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

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# REPORT FOR RELEASE: October and November 2014

## October 2014 product discussions

Eight products reached day 90 of the mutual recognition procedure (MRP) and seven 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. All – except one – were for food-producing species. The types of products concerned were antibacterials (approx. 30 %), antiparasitics (approx. 20 %), and others (e.g. vaccine, analgesic).

| | MRP | DCP | Referrals |
|---|---|---|---|
| **Procedures** reaching D90 (MRP), 210 (DCP) or D60 (referrals) | 8 | 7 | 1 |
| **Products***: | 8 | 7 | 1 |

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

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

| Proc. no. | Product | Active subs. | Legal basis of application | CMS (objecting CMS) | D60 | Grounds for ref. | Outcome |
|---|---|---|---|---|---|---|---|
| HU/V/0120/001/MR | Coglapix suspension for injection for pigs | Actinobacillus pleuropneumoniae serotype 1(strain NT3) and Actinobacillus pleuropneumoniae serotype 2(strains PO, U3, B4, SZ II) Expressing ApxI toxoid min. 28.9 ELISA unit / ml, ApxII toxoid min. 16.7 ELISA unit / ml and ApxIII toxoid min. 6.8 ELISA unit / ml | Article 33(1), Directive 2001/82/EC, as amended | AT, BE, BG, CY, CZ, DE, EE, EL, FI, HR, IE, IS, IT, LT, LV, NL, PL, PT, RO, SE, SI, SK, UK | 17.10.2014 | Quality and Clinical (efficacy) | Referred to CVMP under art. 33(4) |

## November 2014 product discussions

Five products reached day 90 of MRP and eight products reached day 210 of the DCP. The majority of the procedures involved abridged applications submitted under Article 13 of Directive 2001/82/EC.

Two thirds of the products were for companion animals.
The types of products concerned were antiparasitics (approx. 50 %), antibacterials (approx. 25 %) and others (e.g. anaestheticum).

| | MRP | DCP | Referrals |
|---|---|---|---|
| **Procedures** reaching D90 (MRP), 210 (DCP) or D60 (referrals) | 5 | 8 | 0 |
| **Products**[*]: | 5 | 8 | 0 |

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

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

None.

## CMDv updates and advice to applicants

### 1. Work sharing of variations

Four work sharing requests were handled in October. Three were for pharmaceuticals and quality-related, involving changes in the manufacturing process and introduction of a new active substance manufacturer. One of them was a vaccine and also quality-related.
Six work sharing requests were handled in November. Two were for pharmaceuticals and quality-related, involving changes in the test procedure, introduction of a new active substance manufacturer. Four were for vaccines, three of them were quality-related, involving changes in test procedures or in the manufacturing process of the active substance; one was a change in the invented name of the medicinal product.

### 2. Commission's proposal for a new veterinary regulation (EC draft proposal for legislative change of 2001/82/EC)

The CMDv noted the publication of the Commission's proposal for the new veterinary legislation. Whilst a number of clarifications will be necessary, it is understood that the discussions on the proposal will take place in the Council working groups at this stage.

### 3. Vice chair decision

The Group agreed to have an elected vice chair who would provide support in the management of the new tasks of the Group once the new veterinary regulation comes into effect and who would ensure consistency in management of the topics. The roles and responsibilities of the vice chair and the election process were discussed.

### 4. Management of post-authorisation procedures after MAH transfer

The CMDv aims to develop a general document which provides help to applicants in managing the transfer of the marking authorisation from one legal entity to another. Pharmacovigilance is an area that needs to be considered particularly if the resulting authorisation is held by two or more different holders in the MSs. Work on this document will re-start in January 2015.

### 5. Detailed Description of the Pharmacovigilance System (DDPS) declaration pilot phase - extension to scope and permanency

The aim was to avoid repeated assessment of the same DDPS in subsequent application procedures. The pilot phase which started in January 2014 for new DCPs has achieved its goals (reduction of resource requirements, administrative burden and number of questions). It had also been supported and welcomed by Industry. 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). The proposal was endorsed by HMA on

26-28/11/2014. Applicants are further encouraged to make use of the declaration. The documents are available on the CMDv webpage.

### 6. Harmonisation of Part II for purely nationally authorised products

The CMDv briefly discussed the feasibility of harmonising Part II of the dossier for purely nationally authorised products by means of a single Type II variation. This had previously been suggested at CMDv-IFAH-Europe workshop on variations. It is thought that this might be a mechanism for reducing workload and administrative burden for both NCAs and Industry. It was agreed to discuss this possibility within the joint CMDv/Industry task force on variations (see point 12 below).

### 7. Suspension/withdrawal of a GMP/CEP certificate

CMDv is working on a BPG to help enhance communications across the veterinary medicines network after a suspension/withdrawal of a GMP/CEP certificate. An initial document is expected in early 2015.

### 8. QP Declaration Template and its guidance document

CMDv has discussed the use of QP Declaration Template and its guidance document from practical aspects.

### 9. Packaging WG

Further to recent CMDv agreements on species pictograms, the CMDv started its discussions on the proposed use of functional pictograms and standard terms. NCAs' positions are being sought with the intent to provide feedback at the next meeting of the Interested Parties.
In order to achieve a consistent approach between MRP / DCP and centrally authorised procedures, the CMDv Chair is liaising with the QRD working group.

### 10. CMDv answers for questions from the industry

Article 13(2)(b) of Directive 2001/82/EC indicates that the immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. The immediate release oral solution and the immediate release oral powder are within the category of immediate-release oral pharmaceutical forms; an immediate release oral solution can therefore be a generic of an immediate release oral powder.

CMDv received a question to judge on the similarity of the qualitative and quantitative composition of different pharmaceutical forms. Applicants should be aware that CMDv is not the competent body to provide scientific advice. It is recommended that applicants seek scientific advice from the EMA.

### 11. e-Submission matters

CMDv has delegated the Estonian CMDv member to serve on the Veterinary Harmonisation Group.
Work is underway to gather information in order to have a global overview on the interpretations of E-signature existing within the EEA.

### 12. Joint CMDv/Industry task force on variations

It was agreed during the October Interested Parties meeting to establish a joint CMDv/Industry task force on variations. The objective of this task force is to consider opportunites to reduce burdens within the current legislative constraints. A number of initial proposals were put forward during the variations workshop with Interested Parties held on 6 June 2014. It is expected that membership of this taskforce will comprise a small number of representatives from the Industry and from the NCAs. It was felt that a small but focussed group would be the most efficient means to discussing these initial proposals.

### 13. National additional requirements for labelling

A single 'Blue Box' document containing national requirements for products authorized across all procedures is nearing completion. CMDv will publish the document shortly.

## 14. Meeting with Interested Parties in October

A meeting took place between the CMDv and their established Interested Parties on 10 October. Amongst the topics on the agenda were:

- The Industry stated that mock-ups and the different national payment systems contributed significantly to the administrative burden. It was noted that letters would be sent by IFAH-Europe to individual NCAs where appropriate asking them to reconsider their positions. CMDv asked the Industry to present concrete examples with regard to mock-ups to get a better feel for the scale of issue. It was also noted that often mock-ups are not correct first time, sometimes containing significant errors. The meeting was also advised that fees are under national legislation and this can take years to amend it.
- The usefulness of the validation check-list for new applications for marketing authorisation was acknowledged and therefore requested that it is extended to all types of procedures. CMDv confirmed that the checklist has already been extended to renewal procedures however it was not foreseen to extend it to variations.
- CMDv informed stakeholders about discussions on the inclusion of an implementation date for variations. Applicants are advised to give greater thought to completing the relevant section of the application form. This may be from the date of next batch of product or print run. It was not possible to be specific as the types of changes are varied with variable consequences. In cases of doubt the MAH should seek advice from the NCA.
- Tiamulin products are frequently on the market with the different expression of the strength of tiamulin (salt or free base, % expression or mg/g). Expression of strength in these cases creates ambiguity and inconsistency. There are also differences in the expression of strength between the originator and generics. CMDv pointed out that this problem could affect other products containing e.g. tylosin and doxycycline. The administrative burden and costs implied of the possible solution (update all SPCs in all MSs and for all products at the same time) are acknowledged. CMDv was seeking a pragmatic solution and asked for the opinion of stakeholders on the best way to proceed.
- The increasing level of complexity of E-submission caused by the disharmonised approach of MSs was recognised as a pending issue. Industry requested CMDv's support for a renewed commitment to a single EU portal accepted by all MSs for all procedures, without restrictions or additional national requirements.
- CMDv will provide consolidated feedback to IFAH-Europe and EGGVP in due course with regard to their comments on additional national requirements.
- The CMDv Packaging Working Group has published a clarified position with regard to the use of pictograms on the labelling of veterinary medicinal products.
  Comments/questions from the Industry were discussed:
  - The extension of use of pictograms to all immediate labels should be discussed in the context of the review of the legislation.
  - Industry wanted to keep the lines of communication with CMDv in respect of pictograms, although liaison with QRD to ensure consistency of approach with centralised procedure was noted.
  - It is important for Industry to keep own company pictograms in outer packaging materials.
  - Industry requested flexibility towards pictograms size.
  - There was a recognition from Industry that progress had been made and had probably gone as far as possible at this stage.
- Following the CMDv/Industry variations workshop on 6 June 2014, CMDv had prepared an analysis of industry proposals and an action plan.
  Work is in progress. Most issues are still under discussion at CMDv and/or need to be further discussed with EMA and CMDh. CMDv will provide detailed feedback to Industry's proposals. A dedicated Task Force will be created to continue with work (see point 12).
- The Industry presented their experience and point of view on the transfer to MRP following the positive outcome in the framework of an article 34 referral and subsequent harmonisation of SPC / Part II.

Many positive aspects were highlighted such as a harmonised SPC and harmonised quality part, smooth transition to MRP, good collaboration with RMS and the MR procedure for future submissions (fixed timelines, one dossier and one submission). However, some hurdles at national levels were encountered, especially regarding the grace period. The CMDv considered this has been a very positive experience and objectives have been reached with minimum administrative burden. Interested Parties were requested to encourage their members to go through this conversion procedure following the positive outcome of a Commission decision in the framework of article 34 referrals in order to harmonise as many products as possible before the new legislation is in place.
Some negative aspects of the current referral process were highlighted by Industry: generation of new studies (time and cost), loss of indications and species, lengthy process, only applicable to the reference product and not to generics; but these were a consequence of the referral itself and not this post referral opportunity.

## 15. Publications

CMDv/BPG/004 for Type IA Variations

New version was published on the CMDv website on 24.10.2014.

CMDv/BPG/005 for Type IB Variations

New version was published on the CMDv website on 24.10.2014.

CMDv/BPG/007 for Handling Renewals in the Mutual Recognition and Decentralised Procedure

New version was published on the CMDv website on 15.12.2014.

CMDv validation check list for renewals of veterinary medicinal products

New version was published on the CMDv website on 17.10.2014.

## 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**

| | |
|---|---|
| Art | Article |
| AVC | Association of Veterinary Consultants |
| BPG | Best Practice Guide |
| CEP | Certificate of Suitability |
| 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 |
| EC | European Commission |
| EEA | European Economic Area |
| EGGVP | European Group for Generic Veterinary Products |
| EMA | European Medicines Agency |
| EU | European Union |
| GMP | Good Manufacturing Practice |
| IFAH-Europe | International Federation for Animal Health Europe |
| IP | Interested Parties |
| LOQ | List of Questions |
| MAH | Marketing Authorisation Holder |
| MR | Mutual Recognition |
| MRP | Mutual Recognition Procedure |

MS Member State
NCA National Competent Authority
Proc. no. Procedure number
QP Qualified Person
QRD Working Group on the Quality Review of Documents
QWP Quality Working Party
Ref. Referral
RMS Reference Member State
SPC Summary of Product Characteristic
VMRI Veterinary Mutual Recognition Information
WG Working Group