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SCIENCE MEDICINES HEALTH

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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 34[1] referral for Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus and Prazitel Plus and associated names

International non-proprietary name (inn): Praziquantel, pyrantel and febantel

Background information

Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus and Prazitel Plus (and associated names) are veterinary medicinal products as tablets for dogs containing 50 mg praziquantel, 50 mg pyrantel (equivalent to 144 mg pyrantel embonate) and 150 mg of febantel. Praziquantel is a partially hydrogenated pyrazinoisoquinoline derivative. Pyrantel embonate (pamoate) is a tetrahydropyrimidine derivative. Febantel is a probenzimidazole. These veterinary medicinal products are intended for the treatment of various parasitic infections in dogs caused by nematodes and cestodes.

Due to the divergent national decisions taken by Member States regarding the indications and use in pups less than 9 weeks of age and dogs weighing less than 2.5 kg concerning the authorisations of Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus, Prazitel Plus and associated names, on 22 July 2011 France referred the issue to the CVMP under Article 34(1) of Directive 2001/82/EC, in order to resolve the above mentioned divergences.

The referral procedure started on 14 September 2011. The Committee appointed Dr Michael Holzhauser-Alberti as rapporteur and Dr David Murphy as co-rapporteur. Written explanations were provided by the marketing authorisation holder on 2 December 2011.

Based on the evaluation of the currently available data, the CVMP considered that the overall benefit-risk profile for Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus and associated names (authorised via Mutual Recognition Procedure No IE/V/0272-0275/001/MR) remains positive subject to variation of the marketing authorisations in accordance with the recommended changes to the product information. Therefore, the CVMP adopted a positive opinion on 7 March 2012, recommending variations to the

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

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terms of the marketing authorisations for Milaxyn Plus, Strantel Plus, Prazical Plus and Voxical Plus (and associated names) (authorised via Mutual Recognition Procedure No IE/V/0272-0275/001/MR) and the maintenance of the marketing authorisations for Prazitel Plus, Exitel Plus and Cazitel Plus (and associated names) (authorised via Mutual Recognition Procedure No IE/V/0241-0243/001/MR).

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the amended summary of product characteristics, package leaflet and labelling in the Annex III.

The final opinion was converted into a Decision by the European Commission on 18 June 2012.