11 December 2014
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Veterinary Medicines Division

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 35[1] referral for Suanovil 20 and associated names, Captalin and associated names and generic products thereof

International non-proprietary name (INN): spiramycin

Background information

Spiramycin is a macrolide antibiotic exerting bacteriostatic action against Mycoplasma, Gram-negative and Gram-positive bacteria which cause infections in cattle and pigs.

The veterinary medicinal products Suanovil 20 solution for injection and its generic product Spirovet are solutions for injection which contain 20 g spiramycin per 100 ml, corresponding to 600 000 IU spiramycin per ml.

Captalin solution for injection contains 31.25 g spiramycin per 100 ml, corresponding to 1 000 000 IU spiramycin per ml.

On 12 September 2012, Gemany presented to the Agency a referral notification under Article 35 of Directive 2011/82/EC, regarding Suanovil 20 and associated names, Captalin and associated names and generic products thereof. The CVMP was requested to give its opinion on the indications, dosing regimens and withdrawal periods in cattle and pigs, in order to ensure efficacious treatment and lower the risk of development of antimicrobial resistance to spiramycin taking into account the available data and also to harmonise the withdrawal periods in cattle and pigs for the concerned products.

The referral started on 13 September 2012. The Committee appointed C. Ibrahim as rapporteur and B. Urbain as co-rapporteur. Written explanations were provided by the applicants and marketing authorisation holders on 10 December 2012, 14 October 2013, 1 April 2014 and 10 June 2014. Oral explanations were given on 9 September 2014.

Based on the evaluation of the currently available data, the CVMP considered that the overall benefit-risk profile for these products remains positive subject to amendments in the product information.

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

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Therefore, on 9 September 2014 the Committee adopted by majority a positive opinion, recommending variations to the terms of the marketing authorisations for Suanovil 20 and associated names, Captalin and associated names and generic products thereof.

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 11 December 2014.