

REPORT FOR RELEASE: May and June 2014

May 2014 product discussions

Five products reached day 90 of the mutual recognition procedure (MRP), three of which were undergoing a repeat-use MRP to add new markets. Six products reached day 210 of the decentralised procedure (DCP), two of which were duplicate applications. Approximately 90% of the procedures involved abridged applications submitted under article 13 of Directive 2001/82/EC. There was a majority of products for use in companion animal species, which primarily consisted of topical ectoparasiticides, as well as opioids, antibacterials and products for gastrointestinal disorders. The products for food-producing species were NSAIDs, an antibacterial and an antidiarrheal.

	MRP	DCP	Referrals
Procedures reaching D90 (MRP), 210 (DCP) or D60 (referrals)	6	11	1
Products * :	5	6	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 May [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/0505/001/MR	SynVet-50; 50 mg/ 2.5 ml solution for intra-articular injection for horses	Sodium hyaluronate	Article 13a Directive 2001/82/EC 'well-established use'	AT, BE, DK, FI, FR , DE, IE, IT, NL, NO, ES, SE	09.05.2014	Animal health (efficacy)	Agreement reached

June 2014 product discussions

Four products reached day 90 of MRP and 13 products (five of which were duplicate applications) reached day 210 of the DCP. Approximately one third of the products were submitted as full applications under article 12 of Directive 2001/82/EC, primarily involving vaccines. The remaining applications were submitted under article 13. The products were predominantly for use in food-producing species – the highest proportion being antiparasiticides, followed by antibacterials and then an antidiarrheal, a topical disinfectant and an anaesthetic.

	MRP	DCP	Referrals
Procedures reaching D90 (MRP), 210 (DCP) or D60 (referrals)	4	13	0
Products * :	4	13	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 June [article 33(1) of Directive 2001/82/EC]

One DCP was referred to the CMDv in June. The RMS and three out of 24 CMSs could not reach agreement. The product is indicated for use in a food-producing species as an antidiarrheal. Potential serious risk to the environment was cited by the objecting CMSs. This referral procedure, starting in July, is due to conclude after the CMDv meeting in September.

CMDv updates and advice to applicants

1. Worksharing

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

Four worksharing requests were handled in June for three vaccines and one pharmaceutical. The changes were quality-related, including changes to shelf-life, batch size and fulfilment of commitments following a previous worksharing procedure.

On 6 June a workshop on variations was held at the EMA between the CMDv and their established interested parties, IFAH-Europe, EGGVP and AVC. The view from industry was presented on the revised variations' Regulation and guideline and proposals were made to reduce the current administrative burden. CMDv members and the EMA presented the authorities' view on specific topics such as national implementation of EU referrals, worksharing and grouping. It was agreed that the CMDv would further review and consider the seven proposals from industry e.g. handling of administrative changes affecting only one CMS and how best to proceed for harmonisation/updating of Part 2 (quality).

2. Validation checklist

The checklist has been updated taking into account comments received during the pilot phase e.g. a comparative table of the SPCs for the reference product is now mentioned on page 7 of the template under optional information for CMS(s). The CMDv agreed to the continued use of the checklist and the updated version is now published ([link](#)). It is foreseen to update the CMDv's best practice guide (no. 008) on automatic validation of applications in MRP/DCP and to develop another such checklist for renewals.

3. Meeting with interested parties in May

A meeting took place between the CMDv and their established interested parties on 8 May. The topics on the agenda were:

- The CMDv's proposal to reach agreement on the product name during the DCP – see section 5 of the [Mar-Apr 14 report for release](#). Following feedback from the interested parties, the guidance will be published after the CMDv's meeting in July;
- Additional national requirements identified by IFAH-Europe and EGGVP – the CMDv is reviewing these;
- Introduction of transparent outer packaging for vaccines – the industry associations were asked to relay the information presented by the CMDv (see section 4 below) to their members, along with a request for proposals on how to practically manage the risk of light exposure for potentially photosensitive vaccines e.g. information leaflet for veterinary practices.
- QRD issues – there was a request from EGGVP for the CMDv to consider developing a template for a combined label and package leaflet. It was noted that were different interpretations of article 61¹ and that some NCAs have developed national templates/guidance for such cases. It was concluded that development of a new template would be more within the remit of the QRD group and would not be driven by the CMDv.
- National follow-up after a Commission Decision on a European referral procedure (as described in section 3 of the [Mar-Apr 14 report for release](#)).

¹ Directive 2001/82/EC

4. Transparent outer packaging for vaccines

In 2012 the CMDv extensively discussed a request to submit a variation to change from an outer carton to transparent PVC outer packaging for their vaccine ranges. The potential implications were considered, taking into account the standard phrase in the product literature for vaccines to 'protect from light', as well as modern storage conditions such as refrigerators with glass doors and permanent illumination. The agreed variation classification, B.II.e.6.a (Type IA_{IN}), stipulates that "the change does not concern a part of the packaging material, which affects the delivery, use, safety or stability of the finished product". Following consultation with the CVMP's immunologicals working party (IWP), it was considered that provision of additional stability data is not necessarily the appropriate approach in each case. It should be justified in the variation application how the above condition is fulfilled. In case the MAH cannot confirm that the abovementioned condition is met, the variation should be applied for as a default Type IB variation under the same category.

Although photostability is not considered as a mandatory test in vaccine stability studies, for those vaccines that are known to be susceptible to light, appropriate measures are necessary and this should be considered when a vaccine is intended for a market where exposure to extreme environmental factors is a realistic possibility.

5. Increased follow-up by the CMDv on EU referral procedures

In line with section 9.3, Chapter 3, Vol. 6A of the Notice to Applicants ([link](#)), MAHs are expected to engage with the CMDv regarding the required transfer of purely-national MAs to mutual recognition status after referrals in which the SPC has been fully harmonised. The first point of contact is the preferred reference Member State. It is recognised that harmonisation of the quality part of the dossier may present an obstacle but the CMDv previously developed a list of 'critical pharmaceutical characteristics' to facilitate this process – see Annex II of the CMDv's 'Recommendation for MRP after finalisation of an article 34 referral procedures with a positive decision by the EC' ([link](#)).

6. Working group on autogenous vaccines

The mandate of the CMDv's new working group on autogenous vaccines was adopted and published ([link](#)). The first task of this group will be to analyse the responses to an ongoing questionnaire on the practices in different MSs regarding regulation of autogenous vaccines.

7. QP declaration template

Earlier this year the CMDv endorsed the updated QP declaration template. Subsequently there were further amendments and the final version and associated guidance is now published on the EMA's website ([link](#)).

8. Election of the CMDv Chair

As advance information from the July CMDv meeting, on 11 July, Mr 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's next meeting in September.

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