

REPORT FOR RELEASE

Meeting of 19-20 January 2006

Chairperson Dr. Esther Werner announced actions to further develop the organisation of the group with regard to new regulatory requirements and to enhance efficiency. Dr. Eugen Obermayr was appointed as vice chair on behalf of the Austrian Presidency and Dr. Ilian Getchev was welcomed as an observer from Bulgaria. The group discussed several legal issues, 7 products and 17 questions from Industry and Member States.

Development of the organisation

The group decided to update the agenda structure and to optimise the communication between the members. They also adopted a work plan, presented by Dr. Esther Werner, for the development of Standard Operating Procedures (SOP). New SOP will include the following topics:

- Conflict of interest;
- Oral hearings;
- Advice on regulatory issues;
- Relationship with the Committee on Veterinary Medicinal Products (CVMP);
- Relationship with the Heads of Agencies;
- Meetings with interested parties;
- Written procedures.

It was further decided to strengthen co-operation with CVMP, in particular in the field of pharmacovigilance, and to set up a subgroup on the harmonisation of summaries of product characteristics (SPC).

Product discussion

Two applications that reached day 78 of the mutual recognition procedure were accepted. Regarding a third application certain concerns, expressed by concerned member states, remained unresolved at day 78. Four applications were discussed that had been referred to the group because there had been no consensus at day 90 (art. 33.1 of Directive 2001/82/EC as amended by Directive 2004/28/EC).

Adopted documents

The following documents were finalised:

- Rules of procedure of CMD(v);
- Best practice guide (BPG) on processing of type II variations;
- Guidance document on the situation where the product is not authorised in the reference member state.

Public documents will be made available on the website of the Heads of Agencies www.hevra.org

Answers to questions

Conclusions of CMD(v) following questions from applicants and member states:

SPC of variation applications

Applicants are encouraged to submit the SPC in the new format before finalisation of the procedure if the application has been submitted before 1 November 2005. For all applications submitted from 1 November 2005 onwards a SPC in the new format is compulsory.

Reference product outside the EEA

It was clearly stated by the European Commission that it is not allowed to use a reference a product for bioequivalence studies that is not registered in a European Economic Area (EEA) country.

Minor questions

Applicants have to answer 'minor' questions from concerned member states during the mutual recognition procedure, if they are asked to do so.

Information

For questions and further information you may contact the CMD(v) secretariat at the European Medicines Agency, for the attention of Wim Riepma, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
wim.riepma@emea.eu.int