

REPORT FOR RELEASE

Period: June –September 2009

Decentralised Procedures (DCP) – updated

The Best Practice Guide has been revised. The main changes refer to the RMS assessment at Days 120 and 190 of the applicant's responses indicating whether or not the product can be approved at this stage. The document is published on the CMDv website: <http://www.hma.eu/162.html>

Simple diluents - update

The CMDv conclusions and recommendations' document on diluents has been updated and refer only to "simple" diluents e.g. saline, buffered saline, water etc and not those containing adjuvants or antigens.

No sub-procedures are required any more in order to handle a procedure for a product with one or more diluents or an optional diluent.

The document is published on the CMDv website: <http://www.hma.eu/161.html>

Clock stop period - extension under exceptional circumstances

According to the CMDv best practice guide for DCP "*Should the applicant require a clock-off period that exceeds six months, this must be fully justified and agreed by the RMS and all CMS*". CMDv emphasises that extensions of the clock-stop period in excess of 6 months should only be granted under exceptional circumstances. For example, the late provision of additional studies is not considered an exceptional circumstance.

Variations Regulation

CMDv continues its contribution to a successful implementation of the Variations Regulation by active participation in the different working groups established to fulfill the new requirements. The following CMDv best practice guide documents (BPG) are currently under discussion and finalisation is foreseen by the end of 2009,

- BPG004 Variations Type IA ;
- BPG005 Variations Type IB;
- BPG006 Variations Type II;
- BPG016 Variations grouping;
- BPG018 Variations work sharing;
- SOP-001 Disagreement in procedures Referral Art. 33(1) to CMDv.

Starting materials of animal origin

A focus group meeting on starting materials of animal origin took place with representatives of industry, CVMP/IWP and CMDv on 30 June 2009. The focus group defines starting materials as all components used in the production of the veterinary medicinal product as they are introduced into the manufacturing process. The recommendations of the Focus group meeting on substances of animal origin were endorsed by CMDv. The recommendations and the summary record of the meeting are published on the EMEA website: <http://www.emea.europa.eu/htms/vet/statements/statements.htm>

Frequently asked questions (Q&A)

CMDv dedicate a section of the website to frequently asked questions in order to make the CMDv response publicly available on: <http://www.hma.eu/49.html>.

To avoid duplication, all interested parties are invited to consult this page first before addressing a query to the CMDv.

Product discussion June 2009

In June 2009, 3 products reached day 78 of the mutual recognition procedure and a further 11 products reached day 198 of the decentralised procedure. Out of these, 2 were discussed.

	MRP	DCP	Referrals
<i>Procedures</i>	7	12	2
Products	3	11	2
Immunological	0	0	1
Pharmaceutical	3	11	1
Discussed	1	1	1

It was noted that following the May 2009 meeting no agreement was reached on granting marketing authorisations for 1 product following the decentralised procedure. It was consequently referred to CMDv pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60 day referral procedure.

Product discussion July 2009

In July 2009, 9 products reached day 78 of the mutual recognition procedure and a further 3 products reached day 198 of the decentralised procedure. Out of these, 11 were discussed.

	MRP	DCP	Referrals
<i>Procedures</i>	9	3	2
Products	9	3	1
Immunological	0	1	0
Pharmaceutical	9	2	1
Discussed	8	3	1

It was noted that following the June 2009 meeting no agreement was reached on granting marketing authorisations for 1 product following the decentralised procedure. It was consequently referred to CMDv pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60 day referral procedure.

Product discussion September 2009

In September 2009, 8 products reached day 78 of the mutual recognition procedure and a further 4 products reached day 198 of the decentralised procedure. None of these needed discussion.

	MRP	DCP	Referrals
<i>Procedures</i>	10	5	1
Products	8	4	1
Immunological	1	0	0
Pharmaceutical	7	4	1
Discussed	0	0	0

It was noted that following the July 2009 meeting no agreement was reached on granting marketing authorisations for 3 products following the mutual recognition procedure. They were consequently referred to CMDv pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60 day referral procedure.

Change of EU Council Presidency

The Presidency of the European Council changed on 1 July 2009.

The June 2009 meeting was the last under the Czech Republic Presidency of the Council of the European Union. CMDv is grateful to Ms. Iveta Obrovská for her work as vice-chairperson during the first half of 2009.

As Sweden assumed the EU presidency from July to December 2009, Ms. Alenoosh Abedi will be the new vice-chairperson of CMDv during this term.

Informal meeting

In the framework of the presidency of the European Union Sweden will organise an Informal CMDv meeting and joint CMDv/CMDh meeting in Uppsala on 5th and 6th October to broadly discuss subjects of current interest. Among the items scheduled for discussion include:

- Rules of procedures;
- Product Index;
- Transparency policy;
- Variations Regulation with regard to grouped variations and worksharing procedures;
- SPC harmonisation project;
- Review of the veterinary pharmaceutical legislation;
- MUMS / limited markets;
- Electronic dossier submission.

Information

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

For further information, please contact the secretariat at the European Medicines Agency, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK cmdv@emea.europa.eu .