EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 August 2011
EMA/801872/2011
Veterinary Medicines and Product Data Management

EMEA/V/A/068

Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 33(4) referral for Clavudale 50 mg tablet for cats and dogs and associated names

International non-proprietary name (inn): amoxicillin, clavulanic acid

Background information

Clavudale 50 mg tablet for cats and dogs and associated names (Clavudale 50 mg) contains amoxicillin and clavulanic acid. Clavudale 50 mg is intended for the treatment of pathogen-specific skin infections, infections of the oral cavity, urinary tract infections, respiratory disease and enteritis.

The marketing authorisation holder, Dechra Ltd, submitted an application for Clavudale 50 mg via a mutual recognition procedure in Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Luxembourg, the Netherlands, Norway, Poland, Portugal, Slovak Republic, Spain and Sweden on the basis of the marketing authorisation granted by the United Kingdom. The application was submitted as a generic of the reference product, Synulox Palatable Tablets 50 mg marketed by Pfizer Ltd. The mutual recognition procedure (UK/V/0373/001/MR) started on 29 July 2010.

On 28 January 2011, the United Kingdom, as Reference Member State, referred the matter to the European Medicines Agency under Article 33(4) of Directive 2001/82/EC, due to concerns raised by two of the Concerned Member States, the Netherlands and Sweden, that the safety and efficacy of the product had not been sufficiently demonstrated. There was disagreement between the Reference Member State and these Concerned Member States on the demonstration of bioequivalence in the cat target species.

The referral procedure started on 9 February 2011. The Committee appointed Dr Karolina Törneke as rapporteur and Ms Helen Jukes as co-rapporteur. Written explanations were provided by the marketing authorisation holder on 11 April 2011.

Based on the evaluation of the rapporteur's assessment of the currently available data, the CVMP considered that the benefit/risk profile of Clavudale 50 mg tablet for cats and dogs and associated

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

names is positive, and therefore adopted an opinion on 6 April 2011 recommending the granting of the marketing authorisation.

The list of product names concerned is given in Annex I. The scientific conclusions for the granting of the marketing authorisation are provided in Annex II. The summary of product characteristics, labelling and package leaflet are provided in Annex III.

The final opinion was converted into a Decision by the European Commission on 24 August 2011.