

REPORT FOR RELEASE

Meeting of 14-15 March 2008

Annual Report 2007

Strong growth in new applications, fewer referrals and constructive discussions on policy issues summarise the work of CMD(v) in 2007.

Significant decisions were taken on the handling of generic products, diluents, access to documents and the sunset clause, whilst good progress was made on the harmonisation of packaging and labelling requirements. Clarification was also received on the legal requirements for environmental risk assessments, particularly for generic applications. New standard operating procedures, best practice guides and guidance documents were developed and existing documents were updated to provide valuable information for industry as well as to facilitate the work of the CMD(v) itself. In conclusion, the objectives as set out in Work Plan 2007 have been met.

More on these achievements as well as information on other activities and the functioning of CMD(v) can be found in Annual Report 2007, which has been published on the HMA website.

Classification of ectoparasiticide products and teat dips

Following requests from industry, documents VMRFG/107/98 *Ectoparasiticide products for use in "animals for consumption" and "pet animals" respectively* and VMRFG/068/98 *Authorisation of ectoparasiticide collars companion animals* have been updated. Member States that joined the European Union after 1998 have been added whilst the old Member States have reviewed and amended their position where necessary. The documents will be published under a new CMD(v) number.

The classification of teat dips, used either prior or post milking, has been outlined in a separate document and this will also be published.

As the national policies vary as to whether ectoparasiticide products and teat dips are considered veterinary medicinal products or biocidal products, industry is advised to take note of the documents provided and to contact the relevant authorities in the Member States before submitting applications.

Clock start dates

Recommended clock start dates have been established for the mutual recognition procedure and the second phase of the decentralised procedure for the period up to December 2010. Applicants are advised to follow these dates, in order to facilitate smooth running of the procedures. A table with all dates has been published on the website. The start dates for the remainder of 2008 are 1 May, 3 July, 31 July, 28 August, 25 September, 30 October, 27 November and 23 December.

New members

Alenoosh Abedi has been appointed as new CMD(v) member on behalf of Sweden, replacing Christina Wik. Liechtenstein appointed Brigitte Batliner to replace Peter Malin.

Product discussion

In March 2008 three products reached day 78 of the mutual recognition procedure and a further 4 reached day 198 of the decentralised procedure. Out of these 5 were discussed at the meeting.

	MRP	DCP	Referrals
<i>Procedures</i>	3	5	2
Products	3	4	1
Immunological	1	1	0
Pharmaceutical	2	3	1
Discussed	2	3	0

Following the February 2008 meeting no agreement could be reached for 2 products going through the decentralised procedure. The procedures were referred to CMD(v) pursuant to Article 33(1) of Directive 2001/82/EC for a 60 day referral procedure.

CMD(v) noted, however, that agreement was reached on the authorisations for AMOXIVAL VET 200 mg and 400 mg tablets for dogs (Sogeval Laboratories), which had been referred following the December 2007 meeting because of concerns over the efficacy.

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