

Please inform the following:

Name of Country: The Republic of Türkiye

- **Main Government Authority in your country directly involved with veterinary medicines regulation:**General Directorate of Food and Control

- **Main National Administrative body/institution/agency that controls veterinary medicines (evaluation, authorisation, market control, etc.). If more than one, please specify:**Department of Veterinary Medical Products and Public Health

- **Person/s (name, position, address, phone, e-mail) to get in touch with, about this survey:**

  Mustafa BEBEK, Head of the Department
  Üniversiteler Mah. Dumlupınar Bulvarı, No:161, 06800, Çankaya/ANKARA
  Phone: +90 312 258 75 07
  E-mail: mustafa.bebek@tarimorman.gov.tr

  Ömer Faruk BİLGİÇ, Coordinator of the Section
  Üniversiteler Mah. Dumlupınar Bulvarı, No:161, 06800, Çankaya/ANKARA
  Phone: +90 312 258 75 91
  E-mail: omer.bilgic@tarimorman.gov.tr

  Selin YURT, Veterinarian
  Üniversiteler Mah. Dumlupınar Bulvarı, No:161, 06800, Çankaya/ANKARA
  Phone: +90 312 258 75 36
  E-mail: selin.yurt@tarimorman.gov.tr

10.1. Questions:

10.1.1. Does your country have a specific regulation for veterinary use medicines?

X Yes □ No

10.1.2. Do veterinary medicines follow equivalent criteria to medicines for human use (i.e. authorised manufacturers, controlled distributors, need for a veterinary prescription, distribution and/or sales under pharmaceutical control, etc.) in your country?

X Yes □ No

2.1.3. Does your country have specific regulations and/or control the use of bulk API (in food or water for pigs, poultry, fish, etc.) in veterinary medicine?

X Yes □ No

2.1.4. Doesyour country have specific border control (customs control) for veterinary medicines and APIs for veterinary use?

X Yes □ No

2.1.5. Are the offers and sales of veterinary medicines through the Internet regulated in your country (including *e-commerce* platforms)?

□ Yes **X** No

2.1.6 Does your country have any regulation about falsified medicines for veterinary use?

X Yes □ No

2.1.7. Does your country have an effective strategy for the control of falsified veterinary medicines?

X Yes □ No

2.1.8. Doesyour country have an industry-wide/distributors' database of incidents involving falsified veterinary medicines?

□ Yes **X** No

2.1.9. In your experience, which are the main distribution channels/suppliers of veterinary medicines currently existing in your country (rate from 1, less important, to 5, most important; or N/A –not applicable):

Licensed wholesalers	5
Approved physical retailers (pharmacies, merchants)	5
Veterinarians (direct supply from them, if legal in your country)	5
Approved internet retailer/supplier/pharmacy	N/A
Other *e-commerce,* if legal, for veterinary medicines (e.g. eBay, Amazon, Alibaba)	N/A

Unapproved internet pharmacies	N/A
Other unapproved internet sources	N/A
Others (please describe):	
Social media, if legal, for veterinary medicines (e.g. Facebook, Twitter)	N/A
Unapproved physical retailer/ merchants	N/A

2.1.10. Has your country included in their criminal justice regulations any specific subject on falsified veterinary medicines?

X Yes □ No

2.1.11. Is there any regulated and routine control on falsified veterinary medicines and falsified veterinary APIs by:

Customs / Border control authorities at entry ports/airports/terrestrial frontiers alone or in conjunction with other agencies e.g. Interpol/Europol/World Customs Organization, national enforcement or veterinary medicines/pharmaceutical control agencies	**X** Yes □ No
Regulators/Veterinary medicines agency (or equivalent)	**X** Yes □ No
National enforcement officers at destination market	**X** Yes □ No
Approved internet retailer/supplier/pharmacy controllers	□ Yes **X** No
Combined operations, including against falsified websites	**X** Yes □ No
Regulators and enforcement agencies together (federal and state, in case)	**X** Yes □ No
Others (please describe):	

2.1.12. Is there national cooperation and information exchange between veterinary medicines agency (or equivalent), law enforcement, and other competent authorities?

X Yes □ No

2.1.13. Does your country have regulations regarding corporate liability (legal person liable under conditions) for the offenses related to falsified veterinary medicines?

□ Yes **X** No

2.1.14. If your country has regulated sanctionsfor offences related to falsified veterinary medicines, please specify the type (choose all that apply):

Administrative □
Civil □
Criminal/penal **X** Others
(please describe):

2.1.15. Do the following actors have access to regular training in the field of falsified veterinary medicines for (check those that apply)?

Veterinary regulatory Agency	□	Veterinary professional	□
Pharmacists	□	Manufacturers	□
Providers	□	Distributors	□
Police/Enforcement agencies	□	Custom/border control	□
Judges	□	Prosecutors	□
Veterinary/pharmacist Associations	□	Relevant Authorities (politicians)	□
Civil society	□		

Others (please describe):

2.1.16. Does your country have policies or strategies implemented to promote or conduct awareness-raising campaigns targeted at the general public on falsified veterinary medicines?

□ Yes **X** No

Please share any other consideration, comments or aspects that could be noted for this survey:

According to National Legislation of the Republic of Türkiye, offers and sales of veterinary medicines through the internet are banned.

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

T-MEDICRIME(2021)12_Rev_EN

VETERINARY SURVEY

1. INTRODUCTION:

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The continuing rapid growth in online buying and selling of products (*e-commerce*) and a parallel growth in international trade especially of small packages has created new opportunities for trade in falsified veterinary medicines.

In conclusion, we must admit that counterfeit, falsified and unregistered products harm animals and decrease food safety and security, while increasing the risk of zoonotics and antimicrobial/antiparasitic resistance.

Considering the foregoing, this survey aims to get a clearer image on the control of falsified veterinary medicines in Parties to the MEDICRIME Convention. It is envisaged as a first approach to the topic, covering the basic elements of potential legal and regulatory practices. No details on judicial interpretation (case-law analysis) or law enforcement practices are therefore required.

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2. SURVEY

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- "API" to refer to*active pharmaceutical ingredients.*

Please inform the following:

Name of Country: *Ukraine*

- **Main Government Authority in your country directly involved with veterinary medicines regulation:**
  State Service of Ukraine for Food Safety and Consumer Protection (SSUFSCP)
- **Main National Administrative body/institution/agency that controls veterinary medicines (evaluation, authorisation, market control, etc.). If more than one, please specify:**
- *State Scientific Research Control Institute of Veterinary Preparation and Feed Additives (SCIVP) - evaluation, authorisation VMP*
- **Person/s (name, position, address, phone, e-mail) to get in touch with,about this survey:**
  Yuriy Kosenko, Deputy Director SCIVP for international relation,
  11, Donetska str., 79019, Lviv, Ukraine, mob. +380676746887, ykosenko@scivp.lviv.ua

2.1. Questions:

2.1.1. Doesyour country have a specific regulation for veterinary use medicines?

■Yes □ No

2.1.2. Do veterinary medicines follow equivalent criteria to medicines for human use (i.e. authorised manufacturers, controlled distributors, need for a veterinary prescription, distribution and/orsales under pharmaceutical control, etc.) in your country?

■ Yes □ No

2.1.3. Does your country have specific regulations and/or control the use of bulk API (in food or water for pigs, poultry, fish, etc.) in veterinary medicine?

□ Yes ■ No

2.1.4. Doesyour country have specific border control (customs control) for veterinary medicines and APIs for veterinary use?

■ Yes VMP ■ No API

2.1.5. Arethe offers and salesof veterinary medicines through the Internet regulated in your country (including*e-commerce* platforms)?

□ Yes ■ No

2.1.6 Does your country have any regulation about falsified medicines for veterinary use?

□ Yes ■ No

2.1.7.Does your country have an effective strategy for the control of falsified veterinary medicines?

□ Yes ■ No

2.1.8. Doesyour country have an industry-wide/distributors' database of incidents involving falsified veterinary medicines?

□ Yes ■ No

2.1.9.In your experience, which are the main distribution channels/suppliers of veterinary medicines currently existingin your country (rate from 1, less important, to 5, most important; or N/A –not applicable):

Licensed wholesalers	4
Approved physical retailers (pharmacies, merchants)	3
Veterinarians (direct supply from them, if legal in your country)	1
Approved internet retailer/supplier/pharmacy	2
Other *e-commerce,* if legal, for veterinary medicines (e.g. eBay, Amazon, Alibaba)	N/A
Social media, if legal, for veterinary medicines (e.g. Facebook, Twitter)	1
Unapproved physical retailer/ merchants	2
Unapproved internet pharmacies	3

Other unapproved internet sources	3
Others (please describe):	

2.1.10. Has your country included in their criminal justice regulations any specific subject on falsified veterinary medicines?

□ Yes ■ No

2.1.11. Is there any regulated and routine control on falsified veterinary medicines and falsifiedveterinary APIs by:

Customs / Border control authorities at entry ports/airports/terrestrial frontiers alone or in conjunction with other agencies e.g. Interpol/Europol/World Customs Organization, national enforcement or veterinary medicines/pharmaceutical control agencies	■ Yes □ No
Regulators/Veterinary medicines agency (or equivalent)	■ Yes □ No
National enforcement officers at destination market	■ Yes □ No
Approved internet retailer/supplier/pharmacy controllers	□ Yes ■ No
Combined operations, including against falsified websites	□ Yes ■ No
Regulators and enforcement agencies together (federal and state, in case)	■ Yes □ No
Others (please describe):	

2.1.12. Is there national cooperation and information exchange between veterinary medicines agency (or equivalent), law enforcement, and other competent authorities?

■ Yes □ No

2.1.13. Does your country have regulations regarding corporate liability (legal person liable under conditions) for the offenses related tofalsified veterinary medicines?

□ Yes ■ No

2.1.14. If your country has regulated sanctionsfor offences related tofalsified veterinary medicines, please specify thetype (choose all that apply):

Administrative ■
Civil □
Criminal/penal□
Others (please describe):

2.1.15. Do the following actors have access to regular training in the field of falsified veterinary medicines for (check those that apply)?

Veterinary regulatory Agency	□	Veterinary professional	□
Pharmacists	□	Manufacturers	□
Providers	□	Distributors	□
Police/Enforcement agencies	□	Custom/border control	□
Judges	□	Prosecutors	□
Veterinary/pharmacist Associations	□	Relevant Authorities (politicians)	□
Civil society	□		

Others (please describe):

2.1.16. Does your country havepolicies or strategies implemented to promote or conduct awareness-raising campaigns targeted at the general public on falsified veterinary medicines?

□ Yes ■ No

Please share any other consideration, comments or aspects that could be noted for this survey: