8 November 2012
EMA/CVMP/SWP/634672/2012
Committee for medicinal products for veterinary use (CVMP)

Overview of comments received on Guideline on the approach to establish a pharmacological ADI (EMA/CVMP/SWP/355689/2006)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1	IFAH-Europe

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1. General comments – overview

Stakeholder no. *(See cover page)*	General comment (if any)	Outcome (if applicable)
1	IFAH-Europe believes that much of the data requested in this guideline will be obtained during the normal VMP development process and so is, in general, in favour of this guideline.	
1	If the NOEL, as a result of the pharmacological studies, is based on human exposure data, then the applied Safety Factor should by default be equal to 10, not 100.	The use of safety factors is described in Volume 8 of The rules governing medicinal products for use in the European Union.

2. Specific comments on text

Line no.	Stakeholder no. *(To be completed by the Agency)*	Comment and rationale; proposed changes	Outcome *(To be completed by the Agency)*
83-84		Comment: "When there is scientific evidence that the residues (metabolites) in animal derived foodstuffs are devoid of pharmacological activity." Proposed change (if any): please clarify the scientific evidence required.	Accepted. Additional text has been included in brackets.
138-139		Comment: The test for a B2 adrenoceptor agonist in Table 1 of the Annex indicates that the endpoint is bronchospasmolysis in humans. IFAH-Europe wishes to question whether the Sponsor would need to carry out human studies as part of registration requirements for these types of compounds. This seems like a severe and unreasonable request. Proposed change (if any): CVMP should clarify if they are truly proposing human studies as part of a VMP registration.	As indicated in the draft guideline, Table 1 of the Annex provides examples of studies providing information on relevant endpoints. Table 1 does not present data requirements. If human data are available the CVMP will consider these but human data are not required.