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

London, 26 November 2012

REPORT FOR RELEASE: October and November 2012

October 2012 product discussions

Six products reached day 90 of the mutual recognition procedure (MRP) and 10 products reached day 210 of the decentralised procedure (DCP).

	MRP	DCP	Referrals
Procedures reaching D90 (MRP), 210 (DCP) or D60 (referrals)	9	9	1**
Products*:	7	8	1
Immunological	2	0	0
Pharmaceutical	5	8	1

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

** This referral was for a Type II workshared variation according to Article 20 of Regulation (EC) 1234/2008

CMDv referral procedure concluding in October (article 13 of Regulation 1234/2008)

Proc. no.	Product	Active subs.	Legal basis Directive 2001/82	CMS (objecting CMS)	D60	Grounds for ref.	Outcome
UK/V/xxxx/ WS/006 (Type II workshared variation)	Soludox 500 mg/g powder for use in drinking water for pigs (UK/V/0349/ 001/DC) and chickens (UK/V/0141/ 001/DC)	doxycycline	Article 13(1) 'generic'	AT, CZ, DE, EE, EL, FI, FR, IT, LV, NL, SK	18.10.12	NL raised potential serious risk to public health regarding the proposed shortening of the withdrawal period	Applicant attended for oral hearing. No agreement reached; procedure referred to the CVMP under article 13 of Regulation (EC) 1234/2008

November 2012 product discussions

Five 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)	5	17	0
Products*:	5	9	0
Immunological/biological	3	1	
Pharmaceutical	2	8	

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

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

Three DCPs and one MRP were referred to the CMDv at the end November since the Reference (RMS) and Concerned Member States (CMSs) could not reach agreement. Two of the DCPs referred were two pharmaceutical forms of the same (generic) ectoparasiticide for use in food-producing species, where the objecting CMSs identified potential serious risk to the environment. The other DCP referred was for a (generic) hormonal product for use in a food-producing species, where the objecting CMS identified potential serious risk to the environment. The MRP that was referred involves a full application for an immunological product (inactivated bacterial vaccine) for use in a companion animal species, where the objecting CMS identified potential serious risk to animal health for efficacy reasons. These four referral procedures, starting in mid-December are due to conclude after the CMDv meeting in February 2013.

CMDv updates and advice to applicants

1. Harmonised QRD/CMDv product information templates

The European Medicines Agency, the CMDv and the Quality Review of Documents (QRD) Group have revised the veterinary product information templates. This revision is due to a QRD/CMDv harmonisation exercise, resulting in one common template to be used for centralised, MRP and DCP. The template for each European language, as well as an annotated template in English, are available on both the EMA and CMDv websites (identical). However, separate implementation plans are in place for centralised and MR/DC procedures, outlining the deadline by which applicants/marketing authorisation holders should switch to the product information template v.8. The implementation plan for MRP/DCP is published on the CMDv website (document reference no. EMA/CMDv/708985/2012): link here

2. Variations

2.1. October worksharing applications

Five new informal worksharing procedures were discussed. These were for the updating of the documentation supporting a diluent for a range of vaccines; change of supplier & Ph. Eur. CEP for starting materials (vaccine); changes to test methods for control of the finished (pharmaceutical) product; change in manufacturing site for biological product and consequential changes in manufacturing process; change of assay method + impurity specification parameters for a pharmaceutical product.

2.2. November worksharing applications

One new informal worksharing procedures was discussed for addition of a control testing site + change in the sterility testing procedure for an immunological.

2.3. General advice on worksharing variations

The CMDv would like to highlight that when individual supportive data sets are required for each product concerned (thereby requiring separate product-specific assessment), such changes will not benefit from worksharing. An example would be the updating of release specifications for products authorised on a purely-national basis, which may be disharmonised across the Member States. In this case only the changes to the specifications that are common to all national Marketing Authorisations (MAs) may be submitted as a workshared variation. The other changes should be submitted on a national basis, preferably indicating in the covering letter that a worksharing procedure is running alongside the national variations so that the National Competent Authority (NCA) is aware of the full picture of variations. Applicants should keep in mind the possibility of annual reporting for Type IA variations.

3. Withdrawal of the target animal batch safety test for veterinary vaccines

As explained in the previous July-Sept CMDv report for release, each marketing authorisation holder (MAH) will inform the relevant national competent authorities (NCAs) in writing of the products for which they will withdraw the TABST and that the change will be implemented not later than 1 April 2013. After 1 April 2013, MAHs would have to submit a variation to withdraw this test (Type IA, B.II.d.1.d for deletion of an obsolete parameter in the control of the finished product).

There are exceptions to the above general rule:

- For **Porcine actinobacillosis vaccine** (inactivated) (1360) and **Porcine progressive atrophic rhinitis vaccine** (inactivated) (1361) the former TABST with 2 doses of vaccines (former Section 3-3. Safety) was kept because there was an inherent batch-dependent safety risk identified. The name of the test has been changed to 'Residual toxicity test'. The recommendation given in chapter 5.2.9 regarding body temperature was introduced in both monographs. MAHs should inform NCAs about the adaptation of the test procedures in due time.
- For **Tetanus vaccine for veterinary use** (0697) the safety test (former Section 3-3.) performed in guinea-pigs has been renamed to 'Residual toxicity test'. The test itself has not been changed. A TABST for Tetanus vaccines was not required and this has not changed.

4. Addition of a new adjuvanted diluent to a previously unadjuvanted vaccine

The CMDv carried out a questionnaire on this point and the majority view was that the addition of a new diluent containing an adjuvant to a live, previously unadjuvanted vaccine constitutes a marketing authorisation application for a new product rather than a Type II variation for addition of the new diluent.

5. Transfer of information from NtA Vol. 6A, Chapter 7 to CMDv website

Most of the general information on national matters/requirements previously maintained within Chapter 7 of Volume 6A of the European Commission's Notice to Applicants, has now been updated and transferred to the CMDv website under CMDv guidance/General Info on Licensing System. The different sections of the previous Chapter 7 are now published as individual documents, as follows:

Previous section no. and heading within Chapter 7		Updated document	Current location
1	Format for applications in the EU	The rules governing veterinary medicines products in the European Union, Vol. 6B and Vol. 6C	Notice to Applicants webpage: http://ec.europa.eu/health/documents/eudralex/vol-6/index_en.htm
2	Languages to be used for dossier, responses, variations and renewals	**CMDv GUI-28** Dossier languages: to be used for marketing authorisation applications, variations and renewals in the national, mutual recognition and decentralised procedures	CMDv website
3	No. of copies of the dossier, responses, variations and renewals	**CMDv GUI-22** Format and no. of copies of the dossier for **new** marketing authorisation applications via national, mutual recognition or decentralised procedures **CMDv GUI-23** Format and no. of copies of the dossier for **post-authorisation** applications (variations and renewals) via national, mutual recognition or decentralised procedures	CMDv website
4	Dossier check-in procedure	Discontinued	Information on automatic validation: CMDv/BPG/008
5	Specimens and samples	**CMDv GUI-30** Specimens and samples	CMDv website
6	National procedure after a Commission Decision on a referral	Discontinued	Implementation of a Commission Decision is covered by (variation) Regulation (EC) 1234/2008
7	List of official journals	**CMDv GUI-29** List of official journals (for national/European decisions on marketing authorisations)	CMDv website
8	Addresses for delivery of the dossier and subsequent correspondence	**CMDv GUI-26** Addresses for delivery of the dossier for pre- and post-authorisation procedures (paper and e-submissions)	CMDv website
9	Addresses for receipt of fees and terms for payment	**CMDv GUI-25** National authority fees: terms of payment and addresses	CMDv website
10	'Blue-box' requirements	**CMDv GUI-27** Packaging 'blue-box' requirements for products authorised via national, mutual recognition or decentralised procedures	CMDv website

Chapter 7 of Volume 6A will be removed from the Commission's Eudralex webpage but there may be a short delay and from now on, applicants should refer to the more recently updated information on the CMDv website.

6. CMDv borderline working group

A non-veterinary medicinal product (VMP) marketed to improve water quality and thereby to stabilise live vaccines administered via the drinking water was discussed. Some Member States raised concerns that, whilst no claims are made on the packaging, there is no supporting information on such products, which are intended for use with vaccines. In particular, information on possible interactions should be available to the user. Furthermore, if the water stabiliser product contains a dye to visualise the flow of water in the drinking line, this colouring agent should be mentioned in the product information of the vaccines for which it is intended to be used with.

7. Altrenogest

Following the modification of the maximum residue limit (MRL) for altrenogest in February 2012, the CMDv is able to confirm that the withdrawal periods of all national marketing authorisations for products containing altrenogest have been varied in accordance with the revised MRL. The HMA action plan on this issue is therefore completed.

8. CMDv interested parties meeting

A meeting took place between the CMDv and stakeholders (represented on this occasion by IFAH Europe and AVC) on 12 October. The points discussed were as follows:

- Report from IFAH-Europe on issues arising during discussions with NCAs on simplification of authorisation procedures (1-1-1 concept);
- Encouraging MAHs to use the CMDv procedure to lift purely-national MAs to mutual recognition status after a positive Commission Decision for an article 34 referral procedure;
- General update on the outcome of the CMDv's pilot, voluntary SPC harmonisation project;
- Update on the preparation of veterinary guidance on redacting MAA dossiers for access to document requests (in progress and there will be a formal consultation with stakeholders);
- Location of the covering letter within e-submissions (the CMDv had been asked to collect the views of MSs in the context of a discussion within the TIGes[1]-vet group).

9. CESP

The CMDv received an update on the latest developments regarding the Common European Submission Platform (CESP) and noted the new website for this initiative. The CESP is an initiative under the remit of the Heads of Medicines Agencies (HMA), whereby a group of agencies and industry representatives are investigating the feasibility of a submission platform for MRP, DCP and national procedures. The pilot is available to all participating Member States and MAHs for both human and veterinary 'live' submissions. To access to the new system users must register using the "Registration" link at http://cesp.hma.eu.

Online training sessions are scheduled each month and are published in the announcement section of the new site. A number of training videos have also been developed, which are available to download through the FAQ section under the training category of the new site. These videos can be downloaded as a single zip file or individual files and require the adobe flash player to be installed on the PC. If you have any questions on the setup of your organisation please email cesp@hma.eu.

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

MA	Marketing authorisation
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
MS	Member State
NCA	National competent authority

[1] **T**elematics **I**mplementation **G**roup for **e**lectronic **s**ubmission and ICH Implementation (TIGes)