

## REPORT FOR RELEASE

### Meeting of 17-18 January 2008

#### Decentralised applications surge

New applications for marketing authorisations through the decentralised procedure (DCP) went up to 65 products in 2007 from 25 in 2006. The number of new applications under the mutual recognition procedure (MRP) declined slightly to 75 products in 2007 compared to 77 over 2006. In total the number of products for which procedures started rose to 140 from 102, marking industry's confidence in the European market and also in the way in which the DCP and MRP are managed by the member states.

#### Protection period

Following questions from industry CMD(v) confirmed that the marketing authorisation holder of a originator product is not eligible to apply for a generic of this product before the legal data protection period is over, even though it is the company's own data (Article 13.1 of Directive 2001/82/EC as amended).

It was also noted that the protection period starts to count from the date that a product has been authorised in accordance with the European legislation, although the product might have been under national provisions on the local market for a longer period of time. For member states that joined the EU more recently the start date is often the date of accession. However there are 'old' products in other member states that have only recently been updated in accordance with the *acquis communautaire*. The data protection period for these products will commence from the date of update.

Industry is therefore advised to consider carefully the date a potential reference product was authorised in accordance with the *acquis communautaire*, before applying for a generic.

#### Product discussion

Two products reached day 78 of the mutual recognition procedure and 8 day 198 of the decentralised procedure in January 2008. Out of these 7 were discussed at the meeting.

	MRP	DCP	Referrals
<i>Procedures</i>	4	11	0
Products	2	8	0
Immunological	1	1	0
Pharmaceutical	1	7	0
Discussed	1	6	0

It was noted that following the December meeting CMD(v) could not reach an agreement at day 60 of the CMD(v) referral procedure for Compagel gel for horses (heparin sodium, levomenthol, hydroxyethyl salicylate) of Boehringer Ingelheim. Two Member States considered the product to pose a potential serious risk to animal health. The matter was therefore referred to the CVMP.

Following the December 2007 meeting for one product going through the decentralised procedure, no agreement could be reached at day 210 of the decentralised procedure and the matter was referred to CMD(v) pursuant to Article 33(1) of Directive 2001/82/EC for a 60 day referral procedure.

#### **New European Commission representative**

CMD(v) welcomed Mr. Jan Henrik Rotherth as the new representative from the European Commission. Ms. Karin Krauss, who attended CMD(v) and prior to this VMRFG for many years, has become the European representative to the Committee for Medicinal Products for Veterinary Use.

#### **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)