

London, 28 July 2006



REPORT FOR RELEASE

Meeting of 20-21 July 2006

CMD(v) discussed 4 mutual recognition procedures and dealt with questions regarding generics as well as the authorisation of pure active substances.

Generics

CMD(v) addressed the following case.

Product A is a pioneer veterinary medicinal product authorised for one target species. Some years later, a product B, identical to product A and with the same marketing authorisation holder, is authorised for another target species. Product B has a different registration number from product A.

Questions:

1. Taking into account the concept of global marketing authorisation mentioned in the Notice to Applicants (Volume 6A, Chapter 1, Section 2.3) and Article 5 of Directive 2001/82/EC as amended, is it possible for another company to make a single generic product, including both target species, using these two reference products (A and B)?
2. Is the data protection only applicable for product A?

Answers:

1. Yes, in the scenario described, it is possible to have a single generic product based on two different reference products.
2. Yes, products A and B are considered to be the same product for data protection purposes, and the data protection period will begin from the date of authorisation of product A.

Authorisation of a pure active substance

Following a question from Industry, it was confirmed that the legislation does not exclude the registration of a 100% active substance as a veterinary medicinal product. 100% active substances have been authorised in various Member States as well as through the centralised procedure.

Product discussion

In total 7 applications reached day 78 of the MRP. Out of these, 4 were discussed at the meeting, while 3 did not need to be addressed. It was noted that following the June meeting 9 MRP products were approved and 1 product (in 5 different strengths) was referred to the CMD(v)¹.

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

¹ Pursuant to Article 33 of Directive 2001/82/EC, as amended.