

London, 16 June 2010

REPORT FOR RELEASE

Period: April - May 2010

April 2010 product discussions

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

	MRP	DCP	Referrals
Procedures	9	8	0
Products:	6	5	0
Immunological	0	0	0
Pharmaceutical	6	5	0

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

May 2010 product discussions

One product reached day 78 of MRP and a further eight products reached day 198 of DCP.

	MRP	DCP	Referrals
Procedures	1	12	3
Products:	1	8	3
Immunological	1	0	0
Pharmaceutical	0	8	3

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

CMDv referral procedures

The three referral procedures discussed at the May 2010 meeting which reached day 60 of the procedure were referred to CVMP pursuant to Article 33(4) of Directive 2001/82/EC, as amended, as the outstanding concerns remained unresolved. See table below for details.

Proc. no.	Product	Active subs.	Pharm. form	Legal basis	CMS	D60	Grounds for ref.	Outcome
UK/V/0354/001/MR	Combimox lactating cow	Amoxicillin, clavulanic acid, prednisolone	Intra-mammary suspension	Art 13 generic	IE	31 May	Concern with regard to demonstration of bioequivalence in plasma & milk	Oral hearing by applicant at May CMDv. Not resolved, referred to CVMP
UK/V/0355/001/MR	Nisamox lactating cow				NL			
UK/V/0356/001/MR	Combisyn lactating cow				AT, BE, DK, FI, FR, PT, ES			

Update and Advice to Applicants

Variations Regulation

Recent discussions on groupings

CMDv has discussed how to proceed in the case of groupings submitted by applicants when the RMS and CMS disagree on the proposed grouping. Further discussion is required but it is hoped that a position can be taken on this in the coming months so that grouped applications are not delayed for long periods at validation due to discussion between the RMS and CMS. The proposal is for the RMS to take the lead in deciding on the acceptability of a grouping and to start the procedure, whilst clearing advising the applicant that no precedent is being set until such groupings are agreed by CMDv. Applicants are also advised to refer to a recently published CMDh list of acceptable/non-acceptable groupings for MRP/DCP products:

http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Variations/CMDh_173_2010_Examples_groupings.pdf

Article 5 variation classification requests

A request was submitted by a national competent authority for CMDv to provide a recommendation on the classification of a variation, according to article 5 of Regulation 1234/2008. The request was in relation to the harmonisation of product information following minor changes introduced during a repeat-use MRP. The outcome will be published shortly and it is likely that the CMDv's Best Practice Guide on the repeat use procedure will be slightly amended as a result of this discussion.

SPC harmonisation

CMDv continues to work on a procedure for SPC harmonisation. The proposed procedure comprises three steps: (1) SPC harmonisation (2) Standardisation of critical pharmaceutical characteristics of the VMP (3) Transfer of the national MAs to MRP status. This voluntary, informal procedure is product-specific and is foreseen as an alternative to referrals for originator products. The principles applied in the development of this procedure are pragmatism and no re-assessment of 'old' data in line with current guidelines. Companies interested in reducing their administrative, regulatory burden by harmonising the SPC of national MAs are invited to express interest in participating in a pilot procedure (cmdv@ema.europa.eu)

Notice to Applicants (NtA)

In April and May respectively, CMDh and CMDv each sent to the European Commission a list of topics in the NtA for which updates are requested. This need for an update was based on:

- new legislation entered into force since the latest NtA update;
- various legislative interpretations collected over time by the CMDv that would benefit from an explicit mentioning in the NtA;
- the entry into force of the Lisbon Treaty (as of 1st December 2009);
- the nomenclature used by the European Court of Justice to refer to revised legislation.

CMDv guidance

A number of the best practice guides are currently under review and should be finalised in June, for publication in July. These will be the Best Practice Guide on Type IA, IB, II and worksharing variations, ASMF, MRP, DCP and also clock-start dates until 2013. An updated version of the guidance for administration of the sunset clause is available on the website under CMDv guidance, Miscellaneous.

CMDv is also preparing a guidance document to clarify to applicants the basis for informed consent, duplicate and multiple applications, taking into account recent experience of Member States and CMDh published guidance on multiple applications. Further discussion is required.

Meetings

Informal meeting in Madrid

In the framework of the presidency of the council of the European Union, an informal CMDv meeting was held on 27-28 May in Madrid. Presentations were given on the following:

- Review of experience gained so far under the new variations regulation
- Update on HMA/CMDh task force on the availability of resources (including discussions on the procedure for 'booking' an RMS, validation time – when can RMS start procedure)
- Review of the draft CMDv SPC harmonisation procedure
- National phase (time to granting of MA, national requirements for labelling)
- CMDv contribution to future updates of the veterinary legislation

A joint session was also held with CVMP to address issues of common interest (e.g. e-submissions, MUMS, transparency).

Interest Parties meeting

An interested parties meeting was held on 21 May. The meeting was attended by IFAH Europe.

Joint CMDv-h virtual meeting

Scheduled for 10 June. Items on the agenda include duplicate applications, experience of CMD referrals, article 5 variation classification requests, ASMF for biologicals (existing authorisations).

Annex II of (centralised procedure) product information templates

A questionnaire is currently being circulated amongst Member States to establish if there is a benefit to including Annex II from the centralised procedure QRD template into the CMDv product information template. This point was also raised with IFAH during the interested parties meeting in May and IFAH will seek feedback from its members.

Checklist for validation of electronic submissions

The European Medicines Agency is developing a checklist for the validation of veterinary e-submissions and this document has been circulated to CMDv for comments, with the aim of working towards a consistent approach to validation of e-submissions by the Agency and National Competent Authorities.

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