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

London, 6 July 2012

REPORT FOR RELEASE: May and June 2012

May 2012 product discussions

3 products reached day 90 of the mutual recognition procedure (MRP) and 5 products reached day 210 of the decentralised procedure (DCP).

	MRP	DCP	Referrals
Procedures reaching D90 (MRP), 210 (DCP) or D60 (referrals)	3	7	0
Products*:	3	5	0
Immunological	0	0	0
Pharmaceutical	3	5	0

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

June 2012 product discussions

9 products reached day 90 of the MRP and 9 products reached day 210 of the DCP.

	MRP	DCP	Referrals
Procedures reaching D90 (MRP), 210 (DCP) or D60 (referrals)	9	9	0
Products*:	9**	6	0
Immunological	0	0	0
Pharmaceutical	9	6	0

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

** There were originally 12 MRPs reaching Day 90 in June but a line extension for 3 duplicates was withdrawn

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

The details of the three referral procedures that started in April and were finalised in June are summarised in the table below:

Proc. no.	Product	Active subs.	Legal basis Directive 2001/82	CMS (objecting CMS)	D60	Grounds for ref.	Outcome
HU/V/0115/001/MR	CEVAC IBD 2512 L avian infectious bursal disease vaccine for chickens	Live IBD Virus, Strain Winterfield 2512, G-61	Article 13(4) 'biosimilar'	ES, IE, IT, NL, PT, UK	21.06.12	Potential serious risk to animal health: concerns on quality and safety	Agreement reached
CZ/V/0110/001/DC	Strenzen 500/125 mg/g powder for use in drinking water for pigs	Amoxicillin Clavulanic acid	Article 13(1) 'generic'	AT, DK, FR, DE, IE, IT, NL, PT, ES, UK	29.06.12	PSR to the environment: ERA considered incomplete	Applicant attended for oral hearing. No agreement reached; procedure referred to the CVMP under article 33(4) of Directive 2001/82/EC
NL/V/0164/003/DC	Melosolute 40 mg/ml solution for injection for cattle, pigs and horses	Meloxicam	Article 13(3) 'hybrid'	AT, BE, CZ, DE, DK, ES, FR, HU, IE, IT, PL, & UK	29.06.12	PSR to animal health: bioequivalence not accepted for one target species	No agreement reached; procedure referred to the CVMP under article 33(4) of Directive 2001/82/EC

CMDv updates and advice to applicants

1. Variations

1.1. May worksharing applications

Four new informal worksharing procedures were discussed, all involving variations to the quality part of the dossier (Part II) for vaccines/biologicals.

1.2. June worksharing applications

One new informal worksharing procedure for a vaccine was discussed involving addition of an active substance manufacturer.

1.3. General advice on worksharing variations

Please note that according to the CMDv Best Practice Guide on variation worksharing (BPG 018-002), the applicant should propose a National Competent Authority (NCA) to act as the reference authority and it is recommended that the applicant discusses the worksharing procedure, including the proposed classification and eventual grouping, as well as the timeframe for submission, with this NCA before sending the pre-submission notification to the CMDv.

If the proposed worksharing involves an update to the active substance master file, all individual changes should be specified because otherwise this can result in a delay whilst the CMDv asks for clarification from the applicant.

1.4. Future handling of variations to remove the TABST for vaccines

During the 142nd session of the EU Pharmacopoeia Commission in April 2012, 73 monographs were revised for inactivated and live vaccines for veterinary use, with the aim of harmonising the technical requirements to align them with VICH GLs 41 and 44. Further to this, the CMDv is discussing a harmonised approach on variations to remove the target animal batch safety test during the interim period until the updated pharmacopoeial monographs come into effect in April 2013. Once a conclusion is reached, it will be included in a future CMDv report for release.

2. Update on electronic submissions

- The CMDv receives regular feedback from the TIGes vet subgroup and the following are some useful points agreed at the May TIGes vet meeting:
- The pilot for the veterinary e-application forms is running until end of July (see CMDv March-April report for release for more details);
- The importance of being able to navigate electronically from the table of contents to the relevant section of the dossier was highlighted;
- Password protection of electronic submissions is not accepted;
- E-submissions sent via Eudralink should always be a single zip-file and the Eudralink email message should be empty i.e. there is no need for a covering email since all such information should be in the formal covering letter and it should not be necessary to file the Eudralink message.

Upon request from the TIGes vet subgroup, the CMDv is conducting a survey on the best location for the covering letter within the e-submission structure, as well as the accepted format and language of the covering letter. The outcome of this survey will be communicated in a subsequent CMDv report for release.

3. Presidency meeting in Denmark

On 31 May – 1 June, the Danish 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:

- Future of the CMDv's voluntary SPC harmonisation initiative
- Worksharing possibilities, advantages/disadvantages, possible improvements
- Simplification of labelling requirements
- The possible future landscape for marketing authorisation applications after the review of the veterinary legislation
- Discussion on better regulation of currently unregulated areas
- Improvement of the DCP

Agenda points for discussion during the joint CVMP/CMDv session were:

- Farming practices in Denmark
- Transparency and the publication/release of documents
- Update from the CVMP/CMDv task force on SPC harmonisation and referrals
- Assessor training
- Update on the review of the veterinary legislation

4. Development of veterinary guidance on release of information supporting a marketing authorisation following a request for access to documents

The general principles and specific guidance on the identification of commercially confidential information (CCI) and protection of personal data (PPD) within the structure of the marketing authorisation application are finalised and published on the human side:

- HMA/EMA Principles to be applied for the implementation of the HMA/EMA Guidance on the identification of CCI and PPD in MA Applications (link to published version)
- HMA/EMA guidance document on the identification of commercially confidential information and personal data within the structure of the marketing authorisation (MA) application - release of information after the granting of a MA (link to published version)

It should be noted that the above published guidance is very much based on a MA dossier presented in human CTD-format and, for this reason, and taking into account veterinary specific issues, equivalent guidance is being prepared on the veterinary side, in a collaboration between the CMDv and EMA. Once a first draft has been prepared, it is foreseen to hold a public consultation with veterinary stakeholders. The comments received from some veterinary stakeholders during the equivalent consultation on the human side will already be taken into account in the preparation of the first draft.

5. Update on the withdrawal of national marketing authorisations for certain anti-parasitic collars for companion animals in France

Further to the information already published on the CMDv website on this subject (link), the Member States are still in the process of refining the best approach to deal with this matter. A further update will be provided in the July CMDv report for release. If stakeholders have any urgent concerns, please contact the most relevant national competent authority.

6. May meeting of the CMDv borderline working group

Five existing products already marketed under different classifications in several Member States were discussed:

- Alpha-casozepine for use in dogs and cats
- Oral iron paste to use in piglets
- Hypochlorous acid for use in horses
- Permethrin for use in dogs
- Benzoyl-peroxide for use in dogs

The borderline working group drafted recommendations for the above products, on whether they could be considered as veterinary medicinal products (VMPs) or not. These recommendations are circulated for information to all the national competent authorities for VMPs, as well as certain colleagues from other national agencies, who have expressed interest. The recommendations are non-binding since it is clear that they do not substitute the principle laid down in the case-law of the European Court of Justice, according to which borderline products must be classified case-by-case by national authorities, subject to review by the courts and taking into account all their characteristics. It is not within the mandate of the borderline working group to engage in contact with applicants, since only requests for classification coming from NCAs are discussed.

7. Legislation working group

The CMDv finalised their proposals regarding animal welfare, environmental risk assessment, negative assessment report from the RMS during a DCP (currently there is no possibility of referral), harmonisation of older existing products, duplicate applications and very general principles concerning the authorisation of antimicrobials. These proposals have been submitted to the European Commission for consideration within their review of the veterinary legislation.

8. Improving the DCP

The CMDv is starting discussions on practical ways to improve the functioning of the DCP, given that the new veterinary legislation is still some way off coming into effect. An example of a possible improvement would be the introduction of an additional, earlier CMDv discussion during DCP assessment step I. An *ad hoc* CMDv working group has been created to come up with proposed practical solutions to current problems.

9. Transfer of the contents of Volume 6A, Chapter 7 ('General information' of the Notice to Applicants to the CMDv website

As previously reported in the Jan-Feb CMDv report for release, the work is ongoing to collect the updated national information from the Member States.

The following parts within Chapter 7 will be discontinued:

- Part 1 on format of applications in the EU;
- Part 4 on the dossier check-in procedure;
- Part 6 on the national procedure after a Commission Decision on a referral.

Part 2 (languages), Part 3 (no. copies), Part 5 (specimens/samples), Part 7 (official journals), Part 8 (addresses), Part 9 (fee payment) and Part 10 (blue-box) will be reformatted and published under a designated tab on the CMDv website by the end of September 2012.

10.CMDv interested parties meeting

In June, IFAH-Europe, EGGVP and AVC participated at the CMDv interested parties meeting and the following topics were discussed:

- Ongoing drafting of proposals to the Commission for simplification of current labelling requirements (for the review of the vet legislation);
- Request for marketing authorisations, when granted, to be provided by NCAs as Word-version documents (not PDF);
- EMA/HMA transparency policy: how to apply it to the veterinary medicines sector;
- Various points on variations e.g. frequent requests for Type II variations following repeat-use MRP; short Commission consultation on review of variation classifications (link)
- Discussion on review of the vet legislation.

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