

REPORT FOR RELEASE

Meeting of 15-16 May 2008

Reducing packaging costs

CMD(v) adopted conclusions and recommendations for ways to make labelling and packaging requirements more cost effective for industry.

IFAH-Europe, a veterinary pharmaceutical industry representative organisation, raised in 2006 the issue of prohibitive cost of small print runs and indicated that reducing packaging costs could enhance the availability of veterinary medicines in smaller markets.

An ad hoc CMD(v) working group was set up in 2007 to find solutions. As a result of their work the following measures have already been implemented:

- By default mock-ups containing 3 times the English language text for dossier submission will be requested, to obtain an impression of the space required for text for three different languages. In situations where more than 3 languages are envisaged, it is advised to present the worst case scenario mock ups e.g. smallest pack size;
- Templates for product information in all official EU languages as well as Icelandic and Norwegian have been developed and are available on the CMD(v) website. These templates also help to prevent differences between language packs of Member States sharing common languages;
- It is recommended that applicants contact the Reference Member State and Concerned Member State during a procedure to ensure harmonised texts if they wish to have combined packs.
- The Best Practice Guide for the Mutual Recognition Procedure, the Best Practice Guide for the Decentralised Procedure and the Best Practice Guide for the Reference Member State have been adapted in order to reflect the fact that all efforts have to be made during the procedure to agree on a harmonised label and leaflet.

Furthermore, recommendations on matters outside the remit of CMD(v) have been sent to the Heads of Medicines Agencies. After their meeting in July 2008, further recommendations will be forwarded to the European Commission with regard to proposed changes to European legislation and also to industry.

The CMD(v) trusts that as a result of this exercise hurdles have been removed and anticipates to seeing a greater number of products being authorised and available in smaller markets.

Decentralised procedure decision appeal

For the first time since the introduction of the Decentralised Procedure in October 2005, the Reference Member State and all Concerned Member States agreed unanimously at the end of a procedure not to grant a marketing authorisation.

It was noted that in case of agreement among the Member States, whether it is to authorise or not to authorise, a product cannot be referred to CMD(v) and the Committee for Medicinal

Products for veterinary use (CVMP) under article 33 of Directive 2001/82/EC (as amended). With regard to the legal recourse open to applicants to contest the refusal to grant a marketing authorisation, they may consider appealing to each national competent authority under its own national legislation.

In case a national appeal procedure overturns the refusal decision and advises the granting of a marketing authorisation, the matter may be referred by any Member State to the CVMP under article 34 of Directive 2001/82/EC (as amended), on the grounds that different conclusions could have been reached regarding its authorisation.

Product discussion

In May 2008, 12 products reached day 78 of the mutual recognition procedure and a further 3 reached day 198 of the decentralised procedure. Out of these 6 were discussed at the meeting. One referral procedures was discussed.

	MRP	DCP	Referrals
<i>Procedures</i>	12	3	1
Products	12	3	1
Immunological	3	0	0
Pharmaceutical	9	3	1
Discussed	4	2	1

It was noted that following the April 2008 all mutual procedures had been finalised successfully except one decentralised procedure.

Agreement was reached on granting marketing authorisations for:

- Tilmovet 25% (tilmicosin) from Huvepharma; and
 - Hatchpak Avinew (vaccine) from Merial;
- which had been referred to CMD(v).

However, no agreement could be reached in the referral procedures for:

- Unisol (enrofloxacin) from Universal Farma;
- Enro-K (enrofloxacin) from Laboratories Karizoo;
- Pharmasin 100% (tylosin) from Huvepharma;

due to concerns raised by Germany over the environmental risk assessment. The products were consequently referred to CVMP for arbitration pursuant to Article 33(4) of Directive 2001/82/EC.

New member

Iveta Obrovská has been appointed as new CMD(v) member on behalf of the Czech Republic, replacing Daniel Dusek.

Information

CMD(v) 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