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

London, 14 May 2012

REPORT FOR RELEASE: March and April 2012

March 2012 product discussions

4 products reached day 90 of the mutual recognition procedure (MRP) and 7 products reached day 210 of the decentralised procedure (DCP).

	MRP	DCP	Referrals
Procedures reaching D90 (MRP), 210 (DCP) or D60 (referrals)	4	25	0
Products*:	4	7	0
Immunological	3	0	
Pharmaceutical	1	7	

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

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

One MRP was referred to the CMDv at the end of March since the Reference and Concerned Member States could not reach agreement. Potential serious risk to animal health was raised by one CMS relating to aspects of quality and safety. This ongoing referral procedure, due to conclude after the June CMDv meeting, involves an application for a vaccine submitted under article 13(4) of Directive 2001/82/EC (so-called 'biosimilar).

April 2012 product discussions

2 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)	2	9	1
Products*:	2	7	1
Immunological	0	0	0
Pharmaceutical	2	7	1

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

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

The details of the referral procedure finalised in April are summarised in the table below.

Proc. no.	Product	Active subs.	Legal basis	CMS	D60	Grounds for ref.	Outcome
DE/V/0132/001/DX/001 (line extension for use in pigs)	Florgane 300 mg/ml sol. for inj. for cattle and pigs	florfenicol	Article 13(3) of Dir. 2001/82/EC 'hybrid'	AT, BE,, BG, CZ, DK, EL, ES, FR, HU, IE, IT, LT, LU, NL, PL, PT, RO, SK, UK	13 April 2012	Potential serious risk to animal health: proposed posology was considered too low to guarantee the efficacy of the product.	Applicant attended for oral hearing. No agreement reached; procedure referred to the CVMP under article 33(4) of Directive 2001/82/EC

Two DCPs were referred to the CMDv at the end April since the Reference and Concerned Member States could not reach agreement. One procedure involves a generic antimicrobial for use in a food-producing species, for which the objecting Concerned Member States (CMSs) identified

potential serious risk to the environment. The other referral procedure involves a 'hybrid' [article 13(3) of Directive 2001/82/EC] non-steroidal anti-inflammatory for use in food-producing species, where the objecting CMSs identified potential serious risk to animal health for efficacy reasons. These two referrals are due to conclude after the June CMDv meeting.

CMDv updates and advice to applicants

1. Variations worksharing applications

1.1. March

One new informal worksharing procedure was discussed, relating to manufacturing changes to the active substance.

1.2. April

Three new informal worksharing procedures for vaccines were discussed, one for removal of the target animal batch safety test (TABST) and two for a change of potency test for certain components of the vaccines. One formal worksharing procedure was discussed, involving an indication for simultaneous use of two vaccines (same brand).

1.3. Advice on completion of the variation application form informal worksharings

For informal worksharing procedures involving only purely-national marketing authorisations (MAs), the applicant should tick the box on the variation application form for 'national authorisation', not the box for 'national authorisation in MRP' (i.e. worksharing does not elevate a purely-national MA to MRP status).

2. Update on electronic application forms

The electronic application form (eAF) for initial/extension applications is now available for veterinary applicants, as a pilot phase, with additional technical support available from the eAF service desk. Previously the pilot only allowed pharmaceutical companies to apply for variation and renewal applications on the veterinary side but from 2 May, initial veterinary applications are also accepted. The eAF can be used for central, MR/DC or national applications. Please visit the eAF website for more information.

3. Impact of national transfer of marketing authorisation holder for MRP products

The Variation Regulation [(EC) 1234/2008] does not apply to the transfer of a product between marketing authorisation holders (MAHs). Therefore transfers are handled at a national level, usually via a national variation procedure (even for MRP products). It is good practice to notify the Reference Member State (RMS) of each national transfer involving an MRP product. Furthermore MAHs should keep in mind that any changes to the Detailed Description of the Pharmacovigilance System (DDPS) resulting from a transfer of MAH for a product authorised via MRP will need to be submitted via MRP as a variation C.I.8 (which will be handled as a Type IB or a Type II depending on whether or not the DDPS has previously been assessed by a Member State).

4. Links between applicants/products for new marketing authorisation applications

Applicants are reminded to declare any existing national marketing authorisations in section 4 of the MA application form when applying for a new purely-national marketing authorisation in another or the same Member State. If existing MAs are not declared correctly, this may be considered as circumvention of MRP and the national competent authority (NCA) has an obligation to investigate if they are later made aware (e.g. by competitors) that the mutual recognition procedure could have been followed; this can have legal consequences even if the MA is already granted. In cases of doubt, applicants should discuss the matter fully with the NCA before an MA application is submitted. Further guidance on the definition of the same product or the same applicant is available

in Volume 6A, Chapter 2 of the veterinary Notice to Applicants and in the Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03).

5. 'Quick response' codes on product labelling/packaging

The CMDv continued to consider how to approach the issue of 'quick response' (QR) codes on the product packaging. The CMDv agreed that the QR code should only link to information that is in conformity with the approved SPC and not promotional in nature.

6. Legislation working group

The CMDv finalised their proposals on the simplification of current marketing authorisation procedures and on improvements in the area of generics/data protection. These proposals will be submitted to the European Commission for consideration within their review of the veterinary legislation.

7. Checking for possible updates to ATCvet codes

During the CMDv meeting in April, Germany informed that they had recently requested all MAHs to check if the ATCvet code for their products was up-to-date and if not, to submit a variation. The classification is a Type IA under A.6 in the classification GL. Please use the following link to check the most recent ATCvet index

8. CMDv as point of entry for questions to several different Member States

During the monthly CMDv meetings, it regularly becomes apparent that the same applicant has contacted several Member States in parallel with the same question - either a regulatory question or regarding a particular application/product. The CMDv is of the view that it is much more efficient for applicants to submit such questions via the CMDv secretariat to avoid duplication of work at a national level and to provide the most coherent answer to applicants. Unless it is necessary to consult with a different committee/working group in order to answer the question (usually regarding scientific points), the CMDv aims to provide an answer to the applicant after the next CMDv meeting, assuming that the question is received 3 weeks before the meeting. This allows sufficient time for a questionnaire to be circulated to all the Member States to establish the majority view on a particular question. Questions can be sent to the CMDv secretariat using the following email address: CMDv@ema.europa.eu

9. Common European Submission Platform (CESP)

The CESP is a platform designed to enable pharmaceutical companies to submit pre- and post-authorisation applications electronically to participating Member State regulators through a central hub. The proof of concept testing is currently ongoing - please see the following link on the dedicated HMA webpage, which allows applicants to register and provides information on forthcoming demonstration events.

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