FEDERATION OF VETERINARIANS OF EUROPE

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Regulation on Veterinary Medicinal Products

FVE agrees with the text proposed by the Commission about the use of medicines in the absence of authorised products.

FVE calls upon legislators to agree with the text as proposed by the Commission about the use of medicines in the absence of authorised products. A re-introduction of different, consecutive steps that have to be followed (the so-called '*cascade*' system) might easily lead to serious practical difficulties, in particular with regard to the timely availability of the required medicines.

In the absence of veterinary medicinal products authorised in a country for the relevant animal species and indications for use, the licensed veterinarian carrying out their professional responsibility, for safe guarding animal health and welfare, should have the opportunity to make a professionally justified choice out of other suitable veterinary medicinal products, authorised either in their own country or in another EU country.

FVE also recommends replacing the wording "*unacceptable suffering*" by "*in the interest of animal health, welfare and public health"* in art 115 and 116.

The **European Commission's proposal** for a regulation on veterinary medicinal products recognises the lack of authorised veterinary medicines for certain species or indications in EU countries. It gives veterinarians the possibility to use other products through the so called "*cascade"* (art 115-118). The proposal states that the veterinarian who has no authorised veterinary medicinal product to treat the animal under his care, may under his/her direct personal responsibility **select the best option for treatment** from the following:

a) a medicinal product authorised for use in another animal species, or for another condition in the same species;
b) a veterinary medicinal product authorised under this Regulation in another Member State for use in the same species or in another species, for the same condition or for another condition;
c) a medicinal product for human use authorised in the Member State concerned in accordance with Directive 2001/83/EC of the European Parliament and of the Council.

The possibility under b) to use "*a veterinary medicinal product authorised under this Regulation in another Member State for use in the same species, for the same condition*" is from a technical point of view the most preferable option, as these products have been specifically developed and tested for the dedicated animal species or clinical indication. For this reason, it is sometimes argued to place this possibility before other options of the "*cascade system*".

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However, from a practical point of view, it is often not the most preferable option due to the difficulties in obtaining the veterinary medical product in a timely manner. Experience collated over the years from the field teaches us that this option doesn't take **the factors of time and accessibility** into consideration. The importation of veterinary medicinal products from other Member States can be very time consuming, time that is not available when animals are seriously ill.

In the interest of animal health and welfare and public health, FVE calls upon legislators **to accept the proposal from the Commission and not to (re-)introduce different consecutive steps known as the '*cascade*'.**

FVE also recommends replacing the wording "*unacceptable suffering*" by "***in the interest of animal health, welfare and public health***" in art 115 and 116. The reason is that the term "*unacceptable suffering"* is very difficult to interpret and that off-label use should also be allowed for preventative use (*e.g.* using vaccines) and for "*responsible use"* reasons (*e.g.* using a narrow spectrum antibiotic for the specific infection when the causative organism is known, if only a critically important antimicrobial (CIA) for human use antibiotic is available).