

REPORT FOR RELEASE

Meeting of 12-13 July 2007

Overall the Mutual Recognition Procedure functions satisfactorily and it remains an important procedure to market veterinary medicinal products in the European Union.

These are the main conclusions of a survey over 2006, carried out in a joint effort by industry representative organisation IFAH-Europe and CMD(v). The survey also identifies areas of improvement, which CMD(v) is looking into.

For the first time EGGVP, representing generic companies, also contributed to the yearly survey. As the number of mutual recognition procedures in 2006 are equal to the previous year, the introduction at the end of 2005 of the decentralised procedure appears to be an addition to, rather than a replacement of, mutual recognition.

The full report is available on the websites of CMD(v) and IFAH-Europe.

Generics

Following the recent receipt of further guidance from the European Commission and the Heads of Medicines Agencies, CMD(v) resumed the discussion on the conditions under which Concerned Member States can accept target species, indications or (shorter) withdrawal periods as compared to the authorised reference product in their territory. The following principles have been agreed:

1. Concerned Member States accept additional indications or species, as included in the Summary of Product Characteristics of the reference product authorised in the Reference Member State.
2. There is no need for the applicant to provide its own tests to substantiate these indications or target species.
3. The assessment report of the reference product as prepared by the Reference Member State where it is authorised, should be sufficient for the Concerned Member State to accept the indications or target species.
4. Only in the case of a potential serious risk concern can additional data be requested.
5. Additional data may be requested from the Reference Member State by Concerned Member States if they have previously refused to authorise a species, indication or the product itself on potential serious risk grounds.
6. The marketing authorisation holder of a reference product who wishes to keep parity with the generic may apply for a variation or trigger an Article 34(1) referral procedure.

The practical implications will be detailed in a guidance document for the national competent authorities and a guidance document for applicants. The latter will be published in autumn 2007.

Packaging

The newly established ad hoc group for packaging established objectives and a timetable at its first meeting. Christophe Debruyne from Belgium was appointed as the Chair of this group. By November this year the group aims to present a first report for adoption at the CMD(v) plenary session. The group shall categorise in the report the issues identified, according to the level where legal action should be taken and responsible party. The report shall also include recommendations for harmonisation actions at CMD(v) and other levels. Divergent national requirements can be a source of inefficiency in the conduct of procedures and for the manufacturing of medicines.

Changing reference member state

In exceptional circumstances it may be necessary to change the Reference Member State of a product authorised through the mutual recognition or decentralised procedure. This is the case, for example, when the marketing authorisation expires in the Reference Member State.

To facilitate necessary changes, CMD(v) has adopted a position paper which has been published on the website. The paper outlines the conditions for change and provides guidance on the administrative handling. It has been agreed that Member States as well as marketing authorisation holders can request a change. Marketing authorisation holders are advised that:

- a request for a change of reference member state may not be based on scientific disagreement with a member state;
- cannot take place pending the outcome of an ongoing procedure.

Product discussion

Fourteen products reached day 78 of the mutual recognition procedure and 3 products day 198 of the decentralised procedure in July 2007. Out of these twelve were discussed at the meeting.

	MRP	DCP	Referrals
<i>Procedures</i>	20	3	1
Products	14	3	1
Immunological	4	2	0
Pharmaceutical	10	1	1
Discussed	10	2	1

Following the June meeting, no agreement could be reached on 1 product by the end of the decentralised procedure. The areas of disagreement related to the efficacy of the product. The procedure was referred to CMD(v) pursuant to Article 33(1) of Directive 2001/82/EC and a list of concerns, to be addressed by the applicant, was agreed.

For one product going through a mutual recognition procedure, the applicant decided before the end of the procedure to withdraw the application in all concerned member states as well as the marketing authorisation in the reference member state.

It was noted that CMD(v) could not reach an agreement at day 60 of the CMD(v) referral procedure for Ecomectin 18.7 mg/g oral paste for horses (*ivermectin*) of Eco Animal Health Ltd., because a Member State considered the product to pose a potential serious risk to the environment. The matter was therefore referred to the Committee for Medicinal Products for Veterinary Use (CVMP). The Committee has been requested to consider if a Phase II environmental impact assessment is required to complete the environmental risk assessment of the product and if specific risk mitigation measures should be recommended.

Change of members

Paskal Zhelyazkov was welcomed as new member from Bulgaria. Vera Franzén announced her departure as CMD(v) member, as she will be leaving the Swedish Agency.

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