

REPORT FOR RELEASE

Meeting of 11-12 October 2007

Combination products

In the context of an application under article 13b the applicant may use bibliographic data, refer to data of another product with the consent of the marketing authorisation holder, as well as refer to the data of another product without the consent of the marketing authorisation holder after expiry of the data protection period.

Following a question from industry CMD(v) confirmed that the expiry of a data exclusivity period also applies in the context of article 13b (Directive 2001/82/EC) for products that contain a combination of active ingredients. Consequently the applicant can have the right to refer to data on the individual substances which have been previously authorised in the EU as veterinary medicinal products. However, this does not exclude the applicant from the obligation to substantiate the efficacy and safety of the particular combination.

Product discussion

Seven products reached day 78 of the mutual recognition procedure and 3 products day 198 of the decentralised procedure in October 2007. Out of these 5 were discussed at the meeting.

	MRP	DCP	Referrals
<i>Procedures</i>	9	4	0
Products	7	3	0
Immunological	1	0	0
Pharmaceutical	6	3	0
Discussed	3	2	0

It was noted that CMD(v) could not reach an agreement at day 60 of the CMD(v) referral procedure for Equibactin vet. (333 mg/g + 67 mg/g) Oral Paste for Horses (sulfadiazine and trimethoprim) of LeVet BV. One Member State considered the product to pose a potential serious risk to human and animal health. The matter was therefore referred to the Committee for Medicinal Products for Veterinary Use (CVMP).

Information

CMD(v) documents are available on www.hma.eu.

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