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Veterinary Medicines and Product Data Management

**EMEA/V/A/087**

## Committee for medicinal products for veterinary use (CVMP)

# Opinion following an Article 35[1] referral for Dexadreson 2 mg/ml and associated names, and generic products thereof

International non-proprietary name (INN): dexamethasone

## Background information

The veterinary medicinal products Dexadreson 2 mg/ml and its associated names and generic products thereof are solutions for injection which contain 2 mg dexamethasone per ml. Dexamethasone is a long acting synthetic glucocorticoid used as anti-inflammatory, antiallergic and gluconeogenetic agent for administration to agricultural and domestic animals.

On 22 August 2012, Germany presented to the Agency a referral notification under Article 35 of Directive 2011/82/EC, regarding Dexadreson 2 mg/ml and associated names, and generic products thereof. The CVMP was requested to evaluate the adequacy and consumer safety of the withdrawal periods for meat in cattle and horses and the withdrawal periods for milk in cattle for the concerned products.

The referral started on 12 September 2012. The Committee appointed Dr C. Ibrahim as rapporteur and Dr D. Murphy as co-rapporteur. Written explanations were provided by the marketing authorisation holders on 10 December 2012and 21 May 2013.

Based on the evaluation of the currently available data, the CVMP considered that overall benefit-risk profile for these products remains positive subject to changes of the product information related to harmonisation of the withdrawal periods. Therefore, the Committee adopted a positive opinion on 18 July 2013, recommending variations to the terms of the marketing authorisations for Dexadreson 2 mg/ml and its associated names and generic products thereof.

[1] Article 35 of Directive 2001/82/EC, as amended

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The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amendments in the summaries of product characteristics, labelling and package leaflets in Annex III.

The final opinion was converted into a Decision by the European Commission on 18 October 2013.