

REPORT FOR RELEASE

Meeting of 18-19 January 2007

CMD(v) established an ad-hoc working group to find *solutions* for *diluents*. Differences between Member States' approaches regarding the handling of products including diluents can currently be a hurdle in certain mutual recognition and decentralised procedures. The working group will report by April 2007.

The working group made a swift start, as it kicked off on 18 January. There was a broad interest from Member States to participate. The working group members elected Trudy Knol from The Netherlands as chairperson and a timetable was established. It was decided that the scope of the advice would include immunological and pharmaceutical veterinary medicinal products, although most cases have been related to immunologicals. Industry will be given the opportunity to express their views, at a meeting foreseen in March.

Reflection paper on assessment of quality

The joint CHMP/CVMP Quality Working Party has produced a reflection paper on the quality assessment of generic products and of other products containing existing/ known active substances. The key question addressed in the paper is whether the quality of a generic product needs to be assessed on its own merit or in comparison with the originator product. The CMD(v) endorsed the position, as stated in the reflection paper, that in principle the quality should be assessed on the merit of the product itself. An applicant can, however, justify impurities in certain cases by submitting a comparison with the originator product.

Compliance with post authorisation commitments

During a mutual recognition or decentralised procedure, in exceptional cases, applicants can commit to conduct studies after authorisation of the product. Although there is no situation of particular concern, CMD(v) discussed how to deal with situations where a marketing authorisation holder fails to deliver or where the outcome of the studies is not satisfactory. It was concluded that:

- in case time limits cannot be met, the applicant has to inform the reference member state and the concerned member states, to discuss a possible extension;
- the outcome of a commitment can result in the need for a variation of the marketing authorisation;
- any case where a potential serious risk develops, the marketing authorisation should be suspended and the matter can be referred to CVMP;
- in principle no authorisations should be granted pending commitments that may result in a potential serious risk.

Updated Q&A documents

Two published question & answer documents have been updated. The documents concern:

- Data requirements for generic applications;
- Repeated use of the mutual recognition procedure.

Product discussion

Four products, 3 immunological and one pharmaceutical, reached day 198 of the decentralised procedure in January. One pharmaceutical product reached day 78 of the mutual recognition procedure. Out of these, 4 products were discussed. It was noted that following the December meeting agreement was reached on all 8 products by the end of the mutual recognition or decentralised procedure.

Information

Questions & answers as well as other CMD(v) documents are available on www.hevra.org

For further information please 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.europa.eu