29 March 2005
EMA/249887/2014
Veterinary Medicines and Inspections

EMEA/V/A/009

Committee for Medicinal Products for Veterinary Use (CVMP)

Opinion following an Article 34[1] referral for Dectomax injectable solution and its associated names

International non-proprietary name (INN): doramectin

Background information

Dectomax injectable solution and its associated names contain doramectin as an active substance at 10 mg per ml. Doramectin is a semi-synthetic compound of the avermectin family, intended for the treatment of internal and external parasites in cattle, sheep, pigs and reindeer.

Due to divergent national decisions taken by Member States concerning the marketing authorisations of Dectomax injectable solution and its associated names, on 27 January 2004 the United Kingdom referred the issue to the CVMP under Article 34 of Directive 2001/82/EC, in order to resolve discrepancies regarding the withdrawal period for sheep meat and offal across the European Union.

The referral procedure started on 11 February 2004. The Committee appointed C. Friis as rapporteur and J. G. Beechinor as co-rapporteur.

Written explanations were provided by the marketing authorisation holders on 17 June 2004.

Based on the evaluation of the available data, the CVMP considered that for Dectomax injectable solution and its associated names a withdrawal period of 70 days for sheep meat and offal should be recommended. With respect to the subcutaneous use in sheep, the CVMP concluded that no withdrawal period could be set and references to this route of administration should be removed from the product information. Therefore, the CVMP adopted an opinion on 7 September 2004 for the above-mentioned product.

On 17 September 2004 the marketing authorisation holder notified the Agency of their intention to request a re-examination of the CVMP opinion of 7 September 2004.

[1] Article 34 of Directive 2001/82/EC, as amended

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

During its October 2004 meeting the CVMP appointed H. Hoogland as rapporteur and M. Arboix as co-rapporteur for the re-examination procedure.

The detailed grounds for the re-examination were submitted on 8 November 2004. The re-examination procedure started on 8 November 2004.

On 8 December 2004, the CVMP adopted an opinion confirming the recommendation for 70 days withdrawal period for sheep meat and offal and the removal of subcutaneous route of administration in sheep.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II.

The final opinion was converted into a Decision by the European Commission on 29 March 2005.