

REPORT FOR RELEASE

Meeting of 10-11 May 2007

CMD(v) decided to establish an ad hoc group, to provide advice on packaging issues brought forward by industry. The group is formed of CMD(v) members from Finland, Hungary, Lithuania and Portugal. The EMEA offered support for the work of the group and the European Commission will observe its meetings.

IFAH-Europe organised in April 2006 a workshop to identify and address problems faced by industry with the regulatory requirements for the packaging of veterinary medicinal products. Following the workshop, CMD(v) conducted an extensive survey to create an overview of the situation in the Member States, where practices may differ according to national requirements. Based on the survey's outcome, IFAH-Europe proposed a prioritisation of issues to be tackled. The ad hoc group for packaging is to start July 2007, to allow the current ad hoc group on diluents to finalise its work in June 2007. At the first meeting the new ad hoc group will draft its objectives and a time schedule.

New member

Mária Szabó was welcomed as new member from Hungary, replacing Gábor Kulcsár.

Product discussion

Eight products reached day 78 of the mutual recognition procedure and 1 product day 198 of the decentralised procedure in April 2007. One product did not require a discussion.

	MRP	DCP	Referrals
<i>Procedures</i>	9	2	1
Products	8	2	1
Immunological	4	1	0
Pharmaceutical	4	1	1
Discussed	7	1	1

It was noted that following the April meeting no agreement could be reached on 1 product by the end of the mutual recognition procedure. The areas of disagreement related to: the efficacy, the quality, as well as the environmental safety of the product. The procedure was referred to CMD(v) pursuant to Article 33(1) of Directive 2001/82/EC and a list of concerns, to be addressed by the applicant, was adopted during the May meeting.

Information

CMD(v) documents, including the annual report 2006, are available on www.hma.eu.

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