

London, 12 November 2010

REPORT FOR RELEASE

Period: October 2010

October 2010 product discussions

Three products reached day 78 of the mutual recognition procedure (MRP) and a further one product reached day 198 of the decentralised procedure (DCP).

	MRP	DCP	Referrals
Procedures	5	1	0
Products*:	3	1	0
Immunological	0	0	0
Pharmaceutical	3	1	0

* 1 product includes all strengths submitted

It was noted that, following the October 2010 meeting, agreement was reached on the granting of marketing authorisations (MAs) for three of the four products discussed. No agreement was reached on the granting of marketing authorisations for one product following the mutual recognition procedure. This product (3 strengths) was consequently referred to the CMDv pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60-day referral procedure.

Update and Advice to Applicants

National implementation of Regulation 1234/2008 (variations regulation)

A questionnaire on the date from which Member States will apply/have applied the 'new' variations Regulation for purely national Marketing Authorisations (MAs) will be finalised and adopted during the November meeting for publication on the CMDv website.

Worksharing requests to CMDv

Background

Article 20 of Regulation 1234/2008 on variations gives the possibility for a MAH to submit the same Type IB or Type II variation, or the same group of variations affecting more than one marketing authorisation from the same MAH in one application. In order to avoid duplication of work in the evaluation of such variations, a worksharing procedure has been established under which one authority (the 'reference authority'), chosen amongst the competent authorities of the Member States and the European Medicines Agency, will examine the variation on behalf of the other concerned authorities. Purely national MAs are excluded from the worksharing procedure.

The following points should be noted when submitting a worksharing request to CMDv:

- There is a CMDv Best Practice Guide (BPG) for worksharing ([CMDv/BPG/018](#)). The information required in the pre-submission notification is contained in section 4.2 of this document. It should also be clearly identified if the MAH is proposing a grouping of variations and, if so, a justification for this grouping should be given according to the provisions of Regulation 1234/2008;

- Since the new variation regulation is not yet implemented by all Member States for purely national MAs, it is not currently possible to combine purely national and MRP/DCP MAs in a formal worksharing procedure.
- The worksharing procedure does not apply to several variations of only Type IA/IA_{IN} variations. However, it is possible to include a Type IA/IA_{IN} variation(s) with a Type IB or Type II variation, which is submitted for a worksharing procedure.
- Grouped variations can be subject to a worksharing procedure, provided that the same group of variations applies to all medicinal products concerned by the worksharing procedure. However, groups including an extension application are excluded from worksharing.
- Where the 'same' change(s) to different marketing authorisations require the submission of individual supportive data sets for each medicinal product concerned which each require a separate product-specific assessment, such changes will not benefit from worksharing.

Interested parties meeting

An interested parties meeting was held on 15th October 2010 with representatives from IFAH Europe, EGGVP and AVC. An overview of CMDv activities was provided since the last interested parties meeting in May. Items discussed at this meeting included:

- Regulatory issues: new template for product information (joint QRD/CMDv template out for consultation on EMA website¹), packaging and labelling for vaccines and diluents, impact of generics on availability of veterinary medicines;
- Exchange of assessment reports (not data) between national competent authorities to allow environmental risk assessment for older products;
- Availability of supplies for clinical trials (lack of harmonised approach concerning import and labelling requirements).

There was a request for revised/updated CMDv documents to be published in clean and track changes on the CMDv website to improve transparency. This will be done in future by the secretariat.

CMDv Q&As

Following a related question from industry, [Q&A 19/2009](#) on 'autogenerics' was updated to reflect CMDv's view that the data protection period applies equally in the case of autogenerics i.e. the MAH of the originator may not place an 'autogeneric' on the market until the relevant data protection period has elapsed for the originator, despite the fact that they own the proprietary data for the originator.

Maintenance of harmonisation at the national level following a CVMP referral and associated Commission Decision under article 34/35 of Directive 2001/82

CMDv will start work on a document addressing the national steps required to implement a Commission Decision following a referral, with a view to trying to harmonise the current approaches taken by Member States. Additionally the document will cover the transfer to MRP of purely national MAs following the finalisation of a referral procedure with a positive decision by the EC.

¹ The QRD veterinary product information annotated template has been revised following a CMDv / QRD harmonisation exercise aiming at having one common template for use across MRP/DCP/CP procedures. [The revised template is now open for external consultation to all interested parties.](#)

CMDv documents guidance

Following the planned review of documents as part of the 2010 workplan, the following were adopted in October:

- ✦ BPG-003 Repeat use procedure: adopted and sent to interested parties for a one-month consultation period;
- ✦ GUI-009 Actions after CVMP referral opinion: adopted and published in clean and track changes on CMDv website;
- ✦ BPG-009 SPC, labelling and packaging: adopted and published in clean and track changes on CMDv website;
- ✦ **NEW CMDv document:** BPG-012 Informed consent for MRP/DCP: adopted and sent to interested parties for a two-month consultation period, as this is a new CMDv document;

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