

**Questions and Answers from Member States**

**Authorisation of ectoparasiticide collars for companion animals**

<b>Adopted</b>	<b>Status</b>
London, March 2008	Public

## AUTHORISATION OF ECTOPARASITICIDAL COLLARS FOR COMPANION ANIMALS

MS	Do you authorise?	If no, how?	Under 81/851?	If not, what?	Which agency. If not you, then who?
Column No.	1	2	3	4	5
AT	Yes - Products with a claim (treatment or prevention or prophylaxis of a disease) are considered to be a VMP. .		Yes		AGES PharmMed Schnirchgasse 9 1030 Wien  <u>Tel. ++43-50555-36670</u> <u>Mail: abgrenzung@ages.at</u>
BE	Yes 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 ectoparasiticial products are considered VMP's.		See column 4	1. Considered as a VMP if used for therapeutic purposes (pediculosis) - 81/851 2. As a pesticide for non agricultural use for the purpose of eliminating ectoparasiticides. In this case it can be sold without prescription in department stores after authorisation by the Minister of Health on advice of the Higher Council of Hygiene.	If classified as VMP:  Veterinary Unit Federal Agency for Medicines and Health Products Place Victor Horta 40, box 40 1060 Brussels Belgium  <u>Contact: Dries Minne</u> <u>Tel: 0032 2 524 81 27</u> <u>Fax: 0032 2 524 81 36</u>  If classified as biocides:  Federal Public Service for Public Health, Food Chain Safety and the Environment Place Victor Horta 40, box 10 1060 Brussels  <u>Contact : Mr. Marc Leemans</u> <u>Tel:0032 2 524 95 75</u> <u>Fax:0032 2 524 95 27</u>
BG					
CS	Yes		Yes		Institute for State Control of Veterinary Biologicals and Medicaments, Hudcova 56a, Brno-Medlánky Postal Code: 621 00, Czech Republic  (Same department)
CY	Yes		Yes		Council of Veterinary Medicinal Products
DE	Yes		Yes		BVL (Same)
DE					
DK	Not as VMPs - see column 4. As a pesticide – Yes	For information please contact the agency (Column 5).	Refer to the Agency in column 5	A. Pesticides regulation is used. B. For information please contact the agency under column 5.	Danish Environmental Protection Agency The Pesticide Division Strandgade 29

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					DK - 1401 Copenhagen  <u>Contact: Nina Herskin</u>  <u>Tel: 00 45 3266 0100</u> <u>Fax: 00 45 3266 0479</u>
EL	Yes		Yes		National Organisation for Medicines (EOF) Veterinary Section <u>Tel: 30 210 6507277</u> <u>Fax: 30 1 65 37 591</u>
ES	Yes		Yes		AEMPS
EE	Yes		Yes		State Agency of Medicines
FI	Yes*	*Collars containing herbal extracts and used to repel ticks, insects or ectoparasiticides are not classified as VM or pesticides. They do not need any authorisation.	Yes		If classified as VM - National Agency for Medicines.  If classified as pesticide: KTTK (Plant Protection Centre) = case in which collar is used to repel ticks, mosquitoes and insects.
FR	Yes		Yes		French Veterinary Agency (Same)
HU	Yes		Yes		Central Agriculture Office, Directorate of Veterinary Medicinal Products (Same)
IE	Yes		Yes		IMB (Same)
IS	Yes				Lyfjastofnun (same)  In special cases, such products can be classified as biocides. If so, the responsible agency is: Umhverfisstofnun Suðurlandsbraut 24 IS-108 Reykjavik Iceland
IT	Yes		Yes, since March 1997 when Dir. 93/40/CEE has been implemented, Before March 1997 ectoparasiticide collars were authorised by Ministry of Health as Medical Surgical Devices, according national laws.		Ministry of Health Veterinary Department Piazzale Marconi 25 00144 Rome Italy  <u>tel: 00 39 6 59 94 35 84</u> <u>Fax: 00 39 6 59 94 36 76</u>
LT					
LU	Yes		Yes		Same department
LV	Yes		Refer to the Agency in column 5		If product is classified as biocide: State Agency "Latvian Environment, Geology and Meteorology agency"

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					Maskavas street 165 Riga, LV-1019 Latvia Tel: +371 67146138
MT					
NL	Yes		Yes		Medicines Evaluation Board – Veterinary Medicinal Products Unit (BD ) (Same)
NO	Yes		Yes		
PL	Yes 1.Product which contain repellents for example collars, neckties, ears marks, without any lethal effect- <b>biocidal products</b> 2.Products with lethal effect- <b>veterinary medicinal products</b>		1. Directive 98/8/EC 2. Directive 2001/82/EC		Office for Registration of Medicinal Products, Medical Devices and Biocidal Products 41 Zabkowska Str. 03-736 Warsaw, Poland
PT	Yes		No	We cannot accept an assessment report issued under the mutual recognition procedure.	Direcção Geral de Veterinária LGO Academia Nacional de Belas Artes 2 1294 Lisboa Codex  Tel: 00 351 1 323 9500 Fax: 00 351 1 323 9565
RO	Yes*	*collars containing herbal extracts and used as repellents	Yes		Institutul pentru Controlul Produselor Biologice si Medicamentelor de Uz Veterinar Str. Dudului Nr. 37, sect. 6 Bucuresti cod 060603 ROMANIA Tel : +40 2122 02112 Fax : +40 212213171
SE	No	It is considered that preventive treatment of this kind is not necessary as it increases the exposure (amount and time) to the chemical for animals and humans handling the animal to an unnecessary level (benefit/risk unfavourable, no reason to treat healthy animals).	No	The provisions regarding pesticides would in general apply.	National Chemicals Inspectorate Box 1384 17127 SOLNA SWEDEN  <u>Contacts: Margareta Bystedt</u> Ulf Eriksson
SI	Yes if therapeutic claim No - without therapeutic claim	As biocide	Yes (2001/82) if therapeutic claim	Provisions for biocides would in general apply.	National Chemicals Bureau Ajdovščina 4 1000 Ljubljana Slovenia  tel: ++ 386 1 478 60 51 fax: ++386 1 478 62 66

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SK	Yes		Yes	1. Considered as a VMP if used for therapeutic purposes -81/851 2. As a pesticide for non agricultural use for the purpose of eliminating ectoparasiticides.	e-mail: <a href="mailto:gp-ursk.mz(at)gov.si">gp-ursk.mz(at)gov.si</a> Institute for State Control of Veterinary Biologicals and Medicaments – if classified as VMP Centre for Chemical substances and preparations Mierova 19 827 15 Bratislava 212 Tel.: +421 2 4854 14 -15 <u>If classified as pesticides.</u>
UK	Yes		Yes		VMD (Same)