



GAP PRODUCTS FOR MINOR USES MINOR SPECIES

What is FVE?

FVE is the umbrella body for veterinary organisations from more than 30 European countries, including all EU and EFTA countries and most of the Eastern and Central European countries. FVE represents and promotes approximately 175,000 veterinarians throughout Europe.

Members

Austria
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FVE includes four specialised groups, each representing a specific branch of the profession.

- Practising Veterinarians (UEVP)
- Hygienists and Public Health Veterinarians (UEVH)
- State Veterinary Officers (EASVO)
- Veterinarians in Industry and Research (FEVIR)

Within the FVE there is an ad hoc group on Medicines that is comprised of veterinarians from several European countries.

Introduction

The FVE welcomes the proposal of the European Commission to modify the Directive, and in particular the provisions to address the availability problem. But, for some species and some uses, now referred to as MUMS, this proposal is not enough and leaves the practitioners facing situations and conditions where few or no products are licensed. Therefore practitioners remain caught between their obligation of treating animals under their care and the decreasing veterinary therapeutic arsenal. This situation is mainly due to the evolution of the terms of the marketing authorisations, and the lack of return on the investment for pharmaceutical companies.

Specific Proposal

The objective of the FVE is to have for the practitioners, legally available and useable a full range of veterinary medicinal products for the prevention, the diagnosis and treatment of all diseases in all animal species in respect of the animal health and welfare and the consumer safety.

Looking to the future, it should be clear that the first priority should be given to diseases which could be treated 2 years ago, and cannot be treated any more. Diseases on the other hand that have never had any treatment could be given lower priority.

The FVE is aware that the previous list of “gap products” was unfortunately far too long, - which proves however the importance of the MUMS problem-, and impractical and has therefore produced a short list of priority products, which you will find underneath. It should be clear that this is no exhaustive enumeration of gap products, but merely a first priority list of minor uses minor species medicines availability problems. This list could be the basis of future actions compatible with the proposals in the CVMP position paper.

Sections

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FVE PRIORITY LIST OF “GAP PRODUCTS” IN MUMS POLICY

Species	Condition	Product	Family
Turkeys	Histomoniasis	Nitarsons	
Rabbits	Scabies	E.g. Ivermectine	Antiparasitica
Rabbits	Enterocolitis	E.g. bacitracine, tiamuline	Antibiotics
Horses	Small surgery e.g. wound stitching – local anesthesia	E.g. Lidocaine ¹	Local anesthetics
Goats/Sheep	Coccidiosis	E.g. Baycox (toltrazuril)	Coccidiostatics
Goats/Sheep	Nematode infection fascioliasis	E.g. Oxyclozanide ² , levamisole, pyrantel, eprinomectine, Ivomectine, Triclabendazol, ...	Anthelmintic
Goats/Sheep	Ectoparasites	E.g. Amitraz ³	Insecticide
Goats	Mastitis	E.g. Cloxacilline, nafcilline, cefazoline and spiramycine	Intra-mammaire antibiotics
Pigs	Anaesthetics	E.g; combinations ACP (acepromazine), ketamine, xylazine and lidocaine (local anaest.)	Anaesthetics
Bees	Nosemosis	E.g. fumagillin	Antiprotozoa
Fish	Proliferative kidney disease in Salmon	E.g. fumagillin	Antiprotozoa
Fish	Surgery	E.g. MS222 (tricaine methane sulphonate) UK to BE	Anaesthetics
Bees	American Foulbrood	? Oxytetracycline	Antibiotica

¹ <http://www.emea.eu.int/pdfs/vet/mrls/058499en.pdf>

² <http://www.emea.eu.int/pdfs/vet/mrls/081702en.pdf> and [EMEA/CVMP/1129/03](http://www.emea.eu.int/pdfs/vet/mrls/033097en.pdf) extrapolation of MRL to all ruminants including milk

³ <http://www.emea.eu.int/pdfs/vet/mrls/033097en.pdf> and <http://www.emea.eu.int/pdfs/vet/mrls/Amitraz2.pdf>