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REPORT FOR RELEASE: February and March 2015

Applications for MA reaching Day 90/210 in February 2015

Three products reached day 90 of the mutual recognition procedure (MRP) and nine products reached day 210 of the decentralised procedure (DCP). All procedures except for one involved abridged applications submitted under article 13 of Directive 2001/82/EC as amended. Five products were for food-producing species and seven were for companion animals. The types of products concerned were antibacterials (five products), antiparasitics (four products), a vaccine, a neurological product and a product against congestive heart failure.

	MRP	DCP
Procedures reaching D90 (MRP), D210 (DCP)	6	9
Products* :	3	9

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

CMDv referral procedures concluding in February 2015 [article 33(1) of Directive 2001/82/EC]

None.

Applications for MA reaching Day 90/210 in March 2015

One product reached day 90 of the mutual recognition procedure (MRP) and five products reached day 210 of the decentralised procedure (DCP). Half of the procedures involved full applications. Five products were for food-producing species and one was for companion animals. The types of products concerned were a vaccine, a mineral supplement, a serum gonadotrophin, an antibiotic and a peripheral vasodilator.

	MRP	DCP
Procedures reaching D90 (MRP), D210 (DCP)	1	5
Products* :	1	5

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

CMDv referral procedures concluding in March 2015 [article 33(1) of Directive 2001/82/EC]

None.

CMDv updates and advice to applicants

1. Work sharing of variations

Nine worksharing requests were handled in February 2015. Four were for vaccines (extension of a re-test period, change in test procedure for active substance, transfer of the sterility testing) and five were for pharmaceuticals (addition of a new active substance, solvent, vial manufacturer, addition of a quality control site, increase in the solvent batch size, addition of a new shape of the container, submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability for an active substance).
Six worksharing requests were handled in March 2015. Two were for vaccines (update of the Part 2, increase in batch size of the final bulk, additional sterilisation method, harmonisation of specifications) and four were for pharmaceuticals (alternative manufacturing site, change of manufacturing site, alteration of batch size, update of SPC and package leaflet, change of the batch testing and batch release site, change in the specification for finished product).

2. CMDv composition

The Danish Ministry of Health nominated Dr. Asbjørn Brandt of the Danish Health and Medicines Authority as the Danish representative for CMDv for a three-year mandate with immediate effect on 10 March 2014. Dr. Asbjørn Brandt`s curriculum vitae and declaration of interest has previously been forwarded to the EMA. Both documents were published on the EMA website on 10 March 2015.
Stefania Dalfrá from the Italian Authority attended the CMDv for the February meeting. Her curriculum vitae and declaration of interest has previously been forwarded to the EMA. Both documents were published on the EMA website on 17 March 2015.

3. CMDv clock start dates 2016-2017

The CMDv clock start dates 2016-2017 document was reviewed and agreed. The format was changed to one which sets out all the key dates clearly and there is less reliance on footnotes which can sometimes be overlooked.

4. CMDv Annual Report 2014

CMDv Annual Report 2014 was adopted.

5. CMDv work plan 2015

CMDv work plan 2015 was adopted. The document[1] was published on the CMDv website on 6 March 2015.

6. Luxembourg Presidency meeting

A Presidency meeting will be held under the aegis of the Luxembourg EU Presidency between 20 and 22 September 2015. The agenda of the meeting is under preparation.

7. CMDv-Industry Joint Task Force on Variations

The set-up of the CMDv-Industry Joint Task Force on Variations was decided during the CMDv-Industry workshop on variations held on 6 June 2014. After its preparation the first meeting of the Task Force was held on 6 March 2015.
The main goal of the Task Force is to reduce the administrative burden on both sides (Industry & NCAs). One of the biggest financial burdens to manage is in relation to variations. Maintaining the status quo is not sustainable until such times as the new legislation comes into force which may be during 2017 or 2018.
The proposals on which the Task Force, the CMDv and the Industry has started to work are the following:

- Reviewing the change to the name and / or the address of the MAH which is not related to the transfer of the MAH – can this be managed as a national only variation?
- Is providing the latest CEP version by a type IA notification sufficient, even if there are missing versions – particularly when submitting an annual notification?
- Is it necessary to submit full VICH stability studies on all occassions?
- Is it necessary to submit translations early in accordance with the type IB variations BPG, when these could be changed during the procedure?
- How best to remove the manufacturing site where there is no impact on product information from the dossiers?
- Is it possible to use umbrella variations for updating sections of Part II?

[1] Documents referred to in this report are linked in 12. Publications.

- Is there scope for harmonising Part II of the dossier to achieve common quality packages for nationally authorised products?

8. Proposal on a more user-friendly package leaflet

CMDv finished reviewing the package leaflet. A CMDv-QRD joint meeting was prepared for 13 April 2015 in order to explore with QRD whether the template headings and some other issues for the leaflet can be simplified within the current legislation.

The issue of copy-pasting information from the SPC to the package leaflet for veterinary products can partly be blamed on the template for the package leaflet. The use of the same headings in both documents encourages this method.

The proposal suggests for example to change headings` order and terms. Instead of using special expressions intended for healthcare professionals layman's terms should be used. The unnecessary headings should be deleted.

At the same time avoiding longer package leaflets which have already become problematic for multilingual packages.

The changes send a clearer message to the Industry that the package leaflet should be readable for the general public, and not only healthcare professionals.

QRD will discuss the CMDv proposals.

9. The use of the e-application form (eAF)

The use of eAF will be compulsory as of 1 July 2015 for the centralised procedure and from 1 January 2016 for all EU procedures. User acceptance testing is being performed, it is open for the participation of the Industry. An information campaign to Industry and to NCAs was launched (eAF communication leaflet). Current guidance documents will be updated and new ones will be created. Any proposals are welcome and should be sent to EMA. More information can be found here.

10. Revision of the BPG-005 on type IB variations

The Group made the text clear that handling of those variations which have no impact on authorised text and legibility (layout changes) are out of the scope of the BPG.

11. Nordic Packaging Conference

Nordic labelling, harmonization and availability of veterinary medicines conference was held in Copenhagen on 5 March 2015.

The Industry can take advantage of labelling work sharing in Nordic countries. Nordic guidelines have been published recently. Documents and guidance are available here.

12. Publications

Q&A 185 - New working seeds

New version was published on the CMDv website on 12 February 2015

Bee products available in Europe - rev. 8 (Updated 2015 with Estonian information)

New version was published on the CMDv website on 6 March 2015.

December 2014 - January 2015 Report for Release was published on the CMDv website on 3 March 2015

Workplan 2015 was published on the CMDv website on 6 March 2015.

Transitioning to a compulsory usage of the eAFs for Human and Veterinary procedures was published on the CMDv website on 10 March 2015.

Clarification Paper – Agreeing Product Name During the Decentralised Procedure was published on the CMDv website on 10 March 2015.

Information

CMDv documents are available on www.hma.eu/cmdv.html
For further information, please contact the secretariat at the European Medicines Agency, 30 Churchill Place, Canary Wharf, London, E14 5EU, UK; cmdv@ema.europa.eu

Common abbreviations used in this document

BPG	Best Practice Guide
CMD_v	Coordination Group for Mutual Recognition and Decentralised Procedures – veterinary
CMS	Concerned Member State
CVMP	Committee for Medicinal Products for Veterinary Use
D	Day
DCP	Decentralised Procedure
eAF	E-Application Form
EC	European Commission
EMA	European Medicines Agency
EU	European Union
HMA	Heads of Medicines Agencies
IP	Interested Parties
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedure
NCA	National Competent Authority
Ph. Eur.	European Pharmacopoeia
QRD	Working Group on the Quality Review of Documents
QWP	Quality Working Party
RMS	Reference Member State
SPC	Summary of Product Characteristics