

## REPORT FOR RELEASE

Meeting of 16-17 February 2006

**The veterinary Co-ordination Group for Mutual Recognition and Decentralised Procedures accelerates its work on a list of SPCs for harmonisation. New clock start dates for the mutual recognition procedure have been established. Finished product manufacturers are obliged to ensure GMP compliance of active ingredient manufacturers. After repeat use, renewal dates will be decided on a case-by-case basis. The use of a European reference product is only possible when there is no reference product in the Member State.**

### **Harmonisation of summaries of product characteristics**

The legislation<sup>1</sup> provides for the opportunity to harmonise the Summary of Product Characteristics (SPC) of a product in the European Community. Several Member States have proposed veterinary medicinal products, containing different active substances. Based on these proposals the CMD(v) shall agree which products require harmonisation and forward a list to the European Commission. A subgroup has been established to carry out the preparatory work. The CMD(v) has endorsed the mandate for this subgroup. Safety or availability concerns were identified as selection criteria for drawing up the list.

### **Good manufacturing practice and active pharmaceutical ingredients**

Following questions about Good Manufacturing Practice (GMP) and active pharmaceutical ingredients (API) the group was briefed on the legal requirements. It was noted that:

- The holder of a manufacturing authorisation of a finished product is obliged to use only active pharmaceutical ingredients that have been manufactured in accordance with GMP. This should be ensured through audits by the finished product manufacturer.
- A declaration from the qualified person(s) of finished product manufacturers/batch release sites on GMP for active pharmaceutical ingredients is requested.
- Unannounced inspections by the Competent Authority may be carried out whenever there are grounds for suspecting non-compliance with GMP. They may also be requested by other Member States, the European Medicines Agency (EMA), the European Commission, the European Directorate for the Quality of Medicines (EDQM) or by the manufacturer itself.

More information on this subject is available at:

- <http://www.emea.eu.int/Inspections/docs/335103en.doc> (page 60-64)
- <http://www.emea.eu.int/Inspections/GMPfaqAS.html>

### **Renewal dates**

The legislation<sup>2</sup> states that a marketing authorisation shall be valid for five years, after which it may be renewed. Marketing authorisations issued after completion of Mutual Recognition and Decentralised Procedures are national authorisations. Once renewed the authorisation shall be valid for an unlimited period, unless a further renewal is justified on pharmacovigilance grounds. Several questions were raised regarding the common renewal date of mutually recognised products. It was concluded that there is no

<sup>1</sup> Article 34(2) of Directive 2001/82/EC as amended by Directive 2004/28/EC

<sup>2</sup> Article 28(3) and (4) of Directive 2001/82/EC as amended by Directive 2004/28/EC

harmonised approach at the moment and that the reference Member State, the concerned Member State and the Marketing Authorisation Holder should discuss and decide on a case-by-case basis.

### European reference product

Another question was raised whether an applicant is free to choose between a national or European reference product for a generic application. It was concluded that the use of a European reference product is only possible when there is or has been no authorised reference product in the Member State where the generic application is being made.

### Mutual recognition clock start dates

The start dates (day 0) for mutual recognition procedures have been established up to September 2007. Applicants are strongly recommended to inform the reference Member State at least 3 months in advance of an intended application.

Day 0	Day 54	CMDv	Day 90
<b>6-Apr-2006</b>	30-May-2006	23-Jun-2006	5-Jul-2006
<b>4-May-2006</b>	27-Jun-2006	21-Jul-2006	2-Aug-2006
<b>29-Jun-2006</b>	22-Aug-2006	15-Sep-2006	27-Sep-2006
<b>27-Jul-2006</b>	19-Sep-2006	13-Oct-2006	25-Oct-2006
<b>24-Aug-2006</b>	17-Oct-2006	10-Nov-2006	22-Nov-2006
<b>23-Sep-2006</b>	16-Nov-2006	15-Dec-2006	22-Dec-2006
<b>3-Nov-2006</b>	27-Dec-2006	19-Jan-2007	1-Feb-2007
<b>30-Nov-2006</b>	23-Jan-2007	16-Feb-2007	28-Feb-2007
<b>28-Dec-2006</b>	20-Feb-2007	16-Mar-2007	28-Mar-2007
<b>1-Feb-2007</b>	27-Mar-2007	20-Apr-2007	2-May-2007
<b>22-Feb-2007</b>	17-Apr-2007	11-May-2007	23-May-2007
<b>29-Mar-2007</b>	22-May-2007	15-Jun-2007	27-Jun-2007
<b>26-Apr-2007</b>	19-Jun-2007	13-Jul-2007	25-Jul-2007
<b>28-Jun-2007</b>	21-Aug-2007	14-Sep-2007	26-Sep-2007
<b>26-Jul-2007</b>	18-Sep-2007	12-Oct-2007	24-Oct-2007
<b>23-Aug-2007</b>	16-Oct-2007	9-Nov-2007	21-Nov-2007
<b>22-Sep-2007</b>	15-Nov-2007	14-Dec-2007	21-Dec-2007

### Product discussion

Three applications were discussed at day 78 of the mutual recognition procedure. Two applications were discussed for the second time following the 60 days referral procedure<sup>3</sup> and the applicants took the opportunity to explain their views in oral hearings.

One application had been referred to the CMD(v) after the January meeting and it would be scheduled for a first discussion in March 2006. It was noted that two other referred applications had been resolved after the January 2006 meeting and as a consequence a marketing authorisation could be granted in all concerned Member States.

<sup>3</sup> article 33(1) of Directive 2001/82/EC as amended by Directive 2004/28/EC

### **Adopted documents**

The following documents were finalised:

- Best practice guide (BPG) for handling of renewals;
- Best practice guide (BPG) for mutual recognition procedures;
- Best practice guide (BPG) for the processing of SPC, Labelling and Package leaflet;
- Annotated QRD template for MRP and DCP.

Public documents will be made available on the website of the Heads of Agencies [www.hevra.org](http://www.hevra.org)

### **Organisational issues**

Valda Sējanē from Latvia and Trudy Knol from the Netherlands were welcomed as new members. Christophe Debruyne from Belgium was appointed as chair of the IFAH survey subgroup. The IFAH survey is carried out on a yearly basis to investigate the performance of the mutual recognition en decentralised procedures. Dolores Sandoval from Spain was appointed as chair of the Documentation Management subgroup, Paula Kajaste from Finland as chair of the Notice to Applicants subgroup and Eugen Obermayr from Austria as chair of the SPC harmonisation subgroup. The mandate for the Subgroup on document management was agreed.

The membership of the CMD(v) and the professional qualification of all members would be published in due course.

### **Information**

For questions and further information you may contact the CMD(v) secretariat at the European Medicines Agency, for the attention of Wim Riepma, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK  
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