London, 12 October 2012

REPORT FOR RELEASE: July and September 2012

July 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)	7	14	1
Products*:	6	10	1
Immunological	1	0	0
Pharmaceutical	5	10	1

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

September 2012 product discussions

Five products reached day 90 of the MRP and 8 products reached day 210 of the DCP.

	MRP	DCP	Referrals
Procedures reaching D90 (MRP), 210 (DCP) or D60 (referrals)	11	9	0
Products*:	5	8	
Immunological	0	0	
Pharmaceutical	5	8	

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

CMDv referral procedures in August (article 13 of Regulation 1234/2008)

A Type II variation submitted via DCP was referred to the CMDv at the end of August since the Reference Member State (RMS) and Concerned Member States (CMSs) could not reach agreement. Potential serious risk to public health was raised by one CMS relating to the proposed change to the withdrawal period. The Type II variation was submitted as a worksharing procedure involving two generic antimicrobial products [authorised according to the provisions of article 13(1) of Directive 2001/82/EC]. The referral is due to conclude after the October CMDv meeting.

CMDv updates and advice to applicants

1. Organisational

The CMDv member from the Netherlands will act as Vice-Chair of the CMDv during the second half of 2012. The CMDv Vice-Chair also takes on the role of Chair of the CMDv's working group on document management. A number of the CMDv's guidance documents are currently under revision.

2. Variations

2.1. July worksharing applications

Two new informal worksharing procedures were discussed for vaccines/biologicals, for the addition of in indication and for a change in the specification of the active ingredient.

2.2. September worksharing applications

Five new informal worksharing procedures were discussed. These were for harmonisation of release specifications for a pharmaceutical product; change of manufacturer for a biological product; change in the diluent of a vaccine, replacement of a vaccine potency test and addition of a claim for a vaccine.

2.3. General advice on worksharing variations

Please note that according to the updated 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.

2.4. Revised 'Variation Regulation'

Commission Regulation 712/2012 amending EC Regulation 1234/2008 on variations to marketing authorisations comes into force on 2 November 2012, with the exception of points (10), (15), (18)(a) and (c), (21), (22) and (23) of Article 1, mostly relating to the inclusion of products authorised on a purely-national basis within the scope of the variation Regulation, which shall apply from 4 August 2013. The provisions entering into force on 2 November relate to the Commission timeframe for issuing a Decision on centrally authorised products, as well as a change to the submission of unforeseen variation requests (article 5). The CMDv's Best Practice Guide (BPG) on unforeseen (article 5) variations is being updated accordingly and will be re-published (in track changes) in November. The BPG on worksharing will also be updated to reflect the revised scope of the Regulation.

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

The requirement for the target animal batch safety test (TABST), will be formally withdrawn from the European Pharmacopoeia, effective as of 1 April 2013. The CMDv has endorsed a proposal from IFAH-Europe on how to handle the withdrawal of the TABST during the period between the publication of the revised (general and specific) monographs on 1 October 2012 and the implementation date of 1 April 2013. In order to inform the national authorities of the omission of the TABST from the finished product control testing of their vaccines, each Marketing Authorisation Holder (MAH) will inform the relevant authorities in writing (i.e. not via variation) of:

- the products for which they will withdraw the TABST;
- the products for which the TABST will be renamed as a 'residual toxicity test', as indicated by the Ph. Eur.;
- the date at which the changes will be implemented; this will not be later than 1 April 2013.

This approach is valid for all MAHs. After 1 April 2013, a variation will be required to withdraw the TABST (Type IA, B.II.d.1.d for deletion of an obsolete parameter in the control of the finished product).

4. Mutual Recognition Procedure after finalisation of an article 34 referral procedure

After finalisation of an article 34 referral procedure with a positive European Commission Decision, subsequent variations for the product involved must be submitted via the mutual recognition procedure in order to maintain the harmonisation achieved. The CMDv has outlined a procedure to 'lift' existing national MAs to mutual recognition status (link) and MAHs can contact the CMDv via the secretariat with any questions on this procedure for their particular product. The Community Register that tracks EU referrals (including the published Commission Decision) is available here.

5. Update on monitoring of veterinary medicinal products originating from Japan for the possibility of radioactivity

In March this year, the special measures on the import of feed and food from Japan, following the accident at the Fukushima nuclear power station, were updated with the Commission's implementing Regulation (EU) 250/2012. The CMDv will shortly publish a communication summarising the background information to date, given that the current measures are expected to be applicable until 31 October 2012 and will be reviewed again at that time.

6. Usage patents

In their September meeting, the CMDv discussed the situation whereby a generic product authorised via MRP/DCP is obliged to remove an SPC claim on a purely-national basis due to the establishment of patent protection of that claim for the reference product. The CMDv would like to refer applicants/MAHs to the published guidance from the CMDh for such cases, which would equally apply on the veterinary side: link. Depending on the Member State involved, this 'carving out' of indications for generics on a national basis due to patent law can either be handled simply as a notification in writing, or as a purely-national variation.

7. CMDv referrals and regulatory database

In a joint initiative between CMDh and CMDv, a searchable database has been created to act as a 'memory' for regulatory decisions and for CMD referrals [article 33(1) of the veterinary Directive]. This **r**eferrals and **r**egulatory **d**ecisions **d**atabase will improve consistency with previous decisions taken by each group and between CMDh and CMDv. This database is for internal use by the CMDs only.

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

The communication from the CMDv to stakeholders on this subject has been updated on the CMDv website (link) to reflect that in July, the CMDv sent a request for advice to the Committee for Medicinal Products for Veterinary Use (CVMP) on the most appropriate approach to use in the user safety risk assessment of flea collars containing dimpylate (diazinon), tetrachlorvinphos or propoxur.

9. CMDv borderline working group

A document has been published on the CMDv website with contact points in each EU Member State for enquiries on the classification of 'borderline' veterinary medicinal products – link.

The Borderline WG took note of a new court case (C-308/2011) on the classification of human medicinal products. Clarification is provided on the meaning of 'medicinal product by function' and the definition of the term 'pharmacological action'.

10. Legislation working group

The CMDv finalised their proposal on simplification of current labelling requirements and this was submitted to the European Commission in July for consideration within the review of the veterinary legislation.

11.Case-law of the European Court of Justice on validation of MA applications

The CMDv took note of an infringement case (European Commission v. France - ECJ case C-145/11 - Judgment of 19 July 2012) where the Court clarified that the general purpose of validation is a conformity check of the administrative and scientific information presented in a support of a MA application. This particular case involved a medicated premix and 'top dressing' powder submitted via the DCP. During validation, the objecting CMS raised concerns on the incorporation rate in feed and route of administration, which would ultimately have prevented the authorisation of these products in that Member State. However, the Court ruled that any substantive issue can only be raised post-validation.

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