

REPORT FOR RELEASE

Meeting of 13-14 December 2007

Work plan 2008

CMD(v) adopted its work plan for 2008, by which it aims to further improve the conduct of decentralised and mutual recognition procedures, as well as the functioning of the group itself. Focus points in 2008 are speed of decision making, participation, communication and use of management tools. The Work plan for 2008 can be downloaded from the CMD(v) website.

Sunset clause

Pursuant to Article 28 of the amended Directive 2001/82/EC, products that have not been marketed within three years of issuing the marketing authorisation, or products which have not been marketed for a period of three consecutive years, shall become invalid, unless there are fully justified reasons to maintain the marketing authorisation. The implementation of the Sunset clause for products authorised nationally or via Mutual Recognition or the Decentralised Procedure is the responsibility of each member state.

The latest CMD(v) Guidance document addresses questions that a marketing authorisation holder may have on how the competent authority of a member state will monitor the marketing of any veterinary medicinal product, which has been authorised via a mutual recognition (MRP) or decentralised (DCP) procedure. The Guidance document in conjunction with an annex on the implementation date of Directive 2001/82/EC as amended in the Member States is available on the website.

Diluents

Following the agreement reached in June 2007 on the handling of procedures for products containing diluents, CMD(v) adopted a document specifying conclusions and recommendations. This document, in combination with an annex regarding the national requirements in cases which include more than one diluent or an optional diluent with the product, is available on the CMD(v) website.

New members

CMD(v) welcomed two new members:
- Mr. J. Lenharðsson on behalf of Iceland;
- Ms. K. Swiader on behalf of Poland.

Product discussion

Eight products reached day 78 of the mutual recognition procedure and 8 day 198 of the decentralised procedure in December 2007. Out of these 10 were discussed at the meeting. Also discussed was a product referred to CMD(v) under Article 33(1) of Directive 2001/82/EC, as amended. The applicant took the opportunity to express their point of view in a hearing.

	MRP	DCP	Referrals
<i>Procedures</i>	8	8	1
Products	8	5	1
Immunological	3	0	0
Pharmaceutical	5	5	1
Discussed	5	5	1

Following the November meeting CMD(v) could not reach an agreement at day 60 of the CMD(v) referral procedure for Solacyl 100 % powder for oral solution for calves and pigs (sodium salicylate) of Eurovet Animal Health B.V. One Member State considered the product to pose a potential serious risk to animal health. The matter was therefore referred to the CVMP.

Information

CMD(v) documents are available on www.hma.eu/cmdv.html

For further information, please contact the secretariat at the European Medicines Agency, for the attention of Wim Riepma, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK wim.riepma@emea.europa.eu