

## REPORT FOR RELEASE

### Meeting of 14-15 February 2008

#### Downward trend referrals

The percentage of products referred to CMD(v) at the end of the mutual recognition or decentralised procedure has declined considerably since the end of 2005. Experience, dialogue between authorities and with applicants as well as a better understanding of potential serious risk have contributed to a better success rate of procedures.

Directive 2004/28/EC, which had to be implemented in the Member States by 30 October 2005, made it impossible for an applicant to prevent referral by withdrawing an application from a Concerned Member State which had raised an issue of potential serious risk. As a result the number of referrals surged immediately. However, this rise was followed by a drop in referral rate for 2 consecutive years, as presented in the table below.

| Time period                | Percentage of products referred to CMD(v) at day 90/210 of MRP/DCP |
|----------------------------|--|
| 30 October - December 2005 | 22 %   |
| January - December 2006    | 11 %   |
| January - December 2007    | 7 %  |

A total of 19 products were referred to CMD(v) between 30 October 2005 and 31 December 2007. The main areas of disagreement related to efficacy (12 products), animal or human safety (4 products), environmental risk assessment (2 products) and quality (one product). In 9 cases the referral involved a generic product. For generics the major cause of disagreement has been the acceptance of indications, target species or withdrawal periods, not authorised (for the reference product) in a concerned member state. In the mean time CMD(v) has adopted a set of principles for the handling of such applications with view to avoiding unnecessary referrals.

Eventually 10 products have been referred to the Committee for Medicinal Products for Veterinary use (CVMP). For 9 products CVMP delivered a positive opinion, recommending an authorisation. For one product the Committee recommended the suspension of the marketing authorisation.

#### Consider authorisation in Iceland

CMD(v) agreed on a pilot scheme to facilitate industry in authorising products in Iceland. For products already authorised through the mutual recognition or decentralised procedure in other countries in the European Economic Area, an accelerated repeat use procedure may be offered to include Iceland. The trial starts with products for which Belgium and the United Kingdom are the reference member state.

Industry is also advised to consider the inclusion of Iceland in new mutual recognition or decentralised procedures. Although this country is not the geographical focal point of Europe, it may harbour an interesting market and its government welcomes new applicants.

For more information on authorising veterinary medicinal products in Iceland, applicants may contact:

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### **Product discussion**

Twelve products reached day 78 of the mutual recognition procedure and 8 day 198 of the decentralised procedure in February 2008. Out of these 5 were discussed at the meeting.

|                   | MRP | DCP | Referrals |
|-------------------|-----|-----|-----------|
| <i>Procedures</i> | 13  | 8   | 0         |
| Products          | 12  | 8   | 0         |
| Immunological     | 3   | 0   | 0         |
| Pharmaceutical    | 9   | 8   | 0         |
| Discussed         | 4   | 1   | 0         |

Following the January 2008 meeting no agreement could be reached for 2 products going through the decentralised procedure and one going through the mutual recognition procedure. The procedures were referred to CMD(v) pursuant to Article 33(1) of Directive 2001/82/EC 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)