EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 August 2013
EMA/426302/2013
Veterinary Medicines and Product Data Management

EMEA/V/A/090

Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 13[1] referral for Soludox 500 mg/g powder for use in drinking water for pigs and chickens and associated names

International non-proprietary name (INN): doxycycline hyclate

Background information

Soludox 500 mg/g powder for use in drinking water for pigs and chickens contains doxycycline hyclate as active ingredient. It is indicated in chickens to reduce mortality, morbidity, and clinical signs and to reduce lesions due to Pasteurellosis caused by *Pasteurella multocida* or to reduce morbidity and lesions in respiratory infections caused by *Ornithobacterium rhinotracheale* (ORT). There are two authorised dosages: 10 mg/kg bw for 4 consecutive days, for which the withdrawal period is 3 days, and 20 mg/kg bw for 4 consecutive days for which the withdrawal period is 12 days.

The marketing authorisation holder, Eurovet Animal Health BV submitted an application for a type II variation to shorten the withdrawal period in chickens to 6 days for Soludox 500 mg/g powder for use in drinking water for pigs and chickens and associated names, which has been subject to a worksharing procedure by the CMDv according to Article 20 of Commission Regulation (EC) No 1234/2008. The reference Member State (RMS) is the United Kingdom and 12 concerned Member States (CMS) are involved: Austria, Czech Republic, Estonia, Finland, France, Germany, Greece, Italy, Latvia, the Netherlands, Slovakia and Spain.

The worksharing procedure (UK/V/xxxx/WS/006) involving Soludox 500 mg/g powder for use in drinking water for pigs and chickens (NL/V/0141/001/WS/002) and Soludox 500 mg/g powder for use in drinking water for pigs and chickens (UK/V/0349/001/WS/002) started on 6 January 2012. Potential serious risks were identified during the decentralised procedure by the Netherlands regarding the appropriate withdrawal period for chicken meat and offal.

[1] Article 13 of Commission Regulation (EC) No. 1234/2008

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

On day 90, these issues remained unsolved and therefore a referral under Article 13(1) of Commission Regulation (EC) No. 1234/2008 to the Coordination group for Mutual recognition and Decentralised procedures (veterinary) (CMD(v)) was started on 20 August 2012. Day 60 of the CMD(v) procedure was on 18 October 2012, and since the Member States concerned failed to reach an agreement, the procedure was referred to the CVMP.

On 30 October 2012, the reference Member State, the United Kingdom, notified the European Medicines Agency that the CMD(v) had failed to reach an agreement and referred the matter to the CVMP pursuant to Article 13(2) of Commission Regulation (EC) No. 1234/2008.

The referral procedure started on 7 November 2012. The Committee appointed Mr J. Schefferlie as rapporteur and Ms H. Jukes as co-rapporteur. Written explanations were provided by the marketing authorisation holder on 8 January 2013. Oral explanations were given on 5 March 2013.

Based on the evaluation of the available data the CVMP adopted, on 7 March 2013, an opinion recommending the granting of the variation of the marketing authorisations for Soludox 500 mg/g powder for use in drinking water for pigs and chickens (NL/V/0141/001/WS/002) and Soludox 500 mg/g powder for use in drinking water for pigs and chickens (UK/V/0349/001/WS/002). The CVMP concluded a withdrawal period of 9 days is appropriate for chickens for the dose of 20 mg/kg bw for 4 consecutive days.

On 22 March 2013, Eurovet Animal Health BV notified the Agency of their intention to request a re-examination of the CVMP opinion of 7 March 2013.

During its meeting of 9-11 April 2013 the CVMP appointed Prof. C. Friis as the rapporteur and Dr M. Holzhauser-Alberti as the co-rapporteur for the re-examination procedure.

The detailed grounds for the re-examination request were submitted by Eurovet Animal Health BV on 26 April 2013. The re-examination procedure started on 27 April 2013.

On 12 June 2013 the CVMP adopted a final opinion confirming the recommendation included in its opinion of 7 March 2013, that the variation of the marketing authorisations for Soludox 500 mg/g powder for use in drinking water for pigs and chickens (NL/V/0141/001/WS/002) and Soludox 500 mg/g powder for use in drinking water for pigs and chickens (UK/V/0349/001/WS/002) can be granted and a withdrawal period of 9 days is appropriate for chickens for the dose of 20 mg/kg bw for 4 consecutive days.

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 12 August 2013.