Date: 18 September 2025

xxxx
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

**Subject:** Withdrawal of Hydrocortisone Aguettant 1 mg Powder and Solvent for Solution for Injection - **EMEA/H/C/005201**

Dear xxxx

I would like to inform you that, at this point of time, Laboratoire Aguettant has taken the decision to withdraw the application for Marketing Authorisation of Hydrocortisone Aguettant 1 mg Powder and Solvent for Solution for Injection, which was intended to be used for the prevention of bronchopulmonary dysplasia in preterm infants born between 24 and 28 weeks of postmenstrual age.

This withdrawal is based on the following reason:
- feedback from the CHMP indicates that Committee will not be able to conclude that the benefits outweigh the risks on the basis of the data provided.

Laboratoire Aguettant respectfully disagrees with the assessment and considers that the data set provided including the pivotal clinical study along with the post-hoc analyses allows to demonstrate efficacy in line with the "Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence for regulatory purposes – EMA/99865/2025" dated March 2025, and supports a positive benefit-risk balance in this vulnerable population.

This withdrawal does not have any impact on clinical trials with Hydrocortisone Aguettant.

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

Laboratoire Aguettant thanks the (Co-)Rapporteurs and EMA for their time spent reviewing this application.

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

Yours sincerely,