Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

EMA/CMDv/710433/2009
London, 1st December 2009

REPORT FOR RELEASE

Period: October - November 2009

New Variations Regulation

Transition period

Applicants are reminded that Variations Regulation (EC) No 1234/2008 will apply to submissions as of 1st January 2010. Applicants have to make sure that **all** national competent authorities involved in the procedure will receive the applications submitted according to Regulation (EC) No 1084/2003 before 1st January 2010. The date of receipt of the application by the Reference Member State is the crucial date.
A Question & Answer is now available on the CMDv website (http://www.hma.eu/163.html) to address the transition period and answer general questions in relation with the implementation of Regulation (EC) No 1234/2008.
In order to ease the transition, the CMDv **strongly recommends** not submitting any variation intended to be handled according to Regulation (EC) No 1084/2003 after 15th December 2009.

Best practice guides

Variations' applications for Type IA, IB and Type II have been updated in accordance to the new regulation. Furthermore, best practice guides for work-sharing and grouping applications have been respectively finalised.

BPG004 Variations Type IA;
BPG005 Variations Type IB;
BPG006 Variations Type II;
BPG016 Variations grouping;
BPG018 Variations work sharing.

All documents are now available for reference on the CMDv website: http://www.hma.eu/163.html.

Disagreement in procedures - Referral Art. 33(1) to CMDv

The procedure to be followed in case of disagreement between Member States in a Mutual Recognition or Decentralised procedure, a type II variation or those variations (including groupings) that are subject to the work-sharing procedure, has been updated in accordance with the new Variations Regulation.

The updated document is available on the CMDv website: http://www.hma.eu/165.html

E-submission guideline

A guidance document has been developed for those companies wishing to submit their dossiers for marketing authorisations electronically from 1 January 2010.
It should be noted that electronic submissions are not mandatory.
(http://esubmission.emea.europa.eu/tiges/vetesub.htm)

Fees' requirements in the Member States

The CMDv website has been updated to include links to all National Authorities' respective web pages on national fee requirements (http://www.hma.eu/161.html).

Questions and Answers

Answers were reviewed with reference to the following subjects:

- Protection period;
- SPC improvements of generic products;
- Application for a fixed combination;
- Efficacy and/or safety issues in accordance with GLP principles;
- Abridged (generic) application for an antibiotic injection.

All questions are available on the CMDv webite: http://www.hma.eu/49.html.

Product discussion

October 2009

In October 2009, 2 products reached day 78 of the mutual recognition procedure and a further 4 products reached day 198 of the decentralised procedure. Out of these, 2 were discussed.

	MRP	DCP	Referrals
Procedures	*2*	*4*	*3*
Products	2	4	3
Immunological	1	0	0
Pharmaceutical	1	4	3
Discussed	1	1	0

It was noted that following the September 2009 meeting agreement was reached on granting marketing authorisations for all products discussed.

November 2009

In November 2009, 3 products reached day 78 of the mutual recognition procedure and a further 6 products reached day 198 of the decentralised procedure. Out of these, 2 were discussed.

	MRP	DCP	Referrals
Procedures	*4*	*6*	*0*
Products	3	6	0
Immunological	0	0	0
Pharmaceutical	3	6	0
Discussed	1	1	0

It was noted that following the October 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.

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 .