

REPORT FOR RELEASE

Meeting of 12-13 October 2006

Policy-review for generic applications • Referrals made public • New best practice guides adopted • Survey 2005 published

Generics

Following questions from companies and input from the European Commission, CMD(v) is reviewing its policy on generic applications. The European Commission has advised in a letter to CMD(h) that concerned Member States can accept indications authorised in the reference Member State although these are not authorised for the reference product in the concerned Member State, unless there is a potential serious risk for public health. The group was informed by the European Commission that the same principle would be applicable for the veterinary sector for e.g. indications, species and withdrawal periods. CMD(v) is considering the implications, including the possibility for originator products to maintain parity with the generics. The outcome of the review exercise will be made public in due course. In the mean time the current practice will be continued.

Referrals

After consulting industry representative organisations, IFAH-Europe and EGGVP, CMD(v) decided to publish the outcome of referral procedures, including the product name, the company name and the area of disagreement.

If the disagreement is not solved during the CMD(v) referral procedure, the Member States that have approved the assessment report, summary of product characteristics, labelling and package leaflet of the reference Member State, may on request by the applicant grant a marketing authorisation without waiting for the outcome of the consequent referral procedure in CVMP. However, it was noted that granting a marketing authorisation is not possible during the CMD(v) referral procedure.

Adopted best practice guides

Adopted best practice guides will be published on www.hevra.org/vmrfq/sop.asp

Active substance master file

For well defined active substances, for which an applicant is not the manufacturer, he may arrange for an active substance master file (ASMF), to be directly supplied by the manufacturer to the competent authority. Thus the applicant can meet the requirement of providing a detailed description of the manufacturing method, quality control during manufacture and process validation.¹

CMD(v) adopted a best practice guide for the submission, validation and assessment of a ASMF.

¹ Annex I, Title I, Part 2C1 of Directive 2001/82/EC, as amended

Representative organisations

CMD(v) values dialogue with veterinary pharmaceutical industry representative organisations and other stakeholders on regulatory and procedural matters. With their input CMD(v) is able to improve the quality of its work. Quarterly meetings are therefore being held. After consulting representative organisations CMD(v) adopted a best practice guide, describing how the meetings should be handled.

Repeat use procedure

The Notice to Applicants² states that the mutual recognition procedure (MRP) may be used after completion of a first MRP or a decentralised procedure (DCP) for the recognition of a marketing authorisation by other Member States for the same veterinary medicinal product. This procedure is known as 'repeat use'. So it can be used in Member States which were not included, or where the application was withdrawn, during an earlier procedure. CMD(v) adopted a best practice guide, describing what should be done by the reference Member State, the concerned Member States and the applicant during a repeat use procedure.

Survey

The year 2005 report of the annual IFAH-Europe/CMD(v) survey on the mutual recognition procedure for veterinary medicinal products was published on 27 September 2006. The report provides statistical information and indicates the satisfaction of both industry and authorities with the conduct of procedures.

Involved companies and reference Member States described most of the procedures as acceptable to good with some excellent. Reported difficulties mainly related to the interpretation of legislation and additional national requirements. The CMD(v) was pleased to note that the average number of questions per procedure had dropped for the second consecutive year and by about 33% compared to 2004. A total of 95 procedures were finalised in 2005. This is a record since the first survey was held in 1999.

The report is available on: <http://www.hevra.org/what.asp>

Survey 2006 will include the decentralised and referral procedures.

Product discussion

In total 5 products reached day 78 of the MRP, of which 3 were discussed at the meeting. It was noted that following the September meeting 7 MRP products were approved while 2 were referred³. CMD(v) discussed one product at day 53 of the referral procedure.

Information

For questions and 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.eu.int

² Volume 6A – Chapter 2 – item 2.2

³ Article 33(1) of Directive 2001/82/EC, as amended