

London, 08 April 2010

REPORT FOR RELEASE

Period: February - March 2010

February 2010 product discussions

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

	MRP	DCP	Referrals
Procedures	11	2	0
Products:	8	2	0
Immunological	0	0	0
Pharmaceutical	8	2	0

It was noted that, following the January 2010 meeting, agreement was reached on the granting of marketing authorisations (MAs) for all products discussed.

March 2010 product discussions

Three products reached day 78 of MRP and a further five products reached day 198 of DCP.

	MRP	DCP	Referrals
Procedures	3	8	3
Products:	3	5	3
Immunological	0	0	0
Pharmaceutical	3	5	3

CMDv referral procedures

It was noted that, following the February 2010 meeting, no agreement was reached on the granting of marketing authorisations for three products following the mutual recognition procedure. 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.

Three CMDv referrals concluded in March 2010. One referral, involving a premix for medicated feeding stuff containing amoxicillin for use in pigs, was resolved early as the applicant was able to satisfy the objecting CMS by providing further commitments with regard to microbiological quality and stability data. The other referral, involving duplicate applications for a generic ivermectin oral solution for sheep, was resolved after the applicant was able to satisfactorily resolve the outstanding issues on environmental risk assessment and bioequivalence.

Update and Advice to Applicants

Variations Regulation

CMDv continues to discuss the practical implementation of the new variations regulation (1234/2008) and to exchange the experience gained by Member States with regard to classification and grouping. A link is included from the CMDv website to regularly updated Q&As on the CMDh website. CMDv is currently collecting information on status of acceptance by Member States of the variation regulation for national procedures.

In March, following a question from industry, it was discussed that it is possible for applicants to group a single Type IA variation affecting several Marketing Authorisations owned by the same Marketing Authorisation Holder involving different Concerned Member States.

Notice to Applicants

CMDv is currently undertaking a parallel exercise with CMDh to propose a list of requested updates to the Notice to Applicants, which will shortly be sent to the European Commission. CMDv noted that the European Commission has launched a public consultation on the veterinary Notice to Applicants Volume 6B – Presentation and content of the dossier:

http://ec.europa.eu/enterprise/newsroom/cf/newsbytheme.cfm?displayType=consultation&tpa_id=129&lang=en

Active Substance Master File procedure for biologicals

CMDv has discussed the non-applicability of the Active Substance Master File (ASMF) concept to biological active substances and the EDQM decision to exclude from the scope of the Certification procedure those products that have been classified as 'other biological substances' by CMDh¹. Applicants are reminded of the need to present full Part II data for those veterinary medicinal products containing biological active substances.

VMPs for use in horses

The European Commission consulted with CMDv regarding a letter requesting clarification on veterinary medicinal products for use in horses, with the following outcome: If a substance is included in the list of essential substances for the treatment of equidae, it may be used in animals of the equidae family, under the conditions set out in Article 10(3) of Directive 2001/82/EC and Regulation (EC) No 1950/2006, in particular a withdrawal period of six months. The existence of an authorisation for a veterinary medicinal product under Article 6(3) containing that substance would not result in a requirement that any animal of the equidae family treated with it is permanently excluded from the food chain.

Regulatory procedures for different spot-on presentations

CMDv members completed a survey on how applications for different spot-on presentations are best accepted by Member States from a procedural point of view. It was concluded that, currently, the majority of Member States can only accept separate marketing authorisation procedures resulting in a separate SPC for each spot-on presentation. It was acceptable to some Member States to apply separate marketing authorisation procedures resulting in a single SPC.

¹

http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Compilation_Biological_Active_Substance_non-recombinant_origin.pdf

Annual Report 2009

This report provides an overview of the work carried out by the CMDv in 2009. In summary, a large proportion of CMDv's work in 2009 involved preparatory activities required for the implementation of the new Variations Regulation (1234/2008) in January 2010. Regarding MRP and DCP application procedures, a slight decrease was noted, as illustrated in the table below.

Finalised MRPs and DCPs

	2006	2007	2008	2009
MRP products (procedures)	70 (95)	76 (88)	79 (84)	50 (57)
DCP products (procedures)	4 (3)	26 (30)	70 (89)	68 (83)
Total	74 (98)	102 (118)	149 (173)	116 (140)

However, the number of Article 33(1) referrals to CMDv increased compared to previous years. In most cases, these referral procedures facilitated the resolution of outstanding concerns from Member States. As shown in the table below, the number of referral procedures forwarded for arbitration to the Committee for Medicinal Products for Veterinary Use (CVMP) more than halved, compared to previous years.

Referral procedures to CMDv (to CVMP*)

	Reaching D60 of CMDv referral (& CVMP)			to CMDv as % of total products			to CVMP as % of total products		
	2007	2008	2009	2007	2008	2009	2007	2008	2009
MRP	4 (2)	9 (5*)	9 (1*)	5%	11%	8%	3%	6%	0,90%
DCP	3 (2)	9 (4*)	12 (2*)	12%	13%	11%	8%	6%	1,90%
Total	7 (4)	18 (9*)	21 (3*)	7%	11%	13%	4%	6%	2,80%

The increased rate of disagreements resolved during the CMDv referral procedure was a reflection of the progress made in the processing of generic applications (see table below).

Percentage rate of resolving disagreements during the CMDv referral procedure

2006	2007	2008	2009
25%	43%	50%	87%

Details of the overall tasks carried out by the CMDv in 2009 can be viewed in the Annual Report document, as published: (<http://www.hma.eu/159.html>).

Information

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

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