19 July 2023

Dr Harald Enzmann

European Medicines Agency (EMA)
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Lutholaz, (pegfilgrastim), 6 mg pre-filled syringe -

EMA reference EMEA/H/C/005587

Dear Dr Enzmann,

I would like to inform you that, at this point of time, YES Pharmaceutical Development Services GmbH has taken the decision to withdraw the application for Marketing Authorisation of Lutholaz, (pegfilgrastim), 6 mg pre-filled syringe which was intended to be used for reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

This withdrawal is on the basis that the applicant cannot address the Major Objection relating to GMP certification of the manufacturing facility within the timeframe of this MAA procedure.

There are no ongoing clinical trials or compassionate use programmes with this product and therefore there is no impact from the withdrawal of the application.

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

We would like to thank the (Co)Rapporteurs, CHMP and EMA for their consideration of the application and the support provided throughout the procedure.

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

Yours sincerely,

[redacted]

19 July 2023

Date