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

London, 27 January 2010

REPORT FOR RELEASE

Period: December 2009 – January 2010

Product discussion December 2009

In December 2009, eight products reached day 78 of the mutual recognition procedure (MRP) and a further seven products reached day 198 of the decentralised procedure (DCP).

	MRP	DCP	Referrals
Procedures	8	14	0
Products:	8	7	0
Immunological	1	0	0
Pharmaceutical	7	7	0
Discussed	1	4	0

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

Product discussion January 2010

In January 2010, two products reached day 78 of the MRP and a further five products reached day 198 of the DCP. An Article 33(1) referral concerning a paracetamol containing oral solution for pigs reached day 60 of the CMDv procedure. The discussion was cancelled because the applicant accepted the CMS proposal to modify the claim.

	MRP	DCP	Referrals
Procedures	2	11	1
Products:	2	5	1
Immunological	0	0	0
Pharmaceutical	2	5	1
Discussed	2	3	0

Following the December 2009 meeting, no agreement was reached on granting marketing authorisations for three products: one DCP and two MRPs. The grounds for potential serious risk were as follows: microbiological quality of a premix (public health), insufficient ERA data (environmental grounds) and failure to demonstrate bioequivalence (animal health). The procedures were consequently referred to CMDv pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60-day referral procedure.

Update and Advice to Applicants

Workplan

The 2010 CMDv Workplan was adopted in January.

This year the CMDv will focus on:

- Implementation of the Best Practice Guides for variations and integrating experience gained of the new Variations Regulation;
- Harmonisation of CMDv and QRD (Centralised Procedure) product information templates;
- SPC harmonisation project (conversion of national to MRP status), in conjunction with initiatives by the Agency and CVMP to reduce the number of referrals;
- Transparency measures;
- Possible measures to increase availability of veterinary medicinal products (VMPs) for smaller markets, as well as reviewing issues associated with multi-lingual packaging.

Marketing authorisation applications (MAAs)

Applicants are reminded that application dossiers should be presented in accordance with the new Annex I to Directive 2001/82/EC, which is contained in Directive 2009/9/EC.

Variations

The European Commission has published procedural guidance and a classification guideline for variations submitted under Regulation (EC) No 1234/2008 on the website of DG Enterprise:
http://ec.europa.eu/enterprise/sectors/pharmaceuticals/better-regulation-variations-regulations-developments_en.htm

The new variation application form can equally be accessed from the Commission website and should be used (even though the form has 'draft' written on it). The link to the new variation application form from the Notice to Applicants website is provided below:
http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/eudralex/vol-2/upd/variation_form_2009-12.doc

Applicants may find it useful to refer to a 'Questions and Answers' section on the CMDh website regarding submission of variations according to Regulation (EC) 1084/2003:
http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Variations/CMDh-132-2009-Rev1-Clean_2010_01_Q_A_variation.pdf

ERA 'closed' file concept

The CMDv has received several questions from industry on the possibility of submitting environmental risk assessments (ERAs) in the form of a 'closed' master file, in a similar procedure to that for the confidential part of an active substance master file. The CMDv has concluded that this is not possible and a Q&A will be published on the CMDv website. Further guidance on ERAs can be found in the Notice to Applicants, Volume 6C: 'Guidance on the assessment of environmental risks of Veterinary Medicinal Products (June 2009)'.

Multiple ('duplicate') applications

The application for multiple marketing authorisations for an identical medicinal product with a different name by the same or a different marketing authorization holder is possible (applicants may find it helpful to refer to the CMDh 'Recommendations on multiple applications in mutual recognition procedure'). However, it is clear that the submission of multiple marketing authorisation applications should not lead to the circumvention of Community legislation i.e. applications being handled outside the principles of mutual recognition. Applicants are recommended to check the legality of their approach, before submitting such applications.

E-submission

Applicants are advised that the structure of dossiers for electronic submission should be in accordance with the TIGes vet e-submission guideline (http://esubmission.ema.europa.eu/tiges/vetesub.htm).
Information on the current situation for the veterinary and combined agencies in relation to e-readiness for veterinary submissions is available on the HMA website: http://www.hma.eu/285.html

Consequences of a Commission decision following a referral to the CVMP

The CMDv reminded that Commission decisions, which are taken following a Community referral, request Member States that are directly concerned by the referral procedure to comply with the Community decision within 30 days of its notification. Marketing authorisation holders are urged to take appropriate steps necessary to allow the Member States to comply with the Community decision within 30 days after its notification, for instance by timely provision of any necessary translations.

Change of EU Council Presidency

The Presidency of the European Council changed on 1 January 2010. As Spain assumed the EU presidency from January to June 2010, Ms. Carmen Sanchez Martinez will be the new vice-chairperson of CMDv during this term. The December 2010 meeting was the last under the Swedish Presidency of the Council of the European Union. CMDv is grateful to Ms. Alenoosh Abedi for her work as vice-chairperson during the second half of 2009.

Organisational issues

The European Medicines Agency appointed the new CMDv Secretary, Mrs. Emily Drury, who began CMDv duties on 1st December 2009.

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@ema.europa.eu.