EAZA/EAZWV Position Statement on the application of the Veterinary Medicines Cascade in relation to zoological species

Approved by EAZA Council and EAZWV
26 April 2023

Introduction:

This Position Statement has been developed jointly between the European Association of Zoos and Aquaria (EAZA) and the European Association of Zoo and Wildlife Veterinarians (EAZWV).

The Veterinary Medicines Cascade (herein called the Cascade) is an essential component of zoological medicine i.e., the provision of veterinary medicine to non-domestic species. Licenced zoos and aquariums in the European Union have a legal mandate to provide the animals under their care with '*a developed programme of curative and preventative veterinary medicine*' as mandated by Article 3 of the EU Zoos Directive (Council Directive 1999/22/EC). Additionally, Part 9 of Annex I of EU Regulation 2019/2035, a Delegated act supplementing the EU Animal Health Law, requires confined establishments to undertake '*the vaccination and treatment of susceptible kept terrestrial animals against transmissible diseases*'. Application of the Cascade and access to a range of veterinary medicinal products remains essential for these institutions to be able to fulfil these legal obligations.

Some 9,830 different animal species are kept and maintained currently by EAZA Members. Ensuring that the health and welfare needs of these individuals and species are met relies on the ability to prescribe and administer non-authorised veterinary medicines in these non-food producing animals, utilising the previous experience, available scientific evidence, and clinical autonomy and judgement of the prescribing veterinarian. Article 8(a)(iii) of the EU Animal By-products Regulation (Regulation (EC) No 1069/2009), classifies zoo animals as Category 1 material ensuring that they will never enter the human food chain.

Relevant EU Legislation:

The Cascade is laid down in Article 112 of EU Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6):

Article 112

Use of medicinal products outside the terms of the marketing authorisation in non-food-producing animal species

1. By way of derogation from Article 106(1), where there is no authorised veterinary medicinal product in a Member State for an indication concerning a non-food-producing animal species, 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 the following medicinal product:
   (a) veterinary medicinal product authorised under this Regulation in the relevant Member State or in another Member State for use in the same species or another animal species for the same indication or for another indication;
   (b) if there is no veterinary medicinal product as referred to in point (a) of this paragraph, a medicinal product for human use authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004;
   (c) if there is no medicinal product as referred to in point (a) or (b) of this paragraph, a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription.
2. Except as regards immunological veterinary medicinal products, where there is no medicinal product available as referred to in paragraph 1, the veterinarian responsible may under his or her direct responsibility and in particular to avoid causing unacceptable suffering exceptionally treat a non-food-producing animal with a veterinary medicinal product authorised in a third country for the same animal species and same indication.
3. The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility, in accordance with national provisions.
4. This Article shall also apply to the treatment by a veterinarian of an animal of the equine species provided that it is declared as not being intended for slaughter for human consumption in the single lifetime identification document referred to in Article 8(4).
5. This Article shall apply also when an authorised veterinary medicinal product is not available in the relevant Member State.

EAZA/EAZWV Recommendations:

In reference to the above Article, EAZA and EAZWV advocate the following recommendations to ensure the health and welfare of the animals under our respective Members' care can be met using the Cascade:

i. That a pragmatic view is taken towards the phrase 'exceptionally treat the animals concerned' contained in point 1 of the above Article. Given the diversity of species held within EU zoos and aquariums, it is unrealistic, and impractical (both from an ethical and financial standpoint) to expect market authorisations for all of the veterinary medicines currently used in these species. Zoo animals require access to pharmaceuticals and given the limited number of veterinary medicinal products

authorised for use in non-domestic species, so-called exceptional treatment must be considered routine in zoological medicine.

ii. That the burden of responsibility in using the Cascade be placed upon the prescribing veterinarian. In each prescribing circumstance, the responsible veterinarian undertakes the necessary due diligence and understands the legal and professional responsibilities associated with clinical decision making under the Cascade, alongside the potential consequences of inappropriate use.

iii. That all available scientific evidence be reviewed by the prescribing veterinarian ahead of prescribing and administering a non-authorised veterinary medicinal product in a non-food producing species in an EU zoo or aquarium. Such resources may include, but are not limited to: scientific articles, veterinary formularies, previous clinical experience, and expert consultation (e.g., EAZA Reproductive Management Group, EAZA/EAZWV Infectious Diseases Working Group, Veterinary Advisors to EAZA Taxon Advisory Groups (TAGs) and EAZA Ex situ Programmes (EEPs)).

iv. That appropriate records are maintained relating to the prescription of non-authorised veterinary medicinal products in non-food producing species kept in EU zoos and aquariums. These records may be subject to audits by the relevant Member State competent authority through the requirements of Article 123 of Regulation 2019/6 or any additional national requirements as per point 11 of Article 105 of the same Regulation. Member State competent authorities undertaking these audits and controls should perform these fully understanding and respecting point (i) of this Position Statement.

About the Organisations:

EAZA, the European Association of Zoos and Aquaria, is a non-profit association who represents and links over 400 Member institutions in 48 countries (of which 25 are EU Member States). EAZA's mission is to facilitate cooperation across the European zoo and aquarium community towards the goals of education, research and biodiversity conservation through maintaining healthy populations of animals in human care to ensure their long-term survival.

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EAZWV, the European Association of Zoo and Wildlife Veterinarians, is the professional association representing over 500 individual zoo and wildlife vets throughout Europe, as well as 10 regional/national sections with a collective membership of over 1000. EAZWV is committed to promoting the advancement and dissemination of veterinary knowledge and skill in the field of zoo and wild animal management and in so doing advancing the health, welfare, husbandry and conservation of wild animals.

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