

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: 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:

rinary officer Ministry of Agriculture

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2.1.	Questions:	
2.1.1. Doe	s your country have a specific	regulation for veterinary use medicines?
	x □ Yes	□ No
(i.e. autho	orised manufacturers, cont	quivalent criteria to medicines for human use rolled distributors, need for a veterinary under pharmaceutical control, etc.) in your
	x □ Yes	□ No

2.1.3. Does your country have specific regulations and/or control the food or water for pigs, poultry, fish, etc.) in veterinary medicine?	use of bulk API (in
x □ Yes □ No	
2.1.4. Does your country have specific border control (customs commedicines and APIs for veterinary use?	ntrol) for veterinary
x □ Yes □ No	
2.1.5. Are the offers and sales of veterinary medicines through the Ir your country (including <i>e-commerce</i> platforms)?	nternet regulated in
x □ Yes □ No	
2.1.6 Does your country have any regulation about falsified medicuse?	ines for veterinar
x □ Yes □ No	
2.1.7. Does your country have an effective strategy for the control of medicines?	falsified veterinary
□ Yes x□ No	
2.1.8. Does your country have an industry-wide/distributors' data involving falsified veterinary medicines?	abase of incident
□ Yes x□ No	
2.1.9. In your experience, which are the main distribution chaveterinary medicines currently existing in your country (rate from 1, lemost 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 <i>e-commerce,</i> if legal, for veterinary medicines (e.g. eE Amazon, Alibaba)	Bay, 1
Social media, if legal, for veterinary medicines (e.g. Facebook, Twitte	er) 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 subject on falsified veterinary medicines?	ions any specific
x □ Yes □ No	
2.1.11. Is there any regulated and routine control on falsified veterinary APIs by:	ary medicines and
Customs / Border control authorities at entry ports/airports/terrestr	
frontiers alone or in conjunction with other agencies e Interpol/Europol/World Customs Organization, national enforcement veterinary medicines/pharmaceutical control agencies	.g. or □ No
Regulators/Veterinary medicines agency (or equivalent)	x □ Yes
	□ No x □ Yes
National enforcement officers at destination market	
	□ No x □ Yes
Approved internet retailer/supplier/pharmacy controllers	□ No
	x - Yes
Combined operations, including against falsified websites	□ No
Regulators and enforcement agencies together (federal and state, case)	in S No
Others (please describe):	
2.1.12. Is there national cooperation and information exchange be medicines agency (or equivalent), law enforcement, and other compet	
x □ Yes □ No	
2.1.13. Does your country have regulations regarding corporate liable under conditions) for the offenses related to falsified veterinary results.	
x □ Yes □ No	

veterinary medicines, please specify the type (choose all that apply):						
Administrative						
Criminal/penal						
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	S 🗆	Relevant Authorities (politicians)				
Civil society		,				
Others (please describe):						
conduct awareness-raising campain veterinary medicines?	gns targeted e					
x□ Yes		_ N.a				
		□ No				
Please share any other consideration, survey:	comments or a					
-	comments or a					

2.1.14. If your country has regulated sanctions for offences related to falsified