London, 9 January 2013

REPORT FOR RELEASE: Nov and Dec 2013

November 2013 product discussions

Four products reached day 90 of the mutual recognition procedure (MRP) and one product reached day 210 of the decentralised procedure (DCP). In terms of procedures, there was an equal proportion of new, mostly generic, applications (antimicrobials for use in food-producing species and a hormonal product for both food & companion species) and repeat-use mutual recognition of existing products (ectoparasiticide and analgesic for companion animals).

	MRP	DCP	Referrals
Procedures reaching D90 (MRP), 210 (DCP) or D60 (referrals)	5	1	0
Products[*]:	4	1	0

* 1 product includes all strengths and pharmaceutical forms submitted but does not include duplicate applications, which are counted separately

December 2013 product discussions

Seven products reached day 90 of MRP and four products reached day 210 of the DCP. Of the MRPs, the full applications were for immunological products and all but one of the remainder were abridged applications (generic/hybrid/informed consent) for endoparasiticides, primarily for companion animals. The DCPs were all generic applications (NSAID, coccidiostatic, anthelmintic and an immunosuppressant).

	MRP	DCP	Referrals
Procedures reaching D90 (MRP), 210 (DCP) or D60 (referrals)	10	4	0
Products[*]:	7	4	0

* 1 product includes all strengths and pharmaceutical forms submitted but does not include duplicate applications, which are counted separately

Referrals to the CMDv initiated in November [article 33(1) of Directive 2001/82/EC]

A mutual recognition procedure was referred to the CMDv at the end of November. The RMS and one of four CMSs could not reach agreement on the terms of authorisation for an antimicrobial product for use in horses not intended for human consumption. Potential serious risk to animal health (efficacy and target animal safety) was cited by the objecting CMS. This referral procedure, which started at the beginning of December, is due to conclude after the CMDv meeting in January 2014.

A decentralised procedure was referred to the CMDv in late December. The RMS and one of four CMSs could not reach agreement on the terms of authorised for an antimicrobial for use in several food-producing species. Potential serious risk to animal health (efficacy and target animal safety) was cited by the objecting CMS. This referral procedure will start in January and is due to conclude after the CMDv meeting in February 2014.

CMDv updates and advice to applicants

1. Worksharing

Marketing authorisation holders are reminded that, in view of the revised variations' Regulation, the CMDv has published an update on the procedural aspects, which should be referred to before submitting any further requests for worksharing to the CMDv. This update can be found under CMDv guidance/Variations (link). The CMDv's best practice guide on worksharing has also been amended to reflect these procedural changes (link).

Five worksharing requests were handled in November: 2 for vaccines, 1 biological and 2 pharmaceuticals. The changes involved addition of a species linked to a Commission Decision following a referral under article 34 of Directive 2001/82/EC for the reference product, new manufacturing site & consequential changes, changes to antigen manufacture and changes to titre specifications.

Seven worksharing requests were discussed in December: 2 for vaccines and 5 pharmaceuticals. The changes involved the addition of a special precaution in the SPC, change to the indication, change to conditions of antigen manufacture and a large grouping of variations to harmonise the quality part of the dossier. For the latter case, it is useful to highlight that several worksharing applications will be submitted, grouped by those Member States that have quality parameters (e.g. specifications) in common and there is a different reference authority in each case.

2. Presidency meeting Vilnius

On 21-23 October, the Lithuanian Presidency hosted an additional CMDv meeting with individual and joint sessions for the CMDv and CVMP. Agenda points for discussion during the CMDv session were:

- Agreeing the product name in MRP/DCP. The scope of the CMDv's potential work in this area will be further discussed with industry stakeholders.
- Templates for use in the DCP – a potential template for the list of questions will be further discussed and there was continued discussion on possible use of a declaration for applicants to indicate whether a detailed description of the pharmacovigilance system (DDPS) has been previously approved.
- Improving efficiency of CMDv - various internal initiatives are being taken forward by the group.
- Flexible approach to labelling. The possibility of more than one version of the labelling in MRP/DCP to accommodate national prescription status, as well as the use of pictograms was discussed. The CMDv's work on labelling will continue in 2014 within the designated working group and there will be further discussion with the CMDv's interested parties.
- Review of CMDv website. The HMA website will be updated, starting in 2014, and consequently the CMDv will review all documents that are currently published with a view to deleting any that are obsolete and identifying those documents where the content needs to be reviewed/updated.

3. Pilot on validation checklist

As mentioned in the last report for release, the CMDv is collecting feedback on the pilot use of the standard validation checklist in MRP/DCPs since 1 June 2013. A request with questions for feedback from applicants and NCAs was published on the CMDv's website under CMDv guidance/Applications (link), with responses requested by 6 January 2014.

4. Documents

4.1. High-quality national translations

Following a consultation with the CMDv's interested parties, the new best practice guide (BPG-017) on the submission of high quality translations during the national phase following day 90/210 of MR/DCP is now published on the CMDv's website (link). The document is based on the equivalent guidance from CMDh document.

4.2. GUI-001 contact points and GUI-007 list of CMDv members

These two lists showing the contact points within national competent authorities for general enquiries and the list of CMDv members have been updated to reflect changes in CMDv membership (link).

4.3. Q&A on name of a veterinary medicinal product

The CMDv has published the outcome of recent reflections on what constitutes the product name (link).

4.4. Mandate of the new working group on improvement of MRP/DCP

This document is now published on the CMDv's website (link).

5. We wish you all the best for the New Year in 2014

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

Common abbreviations used in this document

BPG	Best practice guide (CMDv)
DDPS	Detailed description of the pharmacoviligance system)
MA	Marketing authorisation
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
MS	Member State
NCA	National competent authority