

**Questions and Answers from Member States**  
**VMP intended for rabbits kept exclusively as pets**

<b>Adopted</b>	<b>Status</b>
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**BACKGROUND:**

**From April 2008 minutes**

**B.10 VMP intended for rabbits kept exclusively as pets**

In the context of article 4.2 of Directive 2001/82 as amended, FR asked whether it is possible in each member state to add rabbits exclusively as pets (i.e.: non food) through an extension to an existing Marketing Authorisation.

Some MS indicated they would accept such an application but others held the view that rabbits are a food producing species and therefore require the active substance to be in annex I; II or III of the MRL regulation.

This document presents an overview of the national rules.

Authority (MS)	Opinion	Comments
AUSTRIA		
BELGIUM	Extension not acceptable	Rabbits are a food producing species and therefore require the active substance to be in annex I; II or III of the MRL regulation.
BULGARIA		
CYPRUS	Extension not acceptable	Rabbits are considered as food producing species so the active substance has to be included in annex I; II or III of the MRL regulation.
CZECH REPUBLIC	We prefer not to add rabbits exclusively as pets through an extension to an existing product.	<p>From the point of assessment of immunological products we prefer:</p> <ul style="list-style-type: none"> <li>- not exclude rabbits as PETs animals</li> <li>- not have special requirements regarding assessment and testing as a special category of the animal</li> </ul> <p>From the point of assessment of pharmaceuticals it seems to us to be necessary to provide:</p> <ul style="list-style-type: none"> <li>- more clear legislative links regarding the definition of the new non-food producing animal (eg. some measures as passports in non-food producing horses)</li> <li>- especially ensure the safety of potential consumer</li> </ul> <p>There have already been rabbits as PETs on the market with the PETs animals in the Czech Republic, but most predominant is the category of rabbits as food producing animals. Therefore it seems to us, that rabbit should be considered especially from the view of consumer safety and the opinion not exclude rabbit as PETs in a special non-food producing category is preferred.</p>
DENMARK	Extension not acceptable	
ESTONIA	Extension not acceptable	

FINLAND	Extension not acceptable	
FRANCE	Extension is acceptable	Article 4.2 of amended directive 2001/82 has been implemented as "abridged" marketing authorisation application.
GERMANY Immunologicals	Extension is acceptable	
GERMANY Pharmaceuticals	Pet rabbits are accepted on condition that the product will be classified for marketing outside of pharmacies.	See section 60 of the German Drug law
GREECE	Extension not acceptable	Our national Law Decree which applies for veterinary medicinal products excludes rabbits kept exclusively as pets (small rodents). This kind of products for rabbits kept exclusively as pets are evaluated under another legislative provision
HUNGARY	Extension is acceptable	
ICELAND	Extension is acceptable	
IRELAND	Extension is acceptable	
ITALY	Pet rabbits are accepted. There should be no problem acting as CMS for the intended application.	In Italy an application intended for pet rabbits can follow a simplified procedure whose minimum criteria are set by a national guidance
LATVIA	We would accept application for extension for rabbits as pets.	There should be added information that this product is for rabbit not intended for food consumption.
LITHUANIA	Extension is acceptable	The information, that product is intended for non food producing rabbits (pet animal) should be introduced in the marketing authorisation and SPC, PIL and label.
LUXEMBOURG		
MALTA		
NETHERLANDS	An application (or variation) for a product to be used in rabbits kept exclusively as pets can not be accepted in NL. This is conform our national legislation, in which article 4(2) of the Directive 2001/82/EC as amended is implemented. Diergeneesmiddelenbesluit, article 19.	The applicant/MAH however is allowed to add pet rabbits to the label and package leaflet.
NORWAY	Extension is acceptable	
POLAND	In Poland rabbits are consider as food-producing animal or as pet so it is possible to add rabbits exclusively as pets through an extension to an existing product.	There should be information added that this product is not to use for rabbit intended for food consumption

PORTUGAL	Extension not acceptable Pharmaceuticals: Our national Law Decree 184/97 which applies for veterinary medicinal products excludes rabbits kept exclusively as pets (small rodents). This kind of products for rabbits kept exclusively as pets are evaluated under another legislative provision (Law Decree 232/99)	Pharmaceuticals: In Portugal we have a national decree (Law Decree 232/99) applicable to "products for veterinary use" which includes products for rabbits kept exclusively as pets.
ROMANIA	Extension not acceptable	Rabbits in RO are predominant in the category of rabbits as food product in animals, and for that reason, the substances need to be included in annex for LMR.
SLOVAK REPUBLIC	Extension is acceptable.	The information, that product is intended for non food producing rabbits (pet animal) should be introduced in the marketing authorisation and SPC, PIL and label.
SLOVENIA		
SPAIN	In Spain rabbit is considered as food-producing animal so this extension, only for rabbit as pet, is not possible	Rabbits kept exclusively as pets can be accepted if the products do not contain substances the use of which requires veterinary control and that all possible measures are taken to prevent unauthorized use of the products for other animals as stated in art 4.2 of the Directive 2004/28
SWEDEN	MPA "would <u>not</u> be prepared to authorise a product for rabbits kept exclusively as pets without the establishment of an MRL, as in Sweden the rabbit is considered to be a food producing animal only."	Since article 4.2 of Directive 2001/82 as amended, has yet not been implemented, there is no legal base for exemptions.
UK	On a case by case basis we may accept an application for rabbits contra-indicated for human consumption providing that in doing so consumer safety is still protected.	The UK has implemented Article 4 (2) of Directive 2001/82, as amended by 2004/28, into national law. This allows certain products to be marketed without the need for a marketing authorisation providing that the substances contained within these products do not require veterinary control.