EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 February 2012
EMA/965903/2011
Veterinary Medicines and Product Data Management

**EMEA/V/A/055**

# Committee for medicinal products for veterinary use (CVMP)

# Opinion following an Article 34[1] referral for Fortekor and associated names

International non-proprietary name (inn): benazepril hydrochloride

## Background information

Benazepril hydrochloride is a prodrug hydrolysed *in vivo* to its active metabolite, benazeprilat. Benazeprilat is a highly potent and selective inhibitor of angiotensin converting enzyme, thus preventing the conversion of inactive angiotensin I to active angiotensin II and thereby also reducing synthesis of aldosterone. Fortekor and associated names is a veterinary medicinal product containing benazepril hydrochloride presented in 2.5 mg, 5 mg and 20 mg flavoured tablets and 5 mg and 20 mg film-coated tablets intended for use in dogs and cats. The product is intended for the treatment of heart failure in dogs and/or the treatment of chronic kidney disease in cats and dogs, and the approved indications and target species varied between the Member States.

Due to the divergent decisions taken by Member States concerning the authorisation of Fortekor and associated names (5 mg benazepril hydrochloride film-coated tablet) and differences between the summary of product characteristics of the product as authorised in the Member States, the issue was referred on 16 October 2009 by Sweden to the CVMP under Article 34(1) of Directive 2001/82/EC.

The referral procedure started on 11 November 2009. The Committee appointed Dr Karolina Törneke as rapporteur and Dr Michael Holzhauser-Alberti as co-rapporteur.

In line with the principles of referrals under Article 34(1) of Directive 2001/82/EC, on 16 September 2010 Sweden sent a revised referral notification under Article 34(1) of Directive 2001/82/EC and extended the scope of the referral procedure to all Fortekor and associated names tablet strengths and formulations.

Written explanations were provided by the marketing authorisation holders on 24 May 2010 and 6 January 2011. Oral explanations were given on 4 May 2011. Further to the marketing authorisation

[1] Article 34 of Directive 2001/82/EC

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

holders' oral explanations to the Committee, the CVMP, at its May 2011 meeting, agreed that an ad-hoc expert group should be consulted regarding the scientific evidence base for angiotensin converting enzyme inhibitor in the treatment of chronic kidney disease in dogs. An ad-hoc expert group meeting was held on 10 October 2011 and the marketing authorisation holders attended the meeting for an oral explanation.

Based on the assessment of the currently available data and further to a consultation with the ad-hoc expert group, the CVMP considered that the benefit-risk balance for Fortekor and associated names remains positive, except for the chronic kidney disease in dogs, subject to variation of the marketing authorisations in accordance with the recommended product information. The Committee adopted a positive opinion by majority on 10 November 2011.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the amended product information in Annex III.

The final opinion was converted into a Decision by the European Commission on 6 February 2012.