

Questions and Answers from Member States

**Ectoparasiticial products for use in
"animals for consumption" and "pet animals" respectively**

Adopted	Status
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"animals for consumption" and "pet animals" respectively**

MS	Is infestation with lice, fleas, mosquitos etc. considered a disease?	Argumentation in favour of considering infestations with ectoparasites a disease	Is use in "pet animals" considered equal to use in "animals for consumption"? If not – the reasons/argumentation to be stated	Is there a possibility for a company to chose whether to apply for authorisation of these products as biocides and veterinary medicinal product's respectively – depending on the claim(s) made?
AT	Yes	Definition according to the National legislation (Austrian Drug Act) and Directive 2001/82 as amended by 2004/28 and Directive 98/8	Yes –	Yes – Products without medicinal claim are classified as pesticides. Products for treatment and prevention are classified as medicinal products
BE	Yes – in case of scabies No – in case of lice and fleas	Product to be used on the animal to keep away / repress parasites, without a deadly effect are considered biocides. These product cannot have therapeutical indications. All other ectoparasitidal products are considered VMP's.	Yes – no distinction mentioned	Yes – Not only depending on the claims made but also depending the nature (pharmacological group) of the active substance and the method of administration. In the future, the status of the product will depend on the implementation of the Biocide Directive.
BG				
CS	Yes	These infestations will cause a disease in the animal and therefore we consider that any products which act as ectoparasiticides are being applied for the purpose of preventing disease. It is important to differentiate between products which kill the parasites and products, which act solely as repellents.	Yes	Yes Products for prevention and treatment are classified as medicinal products. Repellents are classified as biocides.
CY	Yes	These products are applied to eliminate ectoparasites or to prevent the infestation. This is for us clearly a therapeutical claim.	Yes	No – If applied to the animal, a vet product authorisation is necessary. If applied to the environment, separate pesticide legislation applies.

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DE	Yes	These products are applied to eliminate ectoparasites or to prevent the infestation. This is for us clearly a therapeutical claim. These products could lead to residues which can be a danger for human consumption and a withdrawal period needs to be established.	Yes	No
DE				
DK	No , not in general. It is decided on a case by case basis. See also columns 3 and 5	In order to be considered a veterinary medicinal product the claim made has to be in accordance with the Danish legislation on medicinal products, i.e. the product in question has to be administered to the animal (orally, parenterally, by absorption through the skin etc.) in order to prevent, diagnose, alleviate, treat or cure disease, symptoms of disease and pain, or to affect body functions.	Yes	Yes – But as a rule the companies seem to prefer an authorisation as a pesticide for products containing active substances not being absorbed while they usually apply for a marketing authorisation as a veterinary medicinal product when the active substance is being absorbed. Products being administered by the parenteral route have to be applied for as veterinary medicinal products.
EL	Yes	These products are applied to eliminate ectoparasites or to prevent the infestation. This is a therapeutical claim.	Yes	No If the product is administered directly to the animal (oral, topically, etc.) it is considered a veterinary medicinal product. By contrary, if the product is used in the housing of the animal (walls, floor, etc.) it is considered as veterinary pesticide.
ES	Yes	Ectoparasites cause irritation, weakness, decrease in the production, suck blood, are vector for other parasites...	Yes – no distinction mentioned	No – If the product is administered directly to the animal (oral, topically, etc.) it is considered a veterinary medicinal product.

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EE	No		Yes	Yes – it depends on the claims and the active substances.
FI	Yes Any ectoparasite which attacks/sucks blood/lives on the skin/fur needs to be killed as treatment. Therefore, product is classified as vet.med. product. Insecticidal repellents are classified as pesticides (not vet.med. products).		Yes - Classification is same for all animal species	Yes – Sometimes it is very difficult to classify if product is used for preventive treatment or if the use is to repell. Hopefully biosidicide directive – when it is ready – will make classifications easier.
FR	Yes	These products are applied to eliminate ectoparasites or to prevent the infestation. This is for us clearly a therapeutic claim. These products could lead to residues which can be a danger for human consumption and a withdrawal period needs to be established.	Yes - In France the situation is the same, products administered to the animals are considered as veterinary medicinal products.	No – There is no other possibility in France than to apply for a marketing authorisation if the product is administered to the animal.
HU	Yes	Prevention and treatment should be considered as therapeutic claim. If the disinfectant has and/or demonstrated claim of medicinal effects it should be classified as a medicinal product.	Yes – no distinction mentioned	No -If the product can be used on the animals-VMP, if intended to apply in their environment should be considered as the biocide.
IE	Yes	Directive 81/851/EEC & 65/65/EEC	Yes – No distinction mentioned	No – If applied to the animal, a vet product authorisation is necessary. If applied to the environment, separate pesticide legislation applies.
IS	Yes	These infestation either are or can	Yes	No - If applied to the animal and

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	Parasitic repellants are not classified as veterinary medicinal products.	cause a disease. The use of the ectoparasiticidal product is therefore to prevent or cure a disease.	However, in special cases, such products for pet animals can be classified as biocides.	intended to kill the parasite, it is a veterinary medicinal product. However, in special cases, such products for pet animals can be classified as biocides.
IT	Yes	These products are applied to eliminate ectoparasites or to prevent the infestation. This is for us clearly a therapeutic claim.	Yes – In Italy the situation is the same; products administered to the animals are considered as veterinary medicinal products.	No – There is no other possibility in Italy than to apply for a marketing authorisation if the product is administered to the animal.
LT				
LU	Yes	Infestation with <u>endoparasites</u> is a disease with no doubt. Legal definition of medicine (65/65/EEC) is not excluding products applied externally.	Yes – no distinction mentioned	No – Medicine by composition. Some years ago (before an Agency was created) CMV stated these products were to be considered as medicines.
LV	Yes	Infestation with parasites cause the parasitic diseases.	Yes	Yes, but mostly it is decided on case by case basis depending on claim, qualitative and quantitative composition and method of administration.
MT				
NL	Yes, in case it is accompanied by a therapeutic claim	Infestations with parasites can cause irritation (itching, skinlesions etc.) and a general weakening of the animal. A pharmaceutical product (a "substance") used to prevent or diminish such an infestation improves the functioning of the animal or its organs (skin for example). In fact, a substance used to prevent irritation or weakening of the animal by killing parasites is considered in general in the same way as a substance used to prevent illness by killing micro-organisms.	Yes – no distinction mentioned	Yes -to a certain extent. Classification depends on the intended use and/or demonstrated claim. See the Manual of Decisions on the EC-website (europa/environment/biocides).
NO	Yes	Legislation, therapeutic claim	Yes	No — If applied to the animal, a vet

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				product authorisation is necessary.
PL	Yes 1.Product which contain repellents for example collars, neckties, ears marks, without any lethal effect- biocidal products 2.Products with lethal effect- veterinary medicinal products	Manual of Decisions for Implementation of Directive 98/8/EC concerning the placing on the market of biocidal products	Yes - Classification is the same for all animal species	Yes – Manual of Decisions for Implementation of Directive 98/8/EC concerning the placing on the market of biocidal products
PT	No		Yes – no distinction mentioned	No
RO	Yes	Infestations will cause a disease in the animal and these products are applied to eliminate ectoparasites or to prevent the infestation.	Yes There is in principal no difference between farm animals and companion animals	No - If the product is used on the animal it is a veterinary medicinal product. If a product is used to treat the environ-ment (the animal not being present at the time of the treatment) , it has to be authorised as a pesticide.
SE	Initially, the MPA has to clarify that it is difficult to give an unambiguous answer on the question, one have to study each case separate. In principal the MPA is of the opinion that infestations relating from lice, fleas and ticks are diseases. Infestations occurring from mosquitoes may in some cases be listed as a disease.	European pharmaceutical legislation has been implemented in the Swedish Medicinal Products Act (1992:859). The Act regulates what is to be a medicinal product. The definition harmonises with the definition in directive 65/65/EEC and its definition. To identify what is to be a medicinal product one must investigate the range of the term "animals". For animals used for consumption one can state that they are embraced by the term in the legal context.	Yes - There is in principal no difference between farm animals and companion animals. Due to the term "animals" some products intended for animals which fall outside of the legal context of the term "animals" in the Medicinal Products Act are not medicinal products.	Yes - The term medicinal product is constructed by several prerequisites. The intention of the seller/marketing authorisation holder (MAH) is one of the prerequisites that have to be fulfilled. For clarifying the intention of the MAH one may investigate the claims stated on the package. Therefore, depending on what claims to be made the applicant for a marketing authorisation may – to a certain extent – alter the classification of the product.
SI	Yes – in case of scabies No – in case of lice, fleas, mosquitoes etc.		Yes	Yes –depending on claims, route of application etc.
SK	Yes	These products are applied to eliminate	Yes	Yes - If the product is administered

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		<p>ectoparasites or to prevent the infestation. This is for us clearly a therapeutical claim.</p> <p>These products could lead to residues which can be a danger for human consumption and a withdrawal period needs to be established.</p>		<p>directly to the animal (oral, topically, etc.) it is considered a veterinary medicinal product.</p> <p>By contrary, if the product is used in the housing of the animal (walls, floor, etc.) it is considered as biocide.</p>
UK	Yes	<p>In general, these infestations will cause a disease in the animal and therefore we consider that any products which act as ectoparasiticides are being applied for the purpose of preventing disease.</p> <p>It is important to differentiate between products which kill the parasites and products, which act solely as repellents. As stated above, those which kill the parasites on the animal are medicines but those which simply prevent the parasite from making contact with the animal are repellent and are not considered medicinal.</p>	Yes	No