13 February 2012
EMA/CVMP/697961/2011
Committee for Medicinal Products for Veterinary Use (CVMP)

Overview of comments received on the CVMP reflection paper on risk management plans for centrally authorised veterinary medicinal products (EMEA/CVMP/126726/2007)

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

Stakeholder number	General comment (if any)	Outcome (if applicable)
1	IFAH-Europe welcomes the CVMP initiative to develop a standalone veterinary document on the topic of 'Risk Management Plan'. It is also essential that the application of such concept in the veterinary sector be limited to very specific products.	

2. Specific comments on text

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
Lines 43 - 48	1	The document reads: "CVMP considers that it is appropriate, at least initially to limit the scope to very special products for which the need for special arrangements is obvious, i.e. situations where there are identified *potential or actual risks* that cannot be managed through routine pharmacovigilance." **Comment**: this document is being developed to address article 12(3)k of the Directive that reads: "... *and , where appropriate, the risk management system that the applicant will put in place'.* Thus, the scope of this document should remain limited to very specific products, where appropriate, and not only 'initially' that implies that in the long term, the scope would be extended to more products.	Comment accepted and reflection paper re-phrased accordingly
Lines 59 - 68	1	**Comment**: the section on signal detection and how it will apply in the future based on the 'use of extended safety' specification' is quite vague. We would thus welcome if more clarity was brought to this paragraph.	Noted. However, further clarification of the concept of the safety specification (a.k.a. safety profile) and its use in signal detection will be developed with the guidance on signal detection as part of the future revision of the CVMP recommendation for basic surveillance of EudraVigilance Veterinary data