European Medicines Agency
Veterinary Medicines and Inspections

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OVERVIEW OF COMMENTS RECEIVED ON DRAFT GUIDELINE ON USER SAFETY FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

Table 1: Organisations that commented on the draft Guideline as released for consultation

Add name followed by link to individual received comment (upon publication by Web Services)

	Name of Organisation or individual	Country
1	IFAH-Europe (General Comments)	Europe
2	IFAH –Europe (Page 3, **2. Scope,** *1st paragraph, 1st sentence*)	Europe
3	IFAH-Europe (Page 3**. 2.Scope,** 2nd *paragraph, 2nd sentence)*	Europe
4	IFAH-Europe (Page 4, **4.Principles of Assessment,** *3rd paragraph)*	Europe
5	IFAH-Europe (Page 4, **5. Hazard identification and characterization** *2nd paragraph, 1st sentence)*	Europe
6	IFAH-Europe (Page 5, **8. Risk Management,** *2nd bullet point)*	Europe
7	IFAH-Europe (Page 6, **9. Risk Communication**, *3rd paragraph, 2nd sentence*)	Europe

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20)
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Table 2:Discussion of comments

GENERAL COMMENTS - OVERVIEW		
On 4th October 2006 IFAH-Europe submitted a position paper on the "Guideline on User Safety for Immunological Veterinary Medicinal Products (IVMPs)" to the EMEA/CVMP, addressing some concern regarding the adoption of this guideline due to the problems faced by industry with the the "Guideline on User Safety for Pharmaceutical Veterinary Medicinal Products ". IFAH-Europe was of the opinion that the user safety guideline for immunologicals should not be finalised until the experience with the use of the pharmaceutical user guideline has been assessed. Both the guidelines have been discussed at the EMEA/IFAH-Europe Info day on 9-10 November 2006. It was pointed out that the user safety guideline for IVMPs has a different approach with the one on pharmaceuticals.		
As agreed at the Info day, IFAH-Europe would now to submit some specific comments to this guideline here below.		
SPECIFIC COMMENTS ON TEXT		
2.SCOPE		
Paragraph no.	**Comment and Rationale**	**Outcome**
1st *paragraph, 1st sentence*	Although mentioned in section 5, it should be clearly stated in section 2 that no extra experimental work will be required from the applicant. Proposed change : "This guideline applies to new applications and renewals of marketing authorisation for IVMPs and does not require the generation of specific or additional data".	Agreed: This guideline applies to new applications and renewals of marketing authorisation for IVMPs and does not require the generation of specific or additional data.
2nd paragraph, 2nd sentence	The second part of this sentence, "….except…people", is more appropriate for pharmaceuticals and does not relate to IVMPs. Even if IVMPs require special storage conditions etc., they would not be excluded from this guideline (scope) in the first place. Furthermore a vaccine that is "dangerous" would never be licensed in the first place. Proposed change: It does not exclude exposure situations resulting from deliberate misuse.	Agreed: It does not exclude exposure situations resulting from deliberate misuse.

4. Principles of Assessment		
Paragraph no.	**Comment and Rationale**	**Outcome**
3rd paragraph	The second part of this sentence is a generalisation which we believe has not been proven, although there is a lot of guidance provided to pregnant women on e.g. which food to avoid so that they are not exposed to pathogens. Proposed change: Special attention should be paid to categories of potential users, such as immunocompromised persons (due to disease or immunosuppressive treatment) and pregnant women who may be more susceptible , and should therefore avoid exposure to infectious challenges, normally non pathogenic for the general population	Agreed: Special attention should be paid to categories of potential users, such as immunocompromised persons (due to disease or immunosuppressive treatment) and pregnant women who may be more susceptible and should therefore avoid exposure to infectious challenges.
5. Hazard Identification and Characterisation		
Paragraph no.	**Comment and Rationale**	**Outcome**
2nd paragraph, 1st sentence	"Effects have to be assessed primarily for the active ingredients of each category of IVMPs". What is meant by "each category"? this needs clarification in a glossary	Agreed: Effects have to be assessed primarily for the active ingredients of the IVMPs
8. Risk Management		
Paragraph no.	**Comment and Rationale**	**Outcome**
2nd bullet point	Identification of susceptible categories of users (e.g. immunocompromised persons, pregnant women).	Identification of highly susceptible categories of users (e.g. immunocompromised persons, pregnant women).
9. Risk Communication		

Paragraph no.	Comment and Rationale	Outcome
3rd paragraph, 2nd sentence	We believe that the reference to allergies is a fall out from the pharmaceutical guideline and suggest deleting the reference to allergies. In some cases recommendations for appropriate action will be linked with particular characteristics of the user, such as risk for compromise of the immune system.	Agreed: In some cases recommendations for appropriate action will be linked with particular characteristics of the user, such as risk for compromise of the immune system.