

## REPORT FOR RELEASE

Meeting of 17-18 April 2008

### Co-operation with CMD(h)

CMD(v) and its counterpart for human medicinal products, CMD(h), will hold a joint meeting to share experiences and to enhance co-operation in areas of common interest. The meeting is scheduled for 19 June 2008 and the agenda includes the following items:

- the organisation of work under the revised variation regulation;
- generics;
- referrals to CMD(h)/(v);
- validation issues;
- communication between both groups.

### Variations during referrals

CMD(v) discussed how to deal with variation applications whilst a referral procedure is ongoing. The group concluded that in most cases it is not recommended that companies submit variation applications for products for which a referral procedure is ongoing in CMD(v) or CVMP. However, it is recognised that there can be situations where a variation on the product authorised in a Member State needs to be varied. This is for example the case where the product has changed ownership or where there is a new active ingredient supplier.

### Pet rabbits

In the case veterinary medicinal products are intended solely for rabbits kept exclusively as pet, Member States may permit exemptions in their territory from the requirement to establish withdrawal periods for rabbit meat (Article 4.2 of Directive 2001/82/EC as amended). Problems may arise upon the validation of applications through the mutual recognition and decentralised procedure because some Member States do permit exemptions and others not. For the benefit of future applicants CMD(v) has launched a survey with the aim of publishing an overview of Member State policies by July 2008.

### Product discussion

In March 2008, 8 products reached day 78 of the mutual recognition procedure and a further 6 reached day 198 of the decentralised procedure. Out of these 3 were discussed at the meeting. Besides 5 referral procedures were discussed and for 2 of them the applicant attended a hearing.

	MRP	DCP	Referrals
<i>Procedures</i>	9	8	5
Products	8	6	5
Immunological	3	1	1
Pharmaceutical	5	5	4
Discussed	1	2	5

Following the March 2008 meeting no agreement could be reached for 1 product going through the decentralised procedure. The procedure was referred to CMD(v) pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60 day referral procedure.

**Information**

CMD(v) documents are available on [www.hma.eu/cmdv.html](http://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](mailto:wim.riepma@emea.europa.eu)