

REPORT FOR RELEASE

Meeting of 13-14 November 2008

Dr. Esther Werner elected as chairperson

Following the end of the first three year term, elections for CMDv chairperson took place by confidential vote on 13 November 2008. Following the Rules of Procedure, the chairperson has to be elected by and amongst its members with an absolute majority. The members present at the meeting unanimously re-elected sitting chairperson Dr. Esther Werner for a second term.

Dr. Esther Werner is head of the Section Bacterial Vaccines and Immune Sera of the division Veterinary Medicine at the Paul-Ehrlich-Institut. She is a veterinarian by education and has extensive regulatory and scientific experience in pre-marketing assessment and post marketing surveillance of immunological veterinary medicinal products.

Following the election Dr. Esther Werner announced she looks forward to continue stimulating cooperation, communication and mutual trust between the Member States, to achieve a harmonised interpretation of legislation and issues of common interest, to identify and propose meaningful work sharing activities, and to deal with the tasks of the future.

National validation requirements

IFAH-Europe, a European veterinary pharmaceutical industry representative organisation, presented to CMDv earlier this year a list of national validation requirements that in their view present an unnecessary administrative burden. The Member States thus reviewed the list and concluded that a number of reported requirements had been abandoned or resolved over time. For example, not required (anymore) are by:

- Austria, France and Italy a translation of Part IA in the national language (English is accepted);
- Italy an original or certified copy of the marketing authorisation (a copy is sufficient);
- Slovakia a copy of the contract between manufacturer (responsible for batch release) and the marketing authorisation holder;
- Finland, Ireland and UK, final packaging material at day 0 of the procedure.

However, certain national requirements are still in place in some Member States, and applicants are advised to check these before submitting an application. In the mean time these Member States will review their existing national requirements in the light of national law, reducing unnecessary burdens and promoting the availability of veterinary medicinal products. Industry will be informed should more national requirements be lifted.

Unforeseen variations

CMDv agreed on a Best Practice Guide (BPG) for handling requests for recommendations for unforeseen variations in the context of Article 5 of the new Variations Regulation.

Following the publication of the Variations Regulation the European Commission will issue guidelines for the classification of variations to marketing authorisations of medicinal products. Where a proposed variation is not covered by the annexes of the Variation Regulation or the guidelines, a marketing authorisation holder can ask CMDv to issue a recommendation on its classification. CMDv will have to issue a recommendation within 45 days after receipt.

Applicants should send requests to the CMDv secretariat at the EMEA. A table of advised submission dates has been established to facilitate recommendations being discussed during the monthly CMDv meetings.

Upon receipt of a request, the secretariat will allocate a rapporteur using a rota list, establish the timetable, and distribute the request to the CMDv members and the contact points for CMDh and EMEA. The rapporteur is consequently responsible for preparing a draft recommendation, taking into consideration comments received. The final recommendation has to be adopted by an absolute majority of the CMDv members, whilst representatives from CMDh, CVMP and CHMP will be given the opportunity to express their views during the meeting. Company hearings are not foreseen.

Requests can also be addressed to CMDh, the equivalent to CMDv for human medicines, as well as to the EMEA, who will have similar procedures in place.

The BPG will be published on the CMDv website after the publication of Variations Regulation in the Official Journal of the European Union.

Transfer of trade name

A question was put to CMDv, whether the trade name of an original product may be transferred to its generic. Following a survey among the Member States it was concluded that the transfer would be possible under the condition that the name of the original product would be changed or that the marketing authorisation of the original product would be withdrawn.

Exemption from bioequivalence studies

A case was presented where an exemption for performing bioequivalence studies was requested where the reference product is a 100% powder for use in drinking water and the proposed generic a 10% solution of the same active ingredient for use in drinking water.

CMDv considered in general terms that an exemption might be applicable if the final concentration in the drinking water is the same, but that insufficient case details were available to reach a conclusion. The company was advised to seek scientific advice from the CVMP should it require an in-depth analysis of the case.

Product discussion

In November 2008, 4 products reached day 78 of the mutual recognition procedure and a further 13 reached day 198 of the decentralised procedure. Out of these, 10 were discussed at the meeting. Uniferon (Iron(III)hydroxide dextran complex) was tabled for further discussion after having been referred to CMDv in September; however, agreement could not be reached and the product was referred for arbitration to CVMP pursuant to Article 33(4) of Directive 2001/82/EC, as amended.

	MRP	DCP	Referrals
<i>Procedures</i>	4	22	1
Products	4	13	1
Immunological	3	0	0
Pharmaceutical	1	13	1
Discussed	0	10	1

It was noted that following the October 2008 meeting no agreement was reached on granting marketing authorisations for 2 products following 4 different decentralised procedures. The products were consequently referred to CMDv pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60 day referral procedure.

Information

CMDv documents are available on www.hma.eu/cmdv.html

For further information, please contact the secretariat at the European Medicines Agency, for the attention of Wim Riepma, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
wim.riepma@emea.europa.eu