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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 referral for Doxycycline 50% WSP and associated names

International non-proprietary name (inn): doxycycline hyclate

Background information

Doxycycline is a semi-synthetic tetracycline antibiotic. Tetracyclines have broad spectrum activity inhibiting Gram-positive and Gram-negative bacteria, *mycoplasmas*, *chlamydiae*, *rickettsias* and some *protozoa*. Doxycycline 50% WSP and associated names is a powder for use in drinking water containing the active substance doxycycline hyclate 500 mg/g. In pigs and pre-ruminant calves the product is indicated for the treatment of certain infections of the respiratory tract. In chickens the product is indicated for named infections of the respiratory tract and the alimentary tract.

Due to divergent national decisions taken by Member States regarding the target species, indications, amounts to be administered and withdrawal periods concerning the authorisation of Doxycycline 50% WSP and associated names, on 18 June 2010 the United Kingdom referred the issue to the CVMP under Article 34(1) of Directive 2001/82/EC, in order to resolve divergences amongst the nationally authorised summary of product characteristics across the European Union.

The referral procedure started on 14 July 2010. The Committee appointed Mrs Ruth Kearsley as rapporteur and Dr Jiří Bureš as co-rapporteur. Further to the resignation of Mrs Ruth Kearsley as CVMP member, Ms Helen Jukes was appointed to replace her and took over the rapporteurship. Written explanations were provided by the applicant/marketing authorisation holder on 29 October 2010 and 8 March 2011.

Based on the rapporteurs' assessment of the currently available data, the CVMP considered that the benefit/risk profile for Doxycycline 50% WSP and associated names remains positive subject to variation of the marketing authorisations in accordance with the summary of product characteristics, and therefore adopted a positive opinion on 4 May 2011.

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 in Annex III.

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The final opinion was converted into a Decision by the European Commission on 13 July 2011.