EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 October 2006
EMA/250892/2014
Veterinary Medicines and Inspections

EMEA/V/A/014

Committee for Medicinal Products for Veterinary Use (CVMP)

Opinion following an Article 6(13)[1] referral for Cobactan DC and its associated names

International non-proprietary name (INN): cefquinome

Background information

Cobactan DC and its associated names contain cefquinome, a fourth-generation cephalosporin, indicated for the treatment of subclinical mastitis at drying off and the prevention of new bacterial infections of the udder, during the dry period, in the dairy cows caused by the following bacteria: *Streptococcus uberis*, *Streptococcus disgalactiae*, *Streptococcus agalactiae*, *Staphylococcus aureus* and coagulase negative staphylococci.

The marketing authorisation holder, Intervet International B.V., submitted an application for a type II variation to shorten the withdrawal period for milk from 49 days to 35 days after treatment for Cobactan DC and its associated names, according to Article 6 of Commission Regulation (EC) No 1084/2003. The reference Member State is France. The concerned Member States are: Austria, Belgium, Cyprus, Czech Republic, Estonia, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Poland, Portugal, Slovakia, Slovenia, Spain and United Kingdom.

On 6 April 2006, the reference and concerned Member States rejected the terms of the variation proposed by the marketing authorisation holder and agreed on a different withdrawal period to that proposed by the marketing authorisation holder.

On 13 April 2006, Intervet Innovation GmbH, referred the matter to the CVMP under Article 6(13) of Commission Regulation (EC) No 1084/2003.

The referral procedure started on 19 April 2006. The Committee appointed J. Schefferlie as rapporteur and C. Friis as co-rapporteur. Written explanations were provided by the marketing authorisation holder on 20 June 2006. Oral explanations were given on 18 July 2006.

[1] Article 6(13) of Commission Regulation (EC) 1084/2003

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

Based on the evaluation of the available data, the CVMP considered that the withdrawal period for milk should be 1 day after calving when the dry period is more than 5 weeks and 36 days after treatment when the dry period is 5 weeks or less. Therefore, the CVMP adopted a positive opinion on 20 July 2006 recommending the granting of the variation of the marketing authorisations for the above-mentioned 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 13 October 2006.