

REPORT FOR RELEASE

Meeting of 14-15 June 2007

CMD(v) reached agreement on the administrative handling of products containing diluents. Industry can now submit in all Member States one application for a product that can be used with one or more simple diluents.

Validation and labelling problems with some procedures, and long lasting discussions, triggered CMD(v) at the end of 2006 to establish an ad hoc group on diluents. The ad hoc group investigated the problems and proposed resolutions. CMD(v) welcomed the proposals and adopted the following conclusions and recommendations:

- Most Member States can authorise a product which can be used with one or more (non pharmacologically active) diluents under one number. They accept one application and run one procedure.
- Greece, Italy, Poland or Spain require separate national authorisations for each powder-diluent combination.
- Where Greece Italy, Poland or Spain are Concerned Member State in a mutual recognition or decentralised procedures, one stem procedure will be created and one sub-procedure for each combination. So the procedure will be run under one stem procedure and a harmonised Summary of Product Characteristics is retained. Where applicable, the Summary of Product Characteristics is split at national level following the sub-procedures. Applicants will be required to commit to this before the start of the procedure.
- The dossier shall contain all information with regard to the use of the diluent(s) as part of the product: quality, efficacy and safety when used in combination with the powder.
- The diluent should be mentioned in the Summary of Product Characteristics as part of the product or as optional diluent

Product discussion

Five products reached day 78 of the mutual recognition procedure and 2 products day 198 of the decentralised procedure in June 2007. One product did not require a discussion. One referral procedure was discussed and the applicant presented its view at a hearing.

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

Information

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

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