Masuu Pharma Europe Limited
Unit 3d North Point House,
North Point Business Park,
New Mallow Road, Cork, Co. Cork,
T23 WYK5, Ireland

17 October 2025

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

**Subject :** Withdrawal of Insulin Aspart Injection, Insulin Aspart, 100 Units/mL, Solution for injection.

**Procedure Number:** EMEA/H/C/006720/0000

Dear Sir/Madam,

I would like to inform you that, at this point of time, ***Masuu Pharma Europe Limited*** has taken the decision to withdraw the application for Marketing Authorisation of ***Insulin Aspart Injection, Insulin Aspart, 100 Units/mL, Solution for injection,*** which was intended to be used for treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.

This withdrawal is based on the following reason:

As per the EU GMP requirements, the [redacted] Drug substance and Drug product Manufacturing and testing site facility in [redacted] is undergoing mandatory modifications that are essential to maintain uninterrupted supply to current patients in existing markets. These activities mean the site will not be inspection-ready within the pre-approval inspection timelines.

We would like to Resubmit the centralised application in [redacted], when the facility will be fully aligned with inspection readiness expectations. The resubmission will include updated Module 1 and 3 materials reflecting the completed changes and validation status.

We would like to confirm that the applicable fees will be paid at Resubmission on [redacted]

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

[redacted]