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SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

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Committee for medicinal products for veterinary use (CVMP)

Opinion following an Article 33(4)[1] referral for Fiprex CAT 52.5 mg spot-on solution for cats; Fiprex S 75 mg spot-on solution for dogs, Fiprex M 150 mg spot-on solution for dogs, Fiprex L 300 mg spot-on solution for dogs, Fiprex XL 412.5 mg spot-on solution for dogs

International non-proprietary name (INN): fipronil

Background information

Fiprex is a veterinary medicinal product presented as a spot-on formulation containing fipronil as an active substance (pharmacotherapeutic group: ectoparasiticides for topical use). Fiprex is available in five different presentations, one for cats and four for different sizes of dogs. Fiprex for cats is indicated for the treatment and prevention of flea (*Ctenocephalides* spp.) infestations for up to 28 days, as well as for the control of Flea Allergy Dermatitis. Fiprex for dogs is indicated for the treatment and prevention of flea infestations (*Ctenocephalides* spp.) for up to 28 days after administration, for the control of Flea Allergy Dermatitis, as well as for treatment and prevention of tick (*Ixodes* spp., *Rhipicephalus sanguineus* and *Dermacentor reticulatus*) infestations between 7 and 21 days after administration.

The presentations for dogs have been nationally authorised in the Czech Republic since December 2011, and the presentation for cats has also been nationally authorised in the Czech Republic since May 2012. The legal basis of the marketing authorisations granted by the Czech Republic was Article 13a of Directive 2001/82/EC i.e. citing well-established use. Later in 2012 the marketing authorisation holder, Vet-Agro Trading Sp. z o.o., submitted applications for mutual recognition of the marketing authorisation granted by the Czech Republic for the aforementioned five presentations of Fiprex. The legal basis of the applications was also Article 13a of Directive 2001/82/EC. The reference Member State for the mutual recognition procedure was the Czech Republic and ten concerned Member States

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

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were involved (Austria, Belgium, Denmark, Greece, Ireland, Italy, the Netherlands, Spain, the Slovak Republic and the United Kingdom).

The mutual recognition procedures, CZ/V/0116/001/MR concerning the presentation for cats and CZ/V/0116/002-005/MR concerning the four presentations for dogs, started on 25 October 2012. Potential serious risks to animal health were identified during the mutual recognition procedure by Ireland regarding the efficacy and target animal safety of the products.

On day 90 of the mutual recognition procedure these issues remained unsolved and therefore a referral procedure under Article 33(1) of Directive 2001/82/EC to the veterinary coordination group for the mutual recognition and decentralised procedures (CMDv) was started on 18 February 2013. Day 60 of the CMDv referral procedure was on 18 April 2013.

On 29 April 2013, the reference Member State, the Czech Republic, 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 33(4) of Directive 2001/82/EC.

The referral procedure started on 15 May 2013. The Committee appointed D. Murphy as rapporteur and J. Bureš as co-rapporteur. Written explanations were provided by the marketing authorisation holder on 10 September 2013 and 21 October 2013. Oral explanations were given on 10 December 2013.

Based on the evaluation of the available data, the CVMP concluded that Fiprex does not pose a risk in terms of target animal safety. Regarding efficacy, the CVMP concluded that the data provided for Fiprex could not adequately justify the proposed duration of efficacy and consequently it is not possible to establish a positive benefit-risk balance for the product. The CVMP therefore adopted by majority a negative opinion recommending the refusal of the granting of the marketing authorisations and the suspension of the existing marketing authorisations for the aforementioned veterinary medicinal products.

On 20 December 2013, Vet-Agro Trading Sp. z o.o. notified the Agency of their intention to request a re-examination of the CVMP opinion of 11 December 2013.

During its meeting of 14-16 January 2014 the CVMP appointed R. Breathnach as rapporteur and B. Zemann as the co-rapporteur for the re-examination procedure.

The detailed grounds for the re-examination request were submitted by Vet-Agro Trading Sp. z o.o. on 10 February 2014. The re-examination procedure started on 11 February 2014.

On 9 April 2014, the CVMP adopted by majority a final opinion confirming the recommendation included in its opinion of 11 December 2013, that the granting of the marketing authorisations should be refused and the existing marketing authorisations should be suspended for Fiprex CAT 52.5 mg spot-on solution for cats, Fiprex S 75 mg spot-on solution for dogs, Fiprex M 150 mg spot-on solution for dogs, Fiprex L 300 mg spot-on solution for dogs and Fiprex XL 412.5 mg spot-on solution for dogs.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the condition to lift the suspension of the marketing authorisations in Annex III.

The opinion was converted into a Decision by the European Commission on 14 July 2014.