

REPORT FOR RELEASE

Period: June 2010

June 2010 product discussions

Four products reached day 78 of the mutual recognition procedure (MRP) and a further eight products reached day 198 of the decentralised procedure (DCP).

	MRP	DCP	Referrals
Procedures	8	8	0
Products:	4	8	0
Immunological	0	0	0
Pharmaceutical	4	8	0

It was noted that, following the May 2010 meeting, three MRP procedures reached the end of the 60 day referral procedure and agreement could not be reached on granting marketing authorisations.

Update and Advice to Applicants

Variations Regulation

Groupings under point 6 of Annex III of the regulation

It is possible for a grouping to include changes to both the finished product and the active substance as long as all variations are related to the same project intended to improve the manufacturing process and the quality.

However, in those cases where the changes relate to different projects, two different groupings need to be submitted. For example:

1. Project involving changes to improve the manufacturing process of the finished product with no impact on the active substance = one grouping
2. Project involving changes to the manufacturing process of the active substance, which also involves changes to the finished product = one grouping

It would not be possible to submit all changes relating to points 1 and 2 above as a single grouping.

Referring to data in another dossier

Member States receive ongoing queries from industry regarding the possibility of referring to data in another dossier for the purposes of modifying the SPC. CMDv has discussed this extensively and provides the following conclusions to help clarify the current situation:

- Safety (excluding environmental) & residue tests and pre-clinical & clinical data underpinning an MA cannot profit from unlimited protection, regardless of the legal basis used to achieve that authorisation;
- The MAH of a reference product may refer, by means of a variation or extension, to the data generated by the MAH of the generic/hybrid product. However, simply referring to studies conducted by the MAH of the generic product may not be adequate and further data and/or scientific justification may be required to support a change to the originator product e.g. injection site residue data for injectable formulations;
- The MAH of the generic or hybrid product may refer to studies in the dossier of the reference product, which is reflected in the variation classification guideline under C.I.2;
- There is no consensus among the Member States with regard to referring from one originator to another originator dossier by means of a variation. Therefore the MAH would have to submit a new marketing authorisation application as a generic or hybrid;
- It is possible to apply for a marketing authorisation that refers to both the full dossier of a reference product and additional studies in the dossier of a 'variant' of that reference product, where the variant has been authorised under the abridged procedure to a company different from the company holding the initial MA for the reference product. Bioequivalence must be demonstrated to each product referred to.

CMDv guidance

The Best Practice Guides (BPG) on variations: Type IA, IB, II and worksharing were adopted in June, as well as the BPG on MRP and ASMF. The updated BPG on DCP will be adopted at the July meeting. Further review of CMDv documents will continue in September.

CMDv/IFAH-Europe 2009 statistics report on MRP and DCP for veterinary medicinal products

This report is now published on the CMDv website and presents the data received sent by CMDv to IFAH on the procedures concluded in 2009. The data in the survey have been adapted to consider applications for a product in different strengths as one single procedure.

Update on Liechtenstein MRP/DCP

Liechtenstein will not be obliged to participate in the decentralised procedure (DCP) and in the mutual recognition procedure (MRP) and shall, therefore, not be obliged to issue the corresponding marketing authorisations. Instead, Austrian marketing authorisations within the DCP and the MRP will be valid for Liechtenstein upon request of a marketing authorisation applicant.

Information

The Presidency of the European Union changed on 1 July 2010. As Belgium assumed the EU presidency from July to December 2010, Mr. Christophe Debruyne will be the new vice-chairperson of CMDv during this term. The June 2010 meeting was the last under the Spanish Presidency of the Council of the European Union. CMDv is grateful to Ms. Carmen Sanchez Martinez for her work as vice-chairperson during the first half of 2010.

CMDv documents are available on www.hma.eu/cmdv.html
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