

REPORT FOR RELEASE

Meeting of 11-12 December 2008

Work plan 2009

CMDv adopted its work plan for 2009. Next to the regular activities, specific focus points in the year to come will be:

- the implementation of the Variations Regulation;
- “old product” harmonisation; and
- improving meeting efficiency.

The major legislative change to be implemented in 2009 is the new Variations Regulation. CMDv is prepared to take on its new tasks, which include the issuing of recommendations on unforeseen variations as well as the conduct of referral procedures in case of disagreement among Member States. The group will also continue revising current guidance and develop new guidance where necessary for applicants and national competent authorities.

In all aspects of common interest the close cooperation with the CMDh and the EMEA will be continued.

A more strategic issue the group will look into is the disharmony in marketing authorisations granted by Member States for the same product, authorised through national procedures. Applications for generic products bring these differences to the light, which may result in the reference products being referred to CVMP under Article 34 (divergent opinion) or Article 35 (community interest) of the Directive 2001/82/EC (as amended). Such procedures can be time consuming and usually come unexpectedly for the marketing authorisation holder. It is also recognised that the dossiers of the “old” reference products may not have been updated to the latest guidelines. It is thus considered worthwhile exploring mechanisms for harmonising reference products without using heavy referral tools and/or to find ways for better planning and prioritising the use of the referral tool. CMDv will therefore investigate the possibility of voluntary SPC harmonisation through work sharing in variations and also reconsider the option of establishing a list of products for which SPC harmonisation is necessary.

Regarding the CMDv meetings, the use of virtual meeting rooms will be tested for the discussion of products or specific issues to enhance the participation of experts. The meeting format of the plenary will be modified to promote faster decision making.

Apart from these focus points; the work plan covers other topics, such as national validation issues, packaging requirements, biosimilars and cooperation with other groups.

The work plan will be published on the CMDv website.

Informed consent

The following question was put to CMDv: “Does the existing guidance allow an informed consent application to be made in a country which was a Concerned Member State (CMS) in the Mutual Recognition Procedure (MRP) involving the originator, where the proposed Marketing Authorisation Holder is independent of the originator MAH?”

CMDv confirmed that it is allowed to submit an informed consent application in a country that was CMS in a MRP for the product that will be referred to. However, it shall be noted that an informed consent application to a generic product should not be possible as the requirements laid down in Article 13c of Directive 2001/82/EC (as amended) could not be met.

Product discussion

In December 2008, 3 products reached day 78 of the mutual recognition procedure and a further 4 reached day 198 of the decentralised procedure. Out of these, 5 were discussed at the meeting.

	MRP	DCP	Referrals
<i>Procedures</i>	3	4	0
Products	3	4	0
Immunological	1	0	0
Pharmaceutical	2	4	0
Discussed	1	4	0

It was noted that agreement was reached on all procedures that reached day 90 in November.

New Member

Ms Joanna Kubisa has been appointed as new CMDv member on behalf of Poland, replacing Katarzyna Świąder.

Information

CMDv documents are available on 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