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

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REPORT FOR RELEASE

Meeting of 19-20 June 2008

Variations Regulation
The new Variation Regulation is set to allocate new tasks to CMD(v), such as:
- the conduct of referrals in case of disagreement on Type II variations;
- providing recommendations on the classification of unforeseen variations;
- the organisation of work sharing.

The text of the Regulation was adopted by the Standing Committee in Brussels on 10 June 2008. Following adoption by the European Council and the European Parliament the Regulation will enter into force 20 days after publication in the Official Journal. This is anticipated to happen somewhere in the autumn of this year. The task of providing recommendations will apply immediately with the entry into force of the Regulation. Other tasks will start a year later, from autumn 2009.

CMD(v) decided to seek close cooperation with the coordination group for human medicines, CMD(h), and with the European Medicines Agency. A joint subgroup is due to start the preparatory work on 23 July 2008.

Generics guidance
A guidance document on the processing of generic applications in the mutual and decentralised procedure has been adopted and has been published on the CMD(v) website. The document has been drafted following questions from industry, issues raised by Member States and experience gained in the running of procedures. It complements existing guidance as listed below:
- Best Practice Guide for Veterinary Mutual Recognition Procedure - CMD(v)/BPG/001
- Best Practice Guide for the Decentralised Procedure - CMD(v)/BPG/002
- Standard Operating Procedure for Disagreement in Procedures – Referral to CMD(v) - CMD(v)/SOP/001
- Best Practice Guide for the Reference Member State - CMD(v)/BPG/010
- Documentation to be Submitted by a Member State When Reference Medicinal Product is Not Authorised in the Member State - CMD(v)/GUI/006

Actions after CVMP referral
CMD(v) also adopted a guidance document on the actions to be taken by Member States and industry following the finalisation of a referral to the Committee for Medicinal Products for Veterinary Use (CVMP) under Article 33 of Directive 2001/82/EC, as amended. The guidance document has been published on the CMD(v) website.

Pet rabbits
The survey into Member States' policies with regard to exemptions in their territory from the requirement to establish withdrawal periods for rabbit meat (Article 4.2 of Directive 2001/82/EC

as amended) has been finalised (see report for release April 2008). An overview of the Member States that do and do not permit exemptions will be published on the CMD(v) website. In order to avoid difficulties upon validation or later in the procedure, applicants are advised to carefully consider the list before choosing Reference and Concerned Member States.

Change of EU presidency

The June 2008 meeting was the last under the Slovenian Presidency of the Council of the European Union. CMD(v) is grateful to Ms. Katarina Štraus for her work as vice-chairperson during the first half of 2008 and in particular for the organisation of a very successful informal meeting in Slovenia.

The informal meeting was held on 26 and 27 May 2008 in Bled, Slovenia, as part of a programme of events organised under the Slovenian Presidency. CMD(v) discussed the role and the new responsibilities of the CMD(v) after revision of the Variations Regulation, the IFAH-CMD(v) Joint Survey – 2007, referrals, packaging and labelling as well as validation issues.

The main topics discussed at the joint session with the CVMP were experiences on Article 33 referrals, MRL (maximum residue limit) Regulation, withdrawal periods and pharmacovigilance issues.

As France assumes the EU presidency from July to December 2008, Ms. Sandrine Guët will be the vice-chairperson of CMD(v).

No DCP in Liechtenstein

Applicants are advised that Liechtenstein cannot be included in the decentralised procedure, pending an update of the European Economic Area agreement in line with Directive 2004/28/EC of the European Parliament and of the Council.

Applicants should note, however, that the two other non-EU EEA States, Iceland and Norway, do accept applications under the decentralised procedure. Both countries particularly invite industry to submit applications for indications where currently no authorised products are available in their markets.

Product discussion

In June 2008, 7 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. No referral procedures were discussed.

	MRP	DCP	Referrals
Procedures	*7*	*5*	*0*
Products	7	5	0
Immunological	3	0	0
Pharmaceutical	4	5	0
Discussed	5	4	0

It was noted that following the May 2008 meeting no agreement was reached on granting marketing authorisations for 4 products, one following the DCP and 3 following the MRP. The products were consequently referred to CMD(v) pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60 day referral procedure.

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