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

London, October 2014

REPORT FOR RELEASE: July and September 2014

Appointment of new Chair of CMDv

At the July meeting Gavin Hall of the UK's Veterinary Medicines Directorate was elected by majority as the new Chair of the CMDv for a three-year term, with effect from the CMDv meeting in September. Gavin Hall thanked Esther Werner at the beginning of the September meeting for her successful tenure as the previous chair.

New members of CMDv

New members at the September meeting were Joanne Young from the UK and Beate Gasser from Austria.

July 2014 product discussions

Five products reached day 90 of the mutual recognition procedure (MRP) and fourteen products reached day 210 of the decentralised procedure (DCP). The majority of the procedures involved abridged applications submitted under article 13 of Directive 2001/82/EC. There were approximately the same numbers of products for food-producing species and companion animals. The types of products concerned were antibacterials (approx. 50 %), antiparasitics (approx. 25 %), and others (vaccines, anti-inflammatories, fungicides, a product for congestive heart failure).

	MRP	DCP	Referrals
Procedures reaching D90 (MRP), 210 (DCP) or D60 (referrals)	6	20	0
Products* :	5	14	0

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

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

None.

September 2014 product discussions

Three products reached day 90 of MRP and ten products reached day 210 of the DCP. The majority of the procedures involved abridged applications submitted under article 13 of Directive 2001/82/EC. Two thirds of the products were for companion animals.
The types of products concerned were antiparasitics (the majority) and others (e.g.: antibacterials, vaccines).

	MRP	DCP	Referrals
Procedures reaching D90 (MRP), 210 (DCP) or D60 (referrals)	4	14	1
Products* :	3	10	1

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

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

Proc. no.	Product	Active subs.	Legal basis of application	CMS (objecting CMS)	D54 (closed early)	Grounds for ref.	Outcome
UK/V/0501/001/DC	Gutal 1000g/kg premix for medicated feedingstuff	Zinc oxide	Article 13(1) Directive 2001/82/EC 'generic'	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, **FR**, HU, IE, IS, IT, LT, LU, LV, **NL**, PL, PT, RO, SI, SK	12.09.2014	Environment risk	Referred to CVMP under art. 33(4)

CMDv updates and advice to applicants

1. Worksharing of variations

Six worksharing requests were handled in July. All were for vaccines and quality-related, involving changes to in-process/control tests, removal of a preservative and update/harmonisation of Part 2.

Eight worksharing requests were handled in September for four vaccines and four pharmaceuticals. The changes were quality-related, including changes to manufacturer, specifications, test for active substance and safety-related (withdrawal period).

2. CMDv Annual report

The 2013 Annual Report had been published in July 2014.

3. Management of post-authorisation procedures after MAH transfer

Further to a survey of the Member States, it was noted that a change in marketing authorisation holder (change in legal entity) was outside the scope of the variations Regulation and should be handled on a national basis. The issue of different marketing authorisation holders was raised, however in practice few examples of this had arisen. The need to maintain a harmonised dossier was critical and clarity regarding the various Detailed Descriptions of the Pharmacovigilance System was required. A general recommendation will be prepared to harmonise practices.

4. GMP Non Compliance Issues

The CMDv is discussing the need for guidance so that it may more effectively communicate across the network in cases where non-GMP compliance issues are identified.

5. Clarification on the use of pictograms

The CMDv clarified their position with regard to the use of pictograms (LINK) for small immediate labelling, ampoules and blisters. Whilst the outer packaging requirements will be discussed separately, it is likely that a consistent approach with those pictograms printed on the immediate label, will be followed, although this will not affect any corporate branding. The following points should be noted:

- Pictograms must come from an agreed catalogue;
- Can only be used on small immediate labelling, ampoules and blisters;
- Must retain the words "For Animal Treatment Only";
- Pictogram size is 10 mm to 20 mm with caveat that the pictogram must be clear and proportionate to the label;
- Pictogram must be solid and in a colour clearly distinguished from background;
- There should be one pictogram per species;

- Requests for new pictograms for new species must be approved and not linked to the submission of an application.
- It would be possible to continue with existing pictograms that are already part of authorised products, but to change to the standardised pictogram at the next appropriate variation to ensure harmonisation.
- Further discussion or exchange on immediate label text will take place in the context of the new legislation proposals.

6. CMDv answers for questions from the industry

Further to Commission advice, it is the CMDv position that where the holder of the informed consent authorisation is different, then that authorisation is subject to its own data protection period separate from that of the reference product. This applies to any new data that is used to enhance the SPC of the Informed Consent authorisation.

In relation to a separate question on the global marketing authorisation, it was confirmed that the transfer of a more recently authorised product to a new holder would not restart the data protection period. The advice is that as there was no specific data protection applied to the newer product at the point of authorisation, then data protection cannot be created by the transfer to a new holder.

7. Implementation date of variations

The CMDv advises applicants to carefully consider the implementation date to be entered on the application form for variations, for example within six months of the acceptance of the variations or at the next product run. Advice can be sought from the national competent authorities. Applicants are reminded that for IA 'Do and Tell' notifications that the relevant change should have already been implemented.

8. E-submission

The group were informed about the new EU telematics structure. The E-Submission Change Management Board has a Veterinary Harmonisation Group which has replaced the TIGES vet group. HMA had approved the group's terms of reference. A workshop on e-submission for the national competent authorities had been proposed in the margins of the December CMDv meeting; the aim being to fully harmonise technical validation in the EU.

9. Best Practice Guides (BPGs)

The CMDv updated their BPGs for Type IA and Type IB variations (LINKS).

10. Guidance on specimens and samples

The CMDv published updated guidance on specimens and samples in July 2014 (LINK)

11. DCP Improvements Working Group

The recent review of the Decentralised Procedure concluded. In summary, given the legislative constraints, the decentralised procedure is working well and therefore no fundamental changes to the timelines or key steps are necessary. Proposed improvements were therefore limited to other initiatives; for example the use of a single validation checklist by the RMS, the use of DDPS templates to reduce the number of questions asked; and the implementation of a process for agreeing a product name during the clock stop phase.

12. Italian Presidency Meeting 22-23 September 2014

Given the publication of the Commission's proposal for a new veterinary Regulation, time was devoted to a first discussion of the possible impact on the work of the group. Further topics included

the results of autogenous vaccine survey, the follow-up to the CMDv/IFAH-Europe workshop on variations and e-submission matters.

13. Publications

The CMDv finalised the list of products authorised for bees in the EU; the list can be obtained here (LINK). The CMDv has also published its general guidance on a new procedure for applicants to agree a product name during the DCP during the clock stop phase.

The document "Appendix IV – Veterinary Medicinal Products: Terms/Abbreviations for "Batch Number" and "Expiry Date" to Be Used on the Labelling" (LINK) was published on the EMA website on the 1 August 2014.

Information

CMDv documents are available on www.hma.eu/cmdv.html
For further information, please contact the secretariat at the European Medicines Agency, 30 Churchill Place, Canary Wharf, London, E14 5EU, UK; cmdv@ema.europa.eu

Common abbreviations used in this document

BPG	Best practice guide (CMDv)
CESP	Common European Submission Portal
CMS	Concerned Member State
D	Day
DCP	Decentralised Procedure
DDPS	Detailed description of the pharmacoviligance system)
EMA	European Medicines Agency
MA	Marketing authorisation
MAH	Marketing authorisation holder
MRP	Mutual Recognition Procedure
MS	Member State
NSAID	Non-steroidal Anti-inflammatory Drug
SPC	Summary of Product Characteristic