EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 April 2003
EMA/308369/2014
Veterinary Medicines and Inspections

EMEA/V/A/20/002

Committee for Medicinal Products for Veterinary Use (CVMP)

Opinion following an Article 20[1] referral for veterinary medicinal products containing benzathine benzylpenicillin intended for administration to food producing species

International non-proprietary name (INN): benzathine benzylpenicillin

Background information

Benzylpenicillin is a bactericidal antibiotic with a spectrum of activity against most Gram-positive bacteria, Gram-negative cocci and some other Gram-negative bacteria, spirochaetes and actinomycetes.

On 3 October 2001, Ireland presented to the Agency a referral notification under Article 20 of Council Directive 81/851/EEC, as amended, regarding the marketing authorisations for veterinary medicinal products containing benzathine benzylpenicillin intended for intramuscular and/or subcutaneous administration to food producing species. The CVMP was requested to give its opinion regarding the adequacy and consumer safety of the withdrawal periods for the above-mentioned products.

The referral started on 7 November 2001. The Committee appointed R. Kroker as rapporteur. Written explanations were provided by the marketing authorisation holders on 25 March 2002 and 27 March 2002. Oral explanations were given on 3 September 2002.

Based on the evaluation of the available data, the CVMP considered that the benefit-risk balance for the concerned veterinary medicinal products was negative as on the basis of the available data was not possible to establish withdrawal periods. The CVMP therefore adopted by majority a negative opinion on 2 October 2002, recommending suspension of the marketing authorisations for the above-mentioned veterinary medicinal products.

By 21 October 2002, seventeen marketing authorisation holders notified the Agency of their intention to request a re-examination of the CVMP opinion of 2 October 2002.

[1] Article 20 of Council Directive 81/851/EEC, 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

An agency of the European Union

During its meeting of 12-14 November 2002 the CVMP appointed J. Hoogland as rapporteur for the re-examination procedure.

Detailed grounds for the re-examination were submitted by thirteen marketing authorisation holders by 3 December 2002. The re-examination procedure started on 4 December 2002. Oral explanations were given by two marketing authorisation holders on 10 December 2002 and 11 December 2002.

On 15 January 2003, the CVMP adopted an opinion confirming the recommendation for suspension of the marketing authorisations for the above-mentioned veterinary medicinal products.

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

The opinion was converted into a Decision by the European Commission on 22 April 2003.