



EMEA/CMDv/457688/2006
London, 21 November 2006

REPORT FOR RELEASE

Meeting of 9-10 November 2006

At the occasion of its first anniversary, the Co-ordination Group reflected on a smooth start and looked forward to further increase the quality and efficiency of its work, for the benefit of animal health, public health, the environment and, last but not least, the animal health industry.

At the end of October 2005 the CMD(v) was established in accordance with Directive 2001/82/EC, as amended by Directive 2004/28/EC. Competent Authorities nominated members from each Member State, who elected Esther Werner as chairperson for a period of 3 years. To ensure consistent and accurate conduct of activities, the group adopted rules of procedure and developed a number of management- and operating procedures as well as best practice guides, which form now a comprehensive document management system. Industry has been consulted on many documents. The EMEA has supported CMD(v) with a secretariat by preparing and hosting the meetings, carrying out follow up on meetings and providing advice.

During the year CMD(v) dealt with 98 mutual recognition procedures (MRP), comprising 75 products. 22 decentralised procedures (DCP) have started and the first of them are due to be finalised by the end of this month.

For 10 products in the MRP (13%), the group could not reach an agreement at the end of the procedure, because one or more Concerned Member States believed there could be a potential serious risk with regard to efficacy, safety, quality or the environment.

<i>Area</i>	<i>No. products</i>
Efficacy	5
Safety	3
Quality	1
Environment	1

Following the 60 day CMD(v) referral procedure for these 10 products, agreement was reached on 3 products, while 5 were referred to CVMP. At the moment 2 CMD(v) referral procedures are ongoing.

CVMP has issued an opinion on 2 of the products referred to it, with the conclusion that there is no potential serious risk and consequently no reason to withhold a marketing authorisation. The other 3 CVMP referral procedures are ongoing. Referred products for which the CMD(v) referral procedure is finalised, are listed in the table attached to this report.

Several companies took the opportunity for an oral hearing on a referred product, at a CMD(v) meeting. Contacts with industry representative organisations, IFAH-Europe and EGGVP, have been maintained and meetings were conducted on a quarterly basis.

The publication of a comprehensive report on CMD(v) activities for the period November 2005 – December 2006 is due at the beginning of 2007.

Looking forward

Considering the experiences of the past 12 months, the group addressed various ideas to further enhance quality and efficiency in 2007. It reflected on the opportunities for preventing referrals and improving the outcome of referral procedures as well as the functioning of MRP and DCP, speeding up the adoption of documents, intensifying the co-operation with working parties and guidance to new member states.

CMD(v) would welcome and consider suggestions for improvement from stakeholders, to be included in the work programme for 2007. Suggestions can be sent to wim.riepma@emea.eu.int by 6 December 2006 at the latest.

Best practice guide for MRP updated

The best practice guide for the Mutual Recognition Procedure has been updated as a result of experience gained and in particular in relation to referrals. The adopted new edition (01) has been published on www.hevra.org/vmrfq/sop.asp

Product discussion

In November, 5 pharmaceutical products reached day 78 of the MRP, of which 4 were discussed at the meeting. 4 immunological products reached day 78 of the second phase of the DCP and were also discussed. These were the first DCP discussed at CMD(v).

It was noted that following the October meeting all 5 MRP products were approved. CMD(v) discussed one product at day 43 of the referral procedure.

New members

Ms. Helen Mahla has been appointed as member by the Estonian competent authority. She replaces Ms. Triin Teppor. The Spanish competent authority appointed Ms. Carmen Sanchez Martinez, to succeed Ms. Dolores Sandoval.

Information

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

FINALISED CMD(v) REFERRALS NOVEMBER 2005 – OCTOBER 2006

Product	Company	Issue	Outcome CMD(v)	Outcome CVMP
Anipryl (selegiline)	Dahi animal health Ltd.	efficacy	Agreement reached	
Bovilis BVD-MD (immunological)	Intervet International	quality	Referred to CVMP for arbitration	pending
Cobactan IV 4.5% (cefquinome)	Intervet Deutschland	safety	Referred to CVMP for arbitration	no potential serious risk
Cyclix (cloprostenol)	Intervet Deutschland	safety	Agreement reached	
Cyclix porcine (cloprostenol)	Intervet Deutschland	safety	Agreement reached	
Dolovet/Rifen (ketoprofen)	Vetcare	efficacy	Referred to CVMP for arbitration	no potential serious risk
Doxyprex (doxycycline)	Industrial Veterinaria S.A.	efficacy	Referred to CVMP for arbitration	pending
Equimectin (ivermectin)	Le Vet B.V.	efficacy	Referred to CVMP for arbitration	pending