

REPORT FOR RELEASE

Meeting of 18 – 19 September 2008

Exemption for active substances not produced for pharmaceutical use

The primary use of certain substances incorporated in veterinary medicinal products may be independent of the pharmaceutical industry: for example certain vitamins, minerals and disinfectants. Where the pharmaceutical use of these substances represents an insignificant volume of business, their producers may not be aiming to meet the specific requirements of the pharmaceutical industry, i.e. compliance with GMP.

CMDv therefore agreed that in exceptional circumstances such substances may be accepted based on a declaration by the Qualified Person of the pharmaceutical manufacturer. This declaration should set out in detail the basis for declaring that the standards applied provide the same level of assurance as GMP is required.

Information on GMP requirements can be found on the EMEA website under “Inspections”:
<http://www.emea.europa.eu/Inspections/index.html>

Withdrawal does not prevent referral

Applicants are reminded that the withdrawal of an application for a marketing authorisation from a Member State will not prevent referral to CMDv or CVMP under art. 33 of Directive 2001/82/EC, as amended, in case a potential serious risk to human health, animal health or to the environment has been raised during the mutual recognition procedure or in the second phase of a decentralised procedure.

A Member State from where the application has been withdrawn will continue participating in discussions and if concerns stay regarding a potential serious risk the matter will be referred to CMDv and subsequently, if not solved during CMDv referral, to CVMP.

Teat dips, biocides or veterinary products?

Earlier this year CMDv published a Question & Answer document, outlining the Member States' policies for classifying so-called teat dips (http://www.hma.eu/uploads/media/Q_A_39_pre-dipping_requirements_-_EMEA-CMDv-164796-2007_01.pdf).

Following questions received from industry on the policies in the Member States, the European Commission reminded the Standing Pharmaceutical Committee as well as CMDv, that teat dips are to be considered biocides unless genuine medical claims are made.

Information on teat dips as biocides can be found on the website of DG Environment of the European Commission <http://ec.europa.eu/environment/biocides/borderline.htm>.

Product discussion

In September 2008, 11 products reached day 78 of the mutual recognition procedure and a further 5 reached day 198 of the decentralised procedure. Out of these, 9 were discussed at the meeting. Three referral procedures which had been referred to CMDv in July were tabled of which 1 needed further discussion. Agreement was reached on granting marketing authorisations for Pyceze and Alpha Max. However, no agreement could be reached for APPM Respipharm due to concerns raised over the quality and efficacy of the bacterial vaccine. The product was consequently referred to CVMP for arbitration pursuant Article 33(4) of Directive 2001/82/EC, as amended.

	MRP	DCP	Referrals
<i>Procedures</i>	11	7	3
Products	11	5	3
Immunological	1	1	0
Pharmaceutical	10	4	3
Discussed	4	5	1

It was noted that following the September 2008 meeting no agreement was reached on granting a marketing authorisation for one product, following the MRP. The product was consequently referred to CMDv pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60 days referral procedure.

New members

Dr. Damyan Iliev has been appointed as new CMDv member on behalf of Bulgaria, replacing Dr. Paskal Zhelyazkov.

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 wim.riepma@emea.europa.eu