Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

London, 13 February 2015
EMA/CMDv/84925/2015

REPORT FOR RELEASE: December 2014 and January 2015

Applications for MA reaching Day 90/210 in December 2014

Four products reached day 210 of the decentralised procedure (DCP). The majority of the procedures involved abridged applications submitted under article 13 of Directive 2001/82/EC as amended. Two products were for food-producing species and two were for companion animals. The types of products concerned were a vaccine, an antiparasitic product, a product for treatment of false pregnancy and a NSAID.

	MRP	DCP
Procedures reaching D90 (MRP), 210 (DCP)	0	4
Products*:	0	4

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

CMDv referral procedures concluding in December 2014 [article 33(1) of Directive 2001/82/EC]

None.

Applications for MA reaching Day 90/210 in January 2015

Nine products reached day 210 of the DCP. Five procedures involved full applications, four abridged applications submitted under article 13 of Directive 2001/82/EC as amended.
Half of the products were for food-producing animals and half of them were for companion animals.
The types of products concerned were antiparasitics (2), vaccines (3) and others (not antibacterials).

	MRP	DCP
Procedures reaching D90 (MRP), 210 (DCP)	0	9
Products*:	0	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 January 2015 [article 33(1) of Directive 2001/82/EC]

None.

CMDv updates and advice to applicants

1. Work sharing of variations

Eleven worksharing requests were handled in December 2014. Four were for API combinations involving changes in their specifications; two were for APIs (ASMF update, change of API

manufacturing); three were for vaccines (change of batch size, multiple changes) and two were for pharmaceuticals (change in the description of the pharmaceutical form, change of test parameters, multiple changes).
Three worksharing requests were handled in January 2015 for two products. One was for a vaccine (specification changes) and two were for a pharmaceutical product (change of API manufacturer, change of the manufacturing process).

2. CMDv work plan 2015

There was a detailed discussion on CMDv work plan 2015. The work plan reflects also the Commission's proposal for a new veterinary regulation. The main focus points are for 2015:

- Gaining interpretation on the revised legislative proposals from CMDv`s EC liaison in order to consider their potential impacts;
- Maximising resources across the network to help achieve harmonisation and consistency of approach in procedures;
- Introducing efficiencies in processes and procedures;
- Liaison with industry stakeholders, working parties and other regulatory bodies; working together to resolve issues;
- Consideration of issues submitted by the Member States, or by industry (via the website or communication with the Secretariat), for discussion and formal resolution;
- The appointment of an elected vice-chair and developing associated tasks;
- Contributing to the Heads of Medicines Agencies objectives as set out in strategic plan, particularly in the areas of increasing product availability and reduction of burdens.

3. Vice chair decision

The Group agreed to have an elected vice chair who would provide support in the management of the tasks of the Group. The new position of elected vice chair made necessary the modification of CMDv Rules of Procedures. The modification was discussed and adopted. The modified version was discussed at the HMA meeting in Riga. After HMA endorsement the modified Rules of Procedures need an EC approval also.

4. Questionnaire on CMDv position on the functional pictograms/standard terms/abbreviations as proposed in an IFAH-EU document

CMDv has now gone as far as it can go regarding further pictograms. This was largely down to national legislation, which Member States would not be changing ahead of the implementation of the new legislative proposals. What CMDv accepted is stated in the October – November 2014 Report for Release and in the CMDv Clarification Paper on Pictograms. The work undertaken to date will be picked up again when the legislative proposals progress further and concrete suggestions have been obtained around the Commissions proposed pictogram catalogue.

5. Proposal on a more user-friendly package leaflet

CMDv is reviewing the package leaflet and will explore with QRD whether the template headings 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.
The changes to the layout of the package leaflet are mainly aimed at making it easier to find the important information, putting the most important information first and the administrative information last. 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.

6. CMDv answer to question from the industry

The Group first discussed the question related to the use of new working seeds in 2002-2003.
The CMDv opinion has not changed since 2003, but some Member States requested minor modifications. The Q&A document was adopted which is briefly: "A routine change in a working seed which does not change any of the specifications of the final product may be dealt with as a notification, if required, and no data are to be provided during the notification process. Member States that request the protocols of a new working seed for batch release will ask the marketing authorisation holder to submit this information in the submission for official batch release of the first batch using the new working seed in the respective countries."
The Question & Answer document was published on the CMDv website on 12/02/2015.

7. Autogenous Vaccines

The CMDv Autogenous Vaccines Working Group terminated its first round of work on the definitions. During the last WG meeting the members agreed on definitions and on proposals for live and inactivated vaccines. These proposals have been endorsed by the CMDv and presented to HMA.

8. Detailed Description of the Pharmacovigilance System (DDPS) declaration

The aim of the declaration is to avoid repeated assessment of the same DDPS in subsequent application procedures. CMDv agreed to move from the 12 month pilot phase to a permanent phase from January 2015 and to expand the use to all procedure types where use of a DDPS is appropriate (i.e. for new products, not for variations). Applicants are further encouraged to make use of the declaration. The modified DDPS declaration and the modified guidance document are available on the CMDv website.

9. QP declaration template and its guidance document

The QP declaration template and its guidance document were adopted and published on the EMA website.

10. Veterinary user guidance on e-submission

The HMA adopted a roadmap on e-Submissions on 01/10/2014. The use of e-application form (eAF) will be compulsory for centrally authorised products from July 2015, but from January 2016 it will be compulsory for all EU procedures. The e-submission user guidance for human products is under renewal. Such guidance does not exist for veterinary medicinal products. In the light of the new situation it is necessary to provide a guidance document containing technical instructions. The human guidance was a document owned by the Commission. The CMDh took over the document from the Commission and it will update the document. There was an agreement for waiting for the human guidance update so CMDv will need to elaborate only veterinary specific aspects.

11. Pharmacovigilance variation classification

The January-February 2014 Report for Release was updated and adopted regarding the pharmacovigilance variation classification C.I.3.
Quotation from the January-February 2014 Report for Release:
"It has been identified that variation classification C.I.3 on changes in the product information intended to implement changes related to pharmacovigilance now refers specifically to human medicinal products although the overarching heading of C.I applies to both human and veterinary medicinal products. The CMDv agreed that this remains the most appropriate classification for such variations to VMPs and it should continue to be used on the veterinary side."
The sentence in the January-February 2014 Report for Release for national procedures:
"However, the Type IA_{IN} classification under C.I.3 is only applicable to changes in the national version of the product information submitted in the Member State whose NCA assessed the PSUR"
was changed for a new sentence:
„However, the Type IA_{IN} classification under C.I.3 is only applicable to changes that have already been approved by the concerned authorities, i.e.:

- changes in the national version of the product information submitted in the Member State whose NCA assessed the PSUR,
- changes in the harmonised product information for MRP/DCP authorised products that have been agreed between RMS and CMS during PSUR assessment."

12. The use of European Reference Product

CMDv has previously advised applicants that when citing the European Reference Product within a generic application, that they should use the Member State who has authorized that product as the Reference Member State (RMS). During its recent meetings the CMDv has extended this advice to also include situations where the proposed reference product (same marketing authorization holder, same qualitative and quantitative composition) is authorized in many member states but with differing SPCs. The CMDv advice is that applicants, when citing the most advantageous SPC within their generic application, use as the RMS the Member State who has authorized that SPC.

13. ASMF WS procedure

The pilot of the ASMF worksharing procedure would be extended for another year in order to gain more experience in the pre- and post-authorisation steps as none of the procedures where there are ASMFs currently under the WS had finalised.
CMDv adopted the extension.

14. Meeting with Interested Parties in January 2015

A meeting took place between the CMDv and their established Interested Parties on 16 January. Amongst the topics on the agenda were:

- **Update on the Joint CMDv-Interested Parties Task Force on Variations**
  The composition of the task force was noted and agreed. It was agreed that the first meeting should be face to face, with subsequent meetings taking place electronically or via teleconference. It was, however, agreed to retain the option of further face to face meetings if required and would be of benefit.
- **Update on pictograms/labelling, package leaflet**
  See under points 4 and 5.
- **Update on Duplicate Applications BPG**
  See under point 15.
- **Update on CESP / E-submissions**
  A presentation was given to the meeting outlining a few key points following the technical validation workshop, on electronic signatures and the use of CESP. It was noted that a paper is being developed by the change management board regarding electronic signatures in order to provide clarity over their purpose and requirements. It was also noted that the use of CESP submissions has been increasing with 4.7% of the total volume relating to the Veterinary Sector.
- **Update on tables of additional national requirements provided by IFAH-Europe and EGGVP**
  The two summary documents provided by EGGVP and IFAH-Europe had been annotated with Member State views. In some cases the reported practices were outdated and some Member States positions had now changed. Other comments provided clarity as to why the requirement was in place.
  The Interested Parties will now review these documents and will make a single combined document.
- **DDPS Declaration Template**
  The Interested parties noted that the relevant documents have been published on the CMDv website and were encouraged to raise awareness of this option with its membership. Also see under point 8.
- **Mock Ups – Feedback on IFAH-Europe letters**
  It was agreed during the meeting that both sides could do more to improve the current situation and also that both sides have a responsibility to review their processes within the constraints of the current legislation. Applicants should advise the RMS and CMSs of the need

for joint / multi lingual labelling early in the process and not at the end. It was noted that this point will continue to be discussed at future Interested Parties meetings.

- **Fees - Feedback on IFAH-Europe letters and any general fees and invoicing points**
  CMDv has no real influence on national fee regimes. It was recognised that changing the timing over when fees are due might be difficult. One possible option that Member States could consider was put forward – in Ireland and Belgium deposits could be lodged with the bank. Therefore when applications are submitted and fees are required in advance then the appropriate sums can be taken from the account.

15. Publications

Packaging 'blue-box' requirements and additional information on labelling/package leaflet for products authorised via national, mutual recognition, decentralised or centralised procedures

New version was published on the CMDv website on 30/01/2015.

DDPS declaration

New version was published on the CMDv website on 30/01/2015.

Instructions for use of DDPS declaration template

New version was published on the CMDv website on 30/01/2015.

GUI-010 Duplicate applications in MRP-DCP

New version was published on the CMDv website on 30/01/2015.

GUI 003 email use

New version was published on the CMDv website on 15/12/2014.

BPG-003 The Repeat Use Procedure

New version was published on the CMDv website on 15/12/2014.

October – November Report for Release was published on the CMDv website on 30/01/2015.

Recommendations for classification of unforeseen variations according to article 5 of Commission Regulation (EC) 1234/2008

New version was published on the CMDv website on 30/01/2015.

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

API	Active Pharmaceutical Ingredient
ASMF	Active Substance Master File
BPG	Best Practice Guide
CESP	Common European Submission Portal
CMD_h	Coordination Group for Mutual Recognition and Decentralised Procedures – human
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
DDPS	Detailed Description of the Pharmacoviligance System
eAF	E-Application Form
EC	European Commission
EGGVP	European Group for Generic Veterinary Products
EMA	European Medicines Agency
ERP	European Reference Product
EU	European Union
IFAH-Europe	International Federation for Animal Health Europe

IP	Interested Parties
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedure
NCA	National Competent Authority
NSAID	Nonsteroidal anti-inflammatory drug
NtA	Notice to Applicants
PSUR	Periodic Safety Update Report
QP	Qualified Person
QRD	Working Group on the Quality Review of Documents
RMS	Reference Member State
SPC	Summary of Product Characteristic
WG	Working Group
WS	Work Sharing