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

London, 14 March 2014

REPORT FOR RELEASE: January and February 2014

January 2014 product discussions

Two products reached day 90 of the mutual recognition procedure (MRP) and 20 products reached day 210 of the decentralised procedure (DCP). The majority were abridged applications submitted under article 13 of Directive 2001/82/EC. The general picture in terms of applications submitted was that of antimicrobials and antiparasitics, with an emphasis on products intended for use in companion-animal species.

	MRP	DCP	Referrals
Procedures reaching D90 (MRP), 210 (DCP) or D60 (referrals)	2	29**	3
Products* :	2	20**	3

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

** Two procedures (involving two products) ended with a negative assessment from the RMS for which there is no possibility of onward referral to the CVMP.

CMDv referral procedures concluding in January [article 13 of Regulation (EC) 1234/2008]

Proc. no.	Product	Active subs.	Legal basis of application	CMS (objecting CMS)	D60	Grounds for ref.	Outcome
FR/V/0167/ 001/II/017	Resflor injectable solution for cattle	Flofernicol, flunixin	Type II variation	AT, BE, BG, CY, CZ, **DK**, EE, FI, **DE**, EL, HU, IE, IT, LV, LT, LU,NL, PL, PT, RO, SK, SI, ES , UK	23.01.14	Animal health (efficacy)	No agreement reached; referred to CVMP for arbitration
IE/V/0221/ 001/II/006	Ubrolexin intramammary suspension for lactating dairy cows	cefalexin, kanamycin	Type II variation	AT, BE, CY, **CZ**, DE, EE, EL, ES, FR, HU, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK, UK	23.01.14	Public and animal health (target animal safety, efficacy & residues)	No agreement reached; referred to CVMP for arbitration
UK/V/0515/ 001/MR	Genta Equine 10% solution for injection	Gentamicin sulphate	Article 13(1)[1] 'generic'	BE, **DK**, ES, IS	30.01.14	Animal health (efficacy & target animal safety)	No agreement reached; referred to CVMP for arbitration

[1] Directive 2001/82/EC, as amended

February 2014 product discussions

Five products reached day 90 of MRP and six products reached day 210 of the DCP. Most of the MRPs (8 out of 10) were repeat-use. All of the MRPs and all but one of the DCPs were abridged applications submitted under article 13 of Directive 2001/82/EC. The applications covered a range of products: anaesthetic, euthanasia, NSAID, ACE-inhibitor, antimicrobials and antiparasitics (mainly spot-ons). There was a slightly higher number of products for companion-animal species.

	MRP	DCP	Referrals
Procedures reaching D90 (MRP), 210 (DCP) or D60 (referrals)	7	11	0
Products[*]:	5	6	0

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

Referrals to the CMDv initiated in February [article 13 of Regulation 1234/2008]

One mutual recognition procedure was referred to the CMDv at the end of February. The RMS and two out of ten CMSs could not reach agreement. This product is used for disorders of the musculo-skeletal system and is indicated for use in a food-producing species. Potential serious risk to animal health (efficacy) was cited by the objecting CMSs due to their concerns that the application has not met the requirements of article 13a[2] 'well-established use', under which it was made. This referral procedure, starting in March, is due to conclude after the CMDv meeting in May 2014.

CMDv updates and advice to applicants

1. Workplan

The CMDv's workplan for 2014 is now published (link). A focal point is the working group on improvement of MRP and DCP. This includes a pilot on the use of a declaration to indicate that a detailed description of a pharmacovigilance system has been previously assessed in the EU, as well as agreeing a process to reach agreement on the product name and continued review of how to best make use of the product information template in various scenarios such as multilingual packaging and OTC/POM[3].

2. Worksharing

In view of the revised variations' Regulation, last November the CMDv published an update on the procedural aspects, which all MAHs should refer to before submitting any further requests for worksharing to the CMDv. This update can be found under CMDv guidance/Variations (link). Notably, the letter of intent should not be sent to the CMDv secretariat until the variation classification(s) and any proposed grouping have been discussed and agreed with the proposed reference authority, since it may be that changes are required. The final letter of intent can then be re-sent to the proposed reference authority, copying the CMDv secretariat.

Two worksharing requests were handled in January. The changes involved an additional presentation to a range of vaccines and the replacement of an in-process control test for an active substance used in pharmaceutical product range.

Six worksharing requests were handled in February: 5 for pharmaceuticals and 1 vaccine. All were quality-related, including change to shelf-life, change to vial stopper and changes to the manufacturing process (active ingredient and control test).

[2] Directive 2001/82/EC, as amended
[3] OTC: over-the-counter; POM: prescription-only medicine

3. Variation classification C.I.3 in classification guideline C (2013) 2804 dd. 16/05/2013

It has been identified that variation classification C.I.3 on changes in the product information intended to implement changes related to pharmacovigilance now refers specifically to human medicinal products although the overarching heading of C.I applies to both human and veterinary medicinal products. The CMDv agreed that this remains the most appropriate classification for such variations to VMPs and it should continue to be used on the veterinary side.

However, the Type IA_{IN} classification under C.I.3 is only applicable to changes in the national version of the product information submitted in the Member State whose NCA assessed the PSUR.

4. Variation to change/update an AMSF

The CMDv can support the submission of a single Type II variation under category B.I.z in case of substantial changes to the active substance master file. However it is imperative that the 'present/proposed' section of the variation application form identifies each individual change. The CMDh Q&A no. 3.4 (link) was recently updated in this respect, with input from the CMDv.

5. Pilot phase for use of the DDPS declaration

As part of efforts to reduce administrative burden and make best use of available resources, the CMDv has agreed to pilot a process to avoid repeated assessment of the same version of the Detailed Description of the Pharmacovigilance System (DDPS) and consequently try to reduce the number of questions posed on the DDPS.

A DDPS declaration form for use by applicants has been developed to facilitate this process and is available for download from the CMDv pages of the Heads of Medicines Agencies website (link).

The declaration form may be used by an applicant to notify national competent authorities (NCAs) of any previous assessment and approval of the same version of the DDPS and to allow NCAs reviewing that DDPS to decide whether it is necessary to re-assess and pose questions on the DDPS.

The CMDv is now piloting the use of the DDPS declaration form for a twelve month period for new applications submitted using the DCP. Applicants should refer to the published instructions (same link as above) and are encouraged to use the declaration form where appropriate for future applications using the DCP.

6. Interested parties

In January a meeting was held with the CMDv's interested parties, IFAH-Europe, AVC and EGGVP. The following agenda items were discussed:

- Pilot for DDPS declaration (see section 5 above);
- Reaching agreement on the product name during the DCP before the national phase;
- Additional national requirements identified by industry – CMDv to review and provide feedback;
- Pictograms on the immediate label – IFAH-Europe is developing a catalogue of species pictograms on which the CMDv was invited to comment;
- Issues identified by industry with the QRD/CMDv product information template v.8 (e.g. within the national language templates) – the comments have been forwarded to the working group on quality review of documents (QRD). N.B. the CMDv also identified some minor issues, taking into account experienced gained with the latest version of the template, which were equally sent to the QRD group for consideration.
- CMDv's template for applicants to make post-authorisation commitments (link);
- Feedback requested from the interested parties on how the oral hearing can be improved during CMDv referrals.

7. Vet contact points for ASMF EU no.

With regard to the pilot phase of the worksharing procedure for the assessment of the active substance master file (ASMF), the CMDv has published a list of contact points to request the EU/ASMF number from the relevant competent authority (link).

8. Preliminary feedback on the pilot validation checklist

In February the CMDv reviewed the feedback that has been received from a limited number of NCAs, two MAHs and from one industry association (IFAH-Europe). Based on this, the pilot phase of the CMDv's validation checklist was considered successful. Some improvements will be considered to the checklist, as well as the potential extension of its use to other procedures.

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

BPG	Best practice guide (CMDv)
DDPS	Detailed description of the pharmacoviligance system)
MA	Marketing authorisation
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
MS	Member State
NCA	National competent authority