NORTH MACEDONIA

Veterinary Medicines Regulatory System:

Country Snapshot

Presenter: Martin Josheski DVM MSc,

Role and Organisation: WOAH Focal Point,
Food and Veterinary Agency

World Organisation for Animal Health
Founded as OIE

Organisation mondiale de la santé animale
Fondée en tant qu'OIE

Organización Mundial de Sanidad Animal
Fundada como OIE

Mandate and legal basis

- What is the primary legislation governing veterinary medicinal products

Law for veterinary medicinal products („Official Gazette of Republic of Macedonia“ No. 42/10, 136/11, 149/15, 53/16 u 241/18) – in line with the Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

- *the conditions and procedures for approval for placing on the market, production, import, possession, circulation, use and control of veterinary medicinal products*
- *pharmacologically active substances used as raw materials, as well as certain substances that can be used as veterinary medicinal products, and which have anabolic, anti-infective, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties.*
- *premixes for medicated animal feed intended for placing on the market and prepared industrially or by a method involving an industrial process.*

Which authority or body is responsible for each of these?

Activity	Responsible authority	Notes (shared, outsourced, not performed)
Authorisation of veterinary pharmaceuticals	Food and Veterinary Agency	
Authorisation of veterinary biologicals and immunologicals	Food and Veterinary Agency	
Authorisation of ectoparasiticides (veterinary pesticides)	Food and Veterinary Agency	
Authorisation of veterinary medicines for fish	Food and Veterinary Agency	
Pharmacovigilance	Food and Veterinary Agency	
Authorisation and inspection (GDP) of the distribution chain	Food and Veterinary Agency	
Authorisation and inspection (GMP) of the manufacturing site	Food and Veterinary Agency	
Laboratory quality testing	Food and Veterinary Agency	

Who is allowed to manufacture, import, distribute and sell?

- How do you know they are complying?

- *Manufacture (art. 30) - Veterinary medicinal products may be manufactured by legal entities that have an approval for the manufacture of veterinary medicinal products.*

- *Trade in veterinary medicinal products includes import, export, wholesale and retail trade in veterinary medicinal products.*

- Import (art. 43) - The import of veterinary medicinal products is carried out in accordance with customs regulations based on the List of approved veterinary medicinal products.

- Export (art. 30) - Manufacturing approval is also required for veterinary medicinal products intended for export.

- Wholesale (art. 38) - Wholesale trade in veterinary medicinal products includes import, supply, storage, transport, distribution and sale of veterinary medicinal products and may be carried out by a legal entity that has been issued an approval for carrying out the activity of wholesale trade in veterinary medicinal products, issued by the Agency.

- Retail trade (art. 44) - Retail trade includes trade in veterinary medicinal products, i.e. their supply, storage, keeping and dispensing in accordance with this Law and the regulations on veterinary health and may be carried out only by a legal entity that is the holder of an approval for retail trade in veterinary medicinal products (hereinafter referred to as: veterinary pharmacy), issued by the Agency and a legal entity that is the holder of an approval for performing veterinary health activities (hereinafter referred to as: veterinary company), in accordance with the Law on Veterinary Health.

How are veterinary medicines classified for supply?

- Prescription and non-prescription products.
- Can a farmer or a cat owner buy an antimicrobial without a veterinary prescription? **NO ! ! !**

Veterinary medicinal products, according to their properties and the method of dispensing and application, and especially for the purpose of protecting human health, animal health and environmental protection, are classified into:

a) veterinary medicinal products in free circulation;

b) veterinary medicinal products that are dispensed in a veterinary pharmacy without a prescription;

c) veterinary medicinal products that are dispensed in a veterinary pharmacy only on prescription;

d) veterinary medicinal products that are used only in veterinary companies;

e) veterinary medicinal products that can be used only by doctors of veterinary medicine and

f) veterinary medicinal products with a special method of distribution and use.

How do you learn that a product already in use is substandard, falsified or unsafe?

Falsified VMP

- A counterfeit (falsified) veterinary medicinal product is produced, manufactured, placed on the market and used with the aim of deceiving persons who use it or in any way come into contact with the veterinary medicinal product (trade and use), i.e. are owners or persons responsible for the animals on which the product is used.

Misrepresentation of a product

- *It is prohibited to place on the market a product that in any way is presented with properties for treating or preventing diseases in animals, unless it is considered a veterinary medicinal product in accordance with the provisions of law for VMP.*

- *The Agency conducts **official controls** to identify counterfeit (falsified) veterinary medicinal products and pharmacological substances.*

When did you last remove a product from the market?

- How did you know it needed to be removed?
- Information regarding serios GMP non – compliance at a manufacturer

- What actions did you take?
- As GMP was withdrawn, recall of batches already released

- How did you confirm that it had actually gone?

- Extraordinary inspection, recall and withdrawal of batches placed on the market

If you could change anything, what would it be and why?

- What is stopping you?

- New Law for veterinary – medicinal products in line with the Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products – in Government procedure more then 2 years ….
- Adoption of by – laws that will additional regulate some questions regarding VMP authorization, production and trade

GUIDANCE | DELETE THIS BOX BEFORE YOU PRESENT

- *One change, not a list. Be specific enough that someone could picture it happening.*
- *Be specific about the obstacle too. Money, legal authority, staff numbers, skills, political attention, or something else*

Thank you

12, rue de Prony, 75017 Paris, France
T. +33 (0)1 44 15 19 49
F. +33 (0)1 42 67 09 87

woah@woah.org
www.woah.org

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