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

10 September 2026

Subject: Withdrawal of Alhemo® (concizumab) type II variation - **EMEA/H/C/005938**

Dear [redacted],

I would like to inform you that, at this point of time, Novo Nordisk has taken the decision to withdraw the application to add new therapeutic indications: haemophilia A or haemophilia B with or without inhibitors in paediatric patients < 12 years for Alhemo®.

This withdrawal is based on the CHMP consideration that the data provided would not allow the Committee to conclude with a recommendation for all the proposed indications.

This withdrawal does not have any consequences for the ongoing phase 3 studies with concizumab or on the use of concizumab in its approved indications.

Novo Nordisk remains committed to making this treatment available to paediatric patients below 12 years of age in Europe and reserves the right to make further variation applications in support of this patient population.

We would like to thank the Rapporteurs, the EMA, the CHMP and PRAC members for the time dedicated to reviewing this application.

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

Yours sincerely,

[redacted]

[redacted]
Global Regulatory Lead

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