

REPORT FOR RELEASE

Meeting of 14-15 September 2006

The Coordination Group dealt with a record number of 22 mutual recognition procedures at the September meeting, as it had not convened in August. One referral procedure was discussed and finalised successfully. Various regulatory issues were discussed including the application of the sunset clause and the start of a decentralised procedure.

Sunset Clause

In the context of the so-called sunset clause provision, the marketing authorisation of a veterinary medicinal product will cease to be valid if:

- the medicinal product is not placed on the market within three years of the authorisation being granted or,
- where a medicinal product previously placed on the market is no longer actually present on the market for three consecutive years.

The Competent Authority may grant exemptions on human or animal health grounds in exceptional circumstances and if duly justified.

For mutual recognition and decentralised procedures the sunset clause is referred to in Article 28(4-6) of Directive 2001/82/EC, as amended. It applies prospectively to all veterinary medicinal products authorised from the date of implementation of this Directive, being 30 October 2005 at the latest. Consequently the first authorisation could cease to be valid by the end of 2008.

Competent Authorities are to define rules for granting exemptions, to develop procedures and implement systems for monitoring. Within CMD(v) harmonisation could be sought on general principles and definitions, for example for the meaning of 'actual marketing' and 'placing on the market'.

Start of decentralised procedure before withdrawal of national licences

A company addressed the following question to CMD(v): can an application for a marketing authorisation start under the decentralised procedure if a commitment is given that existing national authorisations for the same product would be withdrawn at the end of the procedure. CMD(v) recognised some merits for the company and the competent authority, but turned the proposal down for the reason it would be against the legislation in force.

Classification of variation

Extension of the shelf life for an active ingredient for an immunological veterinary product has been classified as Type II variation. This variation change does not fall in the category in the storage conditions for the active substance (Variation regulation, No. 17 b).

Product discussion

In total 9 products in various strengths (22 procedures), reached day 78 of the MRP. Out of these, 6 products were discussed at the meeting. It was noted that following the July meeting 6 MRP products were approved whilst 1 product was referred to the CMD(v). CMD(v) reached agreement on a product that had been referred¹ to the group in July this year.

Information

For questions and 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 wim.riepma@emea.eu.int

¹ Pursuant to Article 33 of Directive 2001/82/EC, as amended.