European Medicines Agency
Veterinary Medicines and Inspections

London, 15 October 2007
Doc. Ref. EMEA/CVMP/175326/2007

OVERVIEW OF COMMENTS RECEIVED ON THE DRAFT QUESTIONS AND ANSWERS ON APPLICATION OF THE SO-CALLED "SUNSET CLAUSE" TO CENTRALLY AUTHORISED VETERINARY MEDICINAL PRODUCTS

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

	Name of Organisation or individual	Country
1	IFAH Europe	Belgium

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SPECIFIC COMMENTS ON TEXT		
5. EXEMPTIONS		
	Comment and Rationale	**Outcome**
	More examples of obvious grounds for exemption should be included, so that these need not be negotiated individually for each product. Valid exemptions should be:	Accepted
	a) Veterinary medicinal products (VMPs) used in emergency situations like FMD, AI, CSF, Blue Tongue, etc. (already mentioned as example)	Accepted. The text has been modified and an example has been added.
	b) VMP's which have been transferred to another MAH. Any new MAH should have the full 3 years of the sunset period for the products he acquired	Not accepted. Exemptions have to be justified on human/animal health grounds. A transfer to another MAH cannot be considered a human/animal health ground.
	c) VMP's which are 'mother products', which are not marketed themselves, but from which other products are derived, even if these derivatives or extensions have a different core number. (Combination products, fall-out products, bibliographic products)	Not accepted. Exemptions have to be justified on human/animal health grounds. It is not possible to grant an exemption to this type of products as a general rule.
	d) VMP's which are currently of no importance for the EU market, but for which an EU registration is required in order to enable marketing in non-EU countries (i.e. for Export/Free Sale Certificates). Without a licence in the originating country, a product cannot be marketed in many export countries. (Art 28.6 does not say that the human/animal health grounds should be located inside the EU!)	Not accepted. This would be a very rare situation for a centralised application and should be addressed on a case-by-case basis rather than as an example in this guideline.

6.1 TIMER ON		
	Comment and Rationale	**Outcome**
	At the time of marketing, the product may not be immediately placed on the market. First the whole mock-up checking procedure must be followed. The sunset timer should not be on before the first mock-up has been approved (if submitted within a reasonable period after licensing).	Not accepted. The EMEA's mock-up procedure has been reviewed and simplified and approval of the first mock-ups should be at about the time of Commission Decision. Therefore, no significant delays due to mock-up checking are anticipated.
9. REQUIREMENTS FOR NOTIFICATION		
	Comment and Rationale	**Outcome**
	The requirements and format should be as simple as possible: e.g. it should suffice to report at launch without any details about presentations and MSs, as this is not relevant for the 'sunset clause'.	Partly accepted. The electronic reporting form and reporting cycle has been simplified.
9.2.1 *(Marketing status overview)*	Delete the timeline, as there is neither a legal nor a practical requirement	Partly accepted. A timeline of 30 days for reporting of the first launch date is considered reasonable to allow MAH to provide the required information. However, if appropriate, this information should be provided together with the next PSUR.
9.2.2 *(For cessation)*	The procedure is currently too bureaucratic, it should not be required to report details/justifications - this should be entirely optional for the MAH in the letter of withdrawal.	Partly accepted. In the case of cessation due to public or animal health issues, such details/justification should be provided. However, for all other cessations, the regular annual updates are sufficient. The text has been revised to clarify this.
9.3 *(reporting format)*	It is acceptable to request industry to report in either electronic or paper, but not both. It is very important that the industry and EMEA work together to minimise the continual growth of administrative burdens. In this context we feel that it is also important that the reporting form is discussed and agreed with industry.	Accepted. The reporting form has been revised (simplified) and it is recommended to submit it electronically.