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: Croatia

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