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Veterinary Medicines Division

Questions and answers on Seresto and its associated name Foresto

Outcome of a procedure under Article 13 of Regulation (EC) No 1234/2008

On 15 February 2018, the European Medicines Agency (the Agency) completed an arbitration procedure for Seresto and its associated name Foresto. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the change to the marketing authorisation for Seresto to add a new indication can be granted.

What is Seresto?

Seresto is an antiparasitic collar containing 10% imidacloprid and 4.5% flumethrin. It is indicated for the treatment and prevention of infestations with fleas, ticks and lice in dogs and cats, and provides indirect protection against the diseases babesiosis and ehrlichiosis, which can be transmitted to dogs by ticks.

Seresto, sometimes under its associated name Foresto, is authorised in nearly all EU/EEA Member States. The company that markets the product is Bayer Vital GmbH.

Why was Seresto reviewed?

Seresto is authorised in the European Union (EU) under the decentralised procedure with Germany as the reference Member State. The company applied for a change (variation) to the marketing authorisation to add a new indication to be recognised by Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom (the 'concerned Member States'). Because these Member States were not able to reach an agreement, the German Federal Office of Consumer Protection and Food Safety (BVL) referred the matter to the CVMP for arbitration on 18 August 2017.

The proposed new indication was against the disease leishmaniosis, which is caused by the parasite *Leishmania infantum* and transmitted to dogs by sand flies. The grounds for the referral were the concerns of the UK that the efficacy of the product in repelling sand flies had not been sufficiently demonstrated.

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What are the conclusions of the CVMP?

Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CVMP concluded that the efficacy of Seresto in the reduction of the risk of infection with *Leishmania infantum* via transmission by sand flies for up to 8 months had been sufficiently demonstrated and therefore the variation to the marketing authorisation can be approved in all concerned Member States. However, the CVMP recommended inclusion of the statement, in the product information of Seresto, that the demonstrated repellent efficacy against sand flies was variable.

The European Commission issued an EU-wide legally binding decision to implement the CVMP recommendations on Seresto on 25 May 2018.