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Veterinary Medicines and Product Data Management

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 33(4)[1] referral for Prontax 10 mg/ml solution for injection for cattle, sheep and pigs and associated names

International non-proprietary name (inn): doramectin

Background information

Prontax 10 mg/ml solution for injection for cattle, sheep and pigs (and associated names) contains doramectin. Doramectin is a macrocyclic lactone and is closely related to ivermectin. Both compounds share a wide spectrum of antiparasitic activity and produce a similar paralysis in nematodes and parasitic arthropods.

The applicant, Pfizer Limited, submitted an application for a decentralised procedure for the above mentioned veterinary medicinal product in the framework of Article 32 of Directive 2001/82/EC, as amended. The application was submitted to Ireland as reference Member State and Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Greece, Spain, Finland, France, Hungary, Latvia, Lithuania, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia and Sweden as concerned Member States, as well as Iceland and Norway.

The decentralised procedure started on 26 February 2010. Potential serious risks were identified during the decentralised procedure by two concerned Member States regarding the environmental risk assessment (the Netherlands and France) and regarding the proposed withdrawal period for cattle (the Netherlands).

On 26 April 2011 the reference Member State, Ireland, referred the matter to the CVMP pursuant to Article 33(4) of Directive 2001/82/EC.

The referral procedure started on 5 May 2011. The Committee appointed Dr Michael Holzhauser-Alberti as rapporteur and Dr David Murphy as co-rapporteur. Written explanations were provided by the applicant on 13 September 2011 and 11 January 2012.

[1] Article 33(4) of Directive 2001/82/EC, as amended

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Based on evaluation of the currently available data, the CVMP considered that the benefit-risk profile of Prontax 10 mg/ml solution for injection for cattle, sheep and pigs and associated names is deemed to be positive provided that the recommended risk mitigation measures are added to the product information regarding risk to aquatic organisms and dung fauna and the withdrawal period for meat and offal in cattle is set at 70 days. Therefore, CVMP adopted a positive opinion on 8 February 2012 recommending the granting of a Marketing Authorisation for Prontax 10 mg/ml solution for injection for cattle, sheep and pigs and associated names.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the amendments to the Summary of Product Characteristics, labelling and package leaflet of the Reference Member State in the Annex III.

The final opinion was converted into a Decision by the European Commission on 25 May 2012.