

REPORT FOR RELEASE

Meeting of 12 – 13 February 2009

Animal welfare during clinical trials

CMDv discussed how animal welfare during clinical trials comes into play during the assessment of applications of marketing authorisations.

The introduction of Annex 1 of the Directive 2001/82/EC as amended states that: “*Member States ensure that all experiments on animals are conducted in accordance with Council Directive 86/609/EEC of November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes.*”

CMDv agreed to seek clarification from the European Commission whether this statement means that:

- studies done within Member States should be done in accordance with Council Directive 86/609/EEC, or that
- all studies supporting the dossier, including those conducted in third countries, should be done in accordance with that Directive 86/609/EEC.

Clarification will also be sought from the Committee for Medicinal Products for Veterinary Use (CVMP) on the relation between Council Directive 86/609/EEC and the current guidance on the Efficacy of Anthelmintics: Specific Recommendations for Canines (VICH GL19, also known as CVMP/VICH/835/99).

Global marketing authorisation

CMDv received a clarification from the European Commission that the authorisation obtained for a generic veterinary medicinal product by a Marketing Authorisation Holder different from the holder of the reference product, does not belong to the same global marketing authorisation.

The notion of global marketing authorisation is linked to ‘the same Marketing Authorisation Holder’ in the Notice to Applicants, Volume 6A, Chapter 1, Point 2.3.

Honey bees

Following reports on declining honey bee populations in Europe and poor availability of adequate veterinary medicinal products, CMDv will prepare an overview of currently authorised products in the Member States. The overview shall be published in due course and should help honey bee professionals getting access to products not authorised in their own Member State.

Product discussion

In February 2009, 7 products reached day 78 of the mutual recognition procedure and a further 5 reached day 198 of the decentralised procedure. Out of these, 6 were discussed.

	MRP	DCP	Referrals
<i>Procedures</i>	8	5	0
Products	7	5	0
Immunological	1	0	0
Pharmaceutical	6	5	0
Discussed	3	3	0

It was noted that following the January 2009 meeting no agreement was reached on granting marketing authorisations for 2 products following the decentralised procedure. The products were consequently referred to CMDv pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60 day referral procedure.

Information

CMDv documents are available on www.hma.eu/cmdv.html

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
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