EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20th June 2013

Submission of comments on "Revision of EU Commission GMP chapters 3, 5, 6 and 8 "

Comments from:

Name of organisation or individual
IFAH-Europe

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	IFAH-Europe welcomes the opportunity to comment on this guideline and would like to share the issues of concern for the veterinary industry.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
CHAPTER 3 § 3.6		**Comment**: This Guideline is not applicable as is to the Veterinary industry because there are too many combinations possible between the manufactured products and the target species for these products. **Proposed change**: Please add the following text to this paragraph making reference to the "Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities": "In order to recognize the specificity of the veterinary sector (size, fragmentation of products, several species, ADI established database adopted by CVMP from MRL regulation for many actives), the "toxicological evaluation" might be conducted in case of specific class of actives where a risk for the animal/human with potentially contaminated drug product is described by the scientific community /in the site and when an ADI has not been established. In other situations, the maximum permitted contamination of 10 ppm of the previous active substance in the next product manufactured can apply".	
CHAPTER 5 § 5.17		**Comment**: We would like to use this opportunity to clarify the position on ectoparasiticides. **Proposed change**: Please add the following sentence: "For clarity, parasiticidal veterinary products (endoparasiticides and ectoparasiticides) are not to be classified as pesticides in this instance"	
CHAPTER 5 § 5.19		**Comment**: This Guideline is not applicable as is to the Veterinary industry because there are too many combinations possible between the manufactured products and the target species for these products. **Proposed change**: Please add the following text to this paragraph making reference to the "Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities": "In order to recognize the specificity of the veterinary sector (size, fragmentation of products, several species, ADI established database adopted by CVMP from MRL regulation for many actives), the "toxicological evaluation" might be conducted in case of specific class of actives where a risk for the animal/human with potentially contaminated drug product is described by the scientific community /in the site and when an ADI has not been established. In other situations, the maximum permitted contamination of 10 ppm of the previous active substance in the next product manufactured can apply".	
CHAPTER 5		**Comment**: The text of this section "Product shortage due to manufacturing constraints" only refers to articles 23a and 81 of Directive 2001/83/EC on Human medicines. **Proposed change**: Please also refer to article 27a of Directive 2001/82/EC which is equivalent to 23a but for Veterinary	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
§ 5.68		products.	
CHAPTER 6 § 6.37		**Comment**: The second sentence of this section should be amended on the basis that the review is not aimed to confirm that the original validation is in compliance with ICH (they may be very old tests) but to assess in support of the gap analysis mentioned in the following sentence. **Proposed change**: Please amend the text, see hereafter: "Prior to transferring a test method, the transferring site should verify that the test method(s) comply with those as described in the Marketing Authorisation or the relevant technical dossier. The original validation of the test method(s) should be reviewed **~~to ensure compliance with current ICH/VICH requirements~~**. A gap analysis **with current ICH/VICH requirements** should be performed and documented to identify any supplementary validation that should be performed, prior to commencing the technical transfer process."	
CHAPTER 8 Principle -2nd §		**Comment**: This new text requires that all defects which may lead to recall are reported to the authorities. We would like to review the wording so that we have the opportunity to investigate and confirm the defect before it is communicated to authorities. **Proposed change**: Please amend the text to read: "**After investigation,** all concerned competent authorities should be informed **in a timely manner** in case of a **confirmed** quality defect (faulty manufacture, product deterioration, detection of falsification, non-compliance with the marketing authorisation or product specification file, or any other serious quality problems) with a medicinal or investigational medicinal product which may result in the recall of the product or an abnormal restriction in the supply."	

Please add more rows if needed.