Laboratorios Lorien, S.L.
Av. Josep Tarradellas, 8, Ático 1ª
08029 Barcelona
SPAIN

Date: 28/09/2023

CHMP Chairman
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Sugammadex Lorien, (Sugammadex), 100 mg/mL, solution for injection - **EMEA/H/C/006115**

Dear *CHMP Chairman*,

For the withdrawal of initial marketing authorisation applications

I would like to inform you that, at this point of time, *Laboratorios Lorien, S.L.* has taken the decision to withdraw the application for Marketing Authorisation of *Sugammadex Lorien, (Sugammadex), 100 mg/mL, solution for injection*, which was intended to be used for reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults (for the paediatric population, only recommended for routine reversal of rocuronium induced blockade in children and adolescents aged 2 to 17 years).

This decision was taken because the CHMP considers that the data provided do not allow the committee to conclude on a positive opinion on the MAA, and the Applicant cannot address the major objection raised by the CHMP within the framework of this MAA procedure.

We reserve the right to make further Marketing Authorisation Application submissions at a future date in this or other therapeutic indication(s) application for this Marketing Authorisation.

Laboratorios Lorien, S.L. would like to sincerely thank the (Co-)Rapporteurs, EMA, PRAC and CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

I agree for this letter to be published on the EMA website.