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Withdrawal of application for the marketing authorisation of Sugammadex Lorien (sugammadex)

Laboratorios Lorien, S.L. withdrew its application for a marketing authorisation of Sugammadex Lorien as a medicine for reversing the effect of the muscle relaxants rocuronium and vecuronium.

The company withdrew the application on 28 September 2023.

What is Sugammadex Lorien and what was it intended to be used for?

Sugammadex Lorien was developed as a medicine for reversing the effect of the muscle relaxants rocuronium and vecuronium. Muscle relaxants are used during certain operations to relax the muscles, including the muscles that help the patient to breathe. Muscle relaxants make it easier for the surgeon to do the operation. Sugammadex Lorien was to be used to speed up the recovery from the muscle relaxant, usually at the end of the operation, to allow patients to breathe on their own again earlier. The medicine was to be used in adults who have received rocuronium or vecuronium, and in children and adolescents who have received rocuronium.

Sugammadex Lorien contains the active substance sugammadex and was to be available as a solution to be given as an injection into a vein.

Sugammadex Lorien was developed as a 'generic medicine'. This means that Sugammadex Lorien contained the same active substance as an authorised 'reference medicine' called Bridion and was intended to work in the same way. For more information on generic medicines, see the question-and-answer document here.

How does Sugammadex Lorien work?

The active substance in Sugammadex Lorien and Bridion, sugammadex, attaches to the muscle relaxants rocuronium and vecuronium and stops them from having an effect. As a result, the relaxing effect of rocuronium and vecuronium on the muscles is reversed and the muscles start to work normally again.

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What did the company present to support its application?

As for every medicine, the company provided studies on the quality of Sugammadex Lorien and data on the way the product is to be manufactured. Studies on the benefits and risks of the active substance are not needed for a generic medicine because they have already been carried out with the reference medicine. There was no need for 'bioequivalence' studies to investigate whether Sugammadex Lorien is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Sugammadex Lorien is given by injection into a vein, so the active substance enters straight into the bloodstream.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company. After the Agency had assessed the company's responses to the last round of questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the data and the company's responses to the Agency's questions, at the time of the withdrawal, the Agency had some concerns about the manufacturing process for the medicine and therefore its quality and its provisional opinion was that Sugammadex Lorien could not have been authorised for the requested indication.

At the time of the withdrawal, the Agency's opinion was that the company had not fully addressed its concerns and the benefits of Sugammadex Lorien could not be established.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal, the company stated that it could not address the concerns raised by the Agency within the framework of the application.

Does this withdrawal affect patients in clinical trials?

The company did not carry out clinical trials using Sugammadex Lorien.