

## **REPORT FOR RELEASE**

### **Meeting of 14-15 December 2006**

**The co-ordination group has set ambitious targets for 2007, laid down in a publicly available work plan. The plan aims to strengthen efficiency by further harmonising policies and working practices.**

A further increase in mutual recognition and decentralised applications is anticipated in 2007, whilst measures will be implemented to reduce the number of avoidable referrals and to improve the outcome of referral procedures. As Bulgaria and Romania join the European Union, their representatives are welcomed to the group and special attention will be given to guidance, where necessary, to promote a smooth conduct of procedures.

Areas, particularly identified to seek harmonisation are:

- situations where an application for a generic product has more indications, more target species or shorter withdrawal periods than the reference product in a concerned member state;
- the administrative handling of products with diluents;
- harmonisation of national packaging requirements;
- public access to documents and information;
- the application of the sunset clause.

Interested parties were consulted in the preparation of the work plan and their input was very much appreciated.

#### **Agreement on the first environmental referral**

Baycox Bovis Vet was the first product referred to CMD(v) over environmental concerns. The concerns related to the toxicity to plants, persistence in soil and leaching to the groundwater of ponazuril, the major metabolite of active ingredient toltrazuril.

Agreement was reached on granting a marketing authorisation for the product, after the product's use was restricted to use in replacement calves on dairy farms and further risk mitigation measures were included in the product literature.

Since the implementation of Directive 2004/28/EC, amending Directive 2001/82/EC, concerned member states (CMS) in a mutual recognition procedure or decentralised procedure can refer a product to CMD(v) if they believe it poses a potential serious risk to the environment.

### **Update Q&A documents**

Two published question & answer documents have been updated. The documents concern:

- having more than one trade name on a blister;
- the transfer of a marketing authorisation to a new holder, for a product that has been subject to a mutual recognition procedure.

### **Product discussion**

Eight pharmaceutical products reached day 78 of the mutual recognition procedure in December, of which 6 were discussed at the meeting. The referral of Baycox Bovis Vet was discussed and the applicant attended a hearing.

It was noted that following the November meeting no agreement could be reached at day 90 for a product going through MRP and at day 210 for another product going through the decentralised procedure. Both products were referred to the CMD(v).

### **Information**

Work plan 2007, questions & answers as well as other CMD(v) documents are available on [www.hevra.org](http://www.hevra.org)

For further information please 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 [wimr.riepma@emea.europa.eu](mailto:wimr.riepma@emea.europa.eu)