Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

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REPORT FOR RELEASE

Meeting of 16-17 October 2008

Labelling recommendations

Following information released in May this year, the CMDv document on packaging conclusions and recommendations is now published on the CMDv website after a consultation period with HMA. These are the results of a discussion that originally started in 2006 when the need to seek ways to improve availability of veterinary medicinal products by reducing costs of labelling and packaging was highlighted by industry.
Conclusions on IFAH-Europe's proposals for labelling and packaging are listed, including proposals which are not acceptable to certain or all Member States.

CMDv recommends:

- The acceptance of a tri-lingual label as standard. Mock ups using three times the English language text are generally requested in case of multilingual packs in order to evaluate the proposal properly.
- 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. Harmonisation of all templates independent form the marketing authorisation procedure is recommended.
- It is primarily up to the applicants to highlight any problems during the procedure and come up with a proposal.
- The pharmaceutical form should be put in the neighbourhood of the name on the label but is not necessarily part of it. Product information should be an exact translation in all Concerned Member States (CMS) in case of MRP/DCP. The only possible text differences should be mentioned in the blue box requirements.
- Changes to the label after day 90/210 of the mutual recognition or decentralised procedure require the application for a variation.
- Agencies should reconsider their negative responses provided to issues accepted by most other Member States, as most of the proposals require changes to national legislation.

CMDv will monitor the follow up on the recommendations throughout 2009 and will evaluate its effectiveness around mid term next year in light of experience.

Changes to safety warnings in the SPC

Where changes are made to the SPC of the Reference Product, particularly those related to the efficacy and safety parts of the dossier, it is expected that any generic products, which rely on this data, should follow suit. Changes would normally be dealt with through variations, either nationally or through MRP, as applicable. Should the marketing authorisation holder refuse to submit the variation, the marketing authorisation may be suspended or a referral procedure initiated.

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Extension from powder to granulate: full new part II required
A full new pharmaceutical part (II) of the dossier is required for an application to extend the pharmaceutical form to a granulate for a product which is already authorised as powder.

Product discussion
In October 2008, 8 products reached day 78 of the mutual recognition procedure and a further 11 reached day 198 of the decentralised procedure. Out of these 19 products, 14 were discussed at the meeting to seek approval among the MS involved in the procedure. Tildren (tiludronic acid) was tabled for further discussion after having been referred to CMDv in August; however, agreement could not be reached and the product was referred for arbitration to CVMP pursuant to Article 33(4) of Directive 2001/82/EC, as amended.

	MRP	DCP	Referrals
Procedures	*8*	*17*	*1*
Products	8	11	1
Immunological	0	3	0
Pharmaceutical	8	8	1
Discussed	5	9	1

It was noted that following the product discussion at the September meeting no agreement was reached on granting 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 day referral procedure.

Informal meeting
At the beginning of October an informal meeting of CMDv and a CMDv joint meeting with CVMP CMDv was held in Paris. These meetings were organised by France under the French Presidency of the Council of the European Union. Issues discussed included what made CMDv successful, how can it learn from the past and what areas can be improved. The discussion stemmed from the results of the "CMDv self assessment" exercise which was carried out in the second quarter 2008 and which focused on the CMDv areas of work, as covered by the CMDv Rules of Procedure. In addition CMDv explored possible solutions of how to optimise the current agenda format, to strengthen the regulatory and scientific memory, to smoothly implement the upcoming variations regulation, to further reflect on proposals for improvements of the veterinary legislation, to review the validation requirements and to consider the liaison with pharmacovigilance.

In a joint CMDv/CVMP (Committee for Medicinal Products for Veterinary Use) meeting members exchanged views on the role of generics in the veterinary market place and explored some scientific questions in relation to bioequivalence studies.

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