

Withdrawal of the marketing authorisation application

Product name: Imvixa vet

Active substance: Lufenuron

Submission of application: 9 September 2022

Date of withdrawal: 14 August 2023

Company making the application: Elanco GmbH, Germany

Withdrawal type: Initial authorisation

The applicant Elanco GmbH, Germany submitted on 9 September 2022 an application for a marketing authorisation to the Norwegian Medicines (NoMA) for Imvixa vet in the national procedure.

The application was submitted in accordance with Article 8 of Regulation (EU) 2019/6 - full application.

The applicant applied for the following indication: The veterinary medicinal product is indicated for the reduction of attached and mobile salmon lice (*Lepeophtheirus salmonis*) stages when administered at the hatchery to Atlantic salmon (*Salmo salar*) smolts of 80-150 g body weight.

The active substance is lufenuron. Imvixa vet is a premix for medicated feeding stuff for Atlantic salmon (*Salmo salar*) containing 100 mg/g lufenuron as active substance.

The product is intended for oral administration via fish feed.

Lufenuron, the active substance in Imvixa vet, is classified as a vPvB (very persistent, very bioaccumulative). Imvixa vet is intended for the treatment of Atlantic salmon, a food producing species. The overall conclusion in the Norwegian Medicines Agency's assessment report was that a marketing authorisation for Imvixa vet pre-mix shall be refused in accordance with Regulation (EU) 2019/6, Article 37 (2)(j) as the active substance lufenuron is classified as a vPvB and is not considered essential for animal health. Furthermore, a substantial list of questions to the submitted safety and efficacy documentation was identified, and a conclusion on the benefit/risk profile for the product was not possible.

In the withdrawal letter, the applicant states that "After further review of the assessment report and the feedback shared by NoMA at the meeting in March 2023, and under the current circumstances, Elanco has decided to withdraw the application".

Imvixa vet 100 mg/g premix for medicated feeding stuff for Atlantic salmon contains lufenuron and is presented in laminated foil bag heat sealed at one end.

- 5 x 1 kg bags carried in a plastic bucket with lid.
- 2 x 2.5 kg bags carried in a plastic bucket with lid.

On 14 August 2023, during the clock-stop for response to the list of questions, Elanco GmbH communicated the withdrawal of the marketing authorisation application to the NoMA.