

## APPLICATION FORM

### APPLICATION FOR THE ESTABLISHMENT OF MRL(s) FOR A PHARMACOLOGICALLY ACTIVE SUBSTANCE TO BE USED IN VETERINARY MEDICINAL PRODUCTS IN ACCORDANCE WITH REGULATION (EC) No. 470/2009

#### PART I: Administrative Data

Name of substance for review, using INN (where attributed):						
Name and address of applicant:						
Name, address, telephone number and fax number of company contact point for all correspondence arising in connection with the application:						
Type of application (please tick):	Full	<input type="checkbox"/>	Extension	<input type="checkbox"/>	Modification	<input type="checkbox"/>
Legal basis (please tick):	Article 3	<input type="checkbox"/>	Article 15	<input type="checkbox"/>	Article 9a <sup>1</sup>	<input type="checkbox"/>
	Article 9b	<input type="checkbox"/>	Article 11	<input type="checkbox"/>	Article 27 <sup>2</sup>	<input type="checkbox"/>
Marketing authorisation of veterinary medicinal products in the EU (please tick):	<p>Does the applicant hold a marketing authorisation in the EU for a veterinary medicinal product containing the substance?</p> <p>Yes <input type="checkbox"/>                      No <input type="checkbox"/> , or</p> <p>Has the applicant submitted a marketing authorisation application in the EU for a veterinary medicinal product containing the substance?</p> <p>Yes <input type="checkbox"/>                      No <input type="checkbox"/></p> <p>If the response to both questions above is "No":</p> <p>Has the applicant the intention to submit an application for a marketing authorisation containing the substance and concerned species in the EU</p> <p>Yes <input type="checkbox"/>                      No <input type="checkbox"/></p>					
Rapporteur:						
Co-rapporteur:						

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<sup>1</sup> Requests from the European Commission or Member States only.

<sup>2</sup> Requests from the European Commission or Member States only.

**PART II: SUMMARY OF THE EVALUATION PROPOSED BY THE APPLICANT**

Name of Substance for review, using INN (where attributed):						
Is the substance used in veterinary medicinal products as (please tick):		Active ingredient?		<input type="checkbox"/>	Excipient, preservative, etc?	<input type="checkbox"/>
Please summarise the anticipated pattern of veterinary use:						
Target Species	Major indications		Dose regimen			
Overall NOEL used for the determination of ADI (mg/kg bw/day):						
Reference to relevant study (including location in the dossier):						
Uncertainty factor proposed:						
ADI proposed (µg/kg bw):						
ADI proposed (µg/60 kg person):						
MRL required? (Please tick)		Yes <input type="checkbox"/>		No <input type="checkbox"/>		
If yes, what is the marker residue proposed:						
<b>Food commodity</b>	<b>Proposed MRLs (µg/kg)</b>					
Muscle						
Fat/Skin+Fat						
Liver						
Kidney						
Milk						
Eggs						
Honey						
Description of the proposed analytical method:						
Limit of quantification (LOQ)						
Reference (including location in the dossier):						
Evaluations performed by other EU or international bodies:		Has the substance been evaluated by other EU or international bodies? Yes <input type="checkbox"/> No <input type="checkbox"/> If the response to the above question is "yes", please indicate the name of the EU body(ies), the date(s) of evaluation(s) and the outcome(s)				

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I hereby certify that all information relating to the establishment of MRLs for the above-mentioned substance, whether favourable or unfavourable, has been submitted with this application.

Date:		Signature:	
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