

## REPORT FOR RELEASE

### Meeting of 15-16 March 2007

**CMD(v) published its first annual report. The report provides an overview of the work carried out since the start of the group on 30 October 2005 until the end of 2006.**

Records are included regarding the members of the group, the number of procedures dealt with and the development of the quality management system. The number and background of referral procedures have been analysed. The report also summarises discussions held on policy issues related to generic applications, diluents and environmental risk assessment. Interaction with other groups and the work of the secretariat are described.

#### Hybrid applications

CMD(v) discussed situations where applications for generics include all indications authorised for the reference product in the reference member state. It was concluded that in this case Article 13(1) of Directive 2001/82 (as amended) is the appropriate legal basis for the application. This should not be confused with applications where not all claims are included in the reference product in the reference member state. In that case Article 13(3) applies.

#### Diluents

IFAH-Europe presented to the CMD(v) ad hoc working group on diluents their view on the handling of products containing one or more diluent and submitted proposals for labelling, packaging and distribution of diluents. CMD(v) established this working group in January this year, to develop and advise on a harmonised approach regarding the handling of products including diluents. Input from industry to the discussion is very much valued.

#### Product discussion

One product reached day 198 of the decentralised procedure and 5 products day 78 of the mutual recognition procedure in March 2007. Out of these, 3 products were discussed at the meeting.

	MRP	DCP	Referrals
<i>procedures</i>	6	1	0
Products	5	1	0
Immunological	2	0	0
Pharmaceutical	3	1	0
Discussed	3	0	0

It was noted that following the January meeting agreement was reached on all 13 products by the end of the mutual recognition or decentralised procedure. Agreement was also reached on a referral procedure for Gallimune Se+St Vaccine (Merial Animal Health).

**New member**

CMD(v) welcomed Elena-Luminita Paraschiv as the new member from Romania. The published list of CMD(v) members will be updated consequently.

**Information**

CMD(v) documents, including the annual report 2006, are available on [www.hma.eu](http://www.hma.eu).

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