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USE OF VETERINARY MEDICINAL PRODUCTS OUTSIDE THE CONDITIONS OF THE MARKETING AUTHORIZATION

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Abstract: *The use of a product outside the SPC (Summary of Product Characteristics) is sometimes a necessity and an act of great responsibility on the part of the veterinarian. However, this practice must not become a habit and must be applied only in accordance with the approved European legislation.*

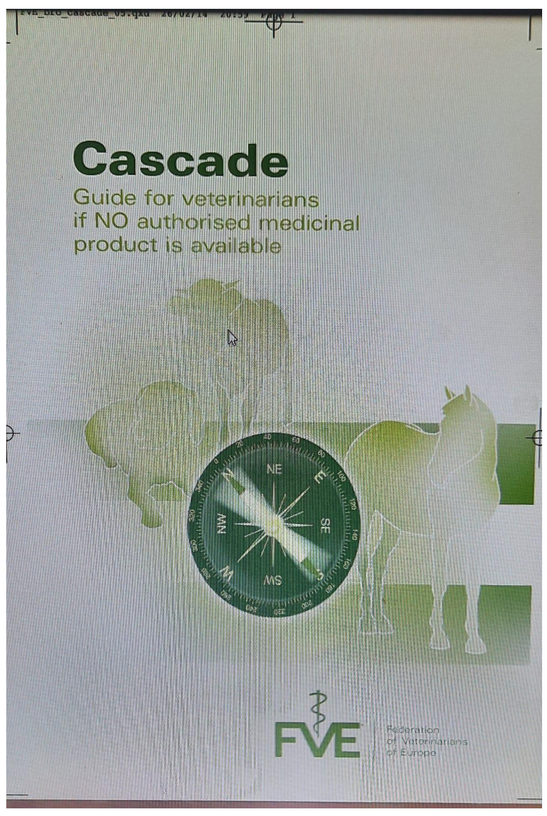
• Introduction

Unfortunately, the active substances authorised for use in animals are sometimes insufficient.
In situations like this, the judgment of the veterinarian, but also the legislation in force are the two essential elements that help us choose the best solution.

• Material and method

The study discussed the results of the analysis of the relevant documents:

- The list of veterinary medicinal products approved in some EU countries (France, Italy);
- The list of veterinary medicinal products approved in UK;
- The list of veterinary medicinal products authorized through the centralized procedure;
- The 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 force since January 2022);
- Cascade Guide for veterinarians if NO authorised medicinal product is available- brochures elaborated by FVE;
- Examination of table 1 of Commission Regulation (EU) No 37/2010 c



• Results and discussions

Authorised veterinary medicinal products (VMP) used to treat cancer, VMP for the treatment of exotic animals, for MUMS (Minor Use, Minor Species) and other categories of VMP are insufficient. In situations like this, we must use other alternatives in accordance with Regulation (Eu) 2019/6:

- Article 112 and Use of medicinal products outside the terms of the marketing authorization in non-food-producing animals species
- Article 113 Use of medicinal products outside the terms of the marketing authorization in food-producing terrestrial animals species of the Regulation.

These articles clearly stipulate the situations when, “By way of derogation…., where there is no authorised veterinary medicinal product in a Member State ……, the veterinarian responsible may, under his or her direct personal responsibility, and in particular to avoid causing unacceptable suffering, exceptionally treat the animals concerned with…..” "borrowed" products.

• Conclusions

After analyzing the available data, we can conclude that:

- It is a shortage of veterinary medicinal products in the case of certain species or diseases.
- The extrapolation of the use of VMP from one indication to another, from one species to another must be done with great care, staying within the lines of the Regulation (Eu) 2019/6, and only when we need to prevent the unnecessary suffering of our patients.