24 September 2013
EMA/539462/2013
Veterinary Medicines Division

EMEA/V/A/093

Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 33(4)[1] referral for Deltanil 10 mg/ml Pour-on Solution for cattle and sheep and Deltanil 100 mg Spot-on Solution for cattle

International non-proprietary name (INN): deltamethrin

Background information

Deltanil 10 mg/ml Pour-on Solution for cattle and sheep and Deltanil 100 mg Spot-on Solution for cattle contain deltamethrin as active ingredient and is intended for use in cattle and sheep as a topical application for the treatment and prevention of infestations by lice and flies on cattle; ticks, lice, keds and established blowfly strike on sheep and lice and ticks on lambs.

The applicant, Virbac, submitted an application for a decentralised procedure for Deltanil 10 mg/ml Pour-on Solution for cattle and sheep and Deltanil 100 mg Spot-on Solution for cattle. These are 'hybrid' applications according to Art. 13(3) Directive 2001/82/EC, as amended, referring to the reference products Pfizer Pour On Insecticide 1% w/v Cutaneous Solution and Pfizer Spot On Insecticide 1% w/v Cutaneous Solution multidose registered in the United Kingdom. The reference Member State is the United Kingdom for both products. For the pour-on product 24 concerned Member States are involved: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia and Spain. For the spot-on product Belgium, France, Germany and the Netherlands are involved as concerned Member States.

The decentralised procedure started on 19 December 2011. Potential serious risks were identified during the decentralised procedure by Germany and the Netherlands regarding the environmental safety of the product.

On day 210, these issues remained unsolved and therefore a referral under Article 33(1) of Directive 2001/82/EC to the Coordination group for Mutual recognition and Decentralised procedures

[1] Article 33(4) of Directive 2001/82/EC, as amended

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

(veterinary) (CMD(v)) was started on 17 December 2012. Day 60 of the CMD(v) procedure was on 14 February 2013, and since the Member States concerned failed to reach an agreement regarding the product the procedure was referred to the CVMP.

On 26 February 2013, the reference Member State, the United Kingdom, notified the European Medicines Agency that the CMD(v) had failed to reach an agreement regarding the product and referred the matter to the CVMP pursuant to Article 33(4) of Directive 2001/82/EC.

The referral procedure started on 6 March 2013. The Committee appointed Dr C. Ibrahim as rapporteur and Ms H. Jukes as co-rapporteur. Written explanations were provided by the applicant on 22 May 2013.

Based on the evaluation of the currently available data, the CVMP considered that the benefit-risk profile of Deltanil 10 mg/ml Pour-on Solution for cattle and sheep and Deltanil 100 mg Spot-on Solution for cattle is positive. Therefore, the Committee adopted by majority a positive opinion on 17 July 2013 recommending the granting of the marketing authorisations for Deltanil 10 mg/ml Pour-on Solution for cattle and sheep and Deltanil 100 mg Spot-on Solution for cattle.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the Summary of Product Characteristics and package leaflet in Annex III.

The opinion was converted into a Decision by the European Commission on 24 September 2013.