

Amgen Technology (Ireland) UC

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Date: 22 March 2024

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

Subject: Withdrawal of UPSTELDA (ustekinumab) - **EMA/H/C/006415**

Dear *CHMP Chair*

For the withdrawal of initial marketing authorisation application

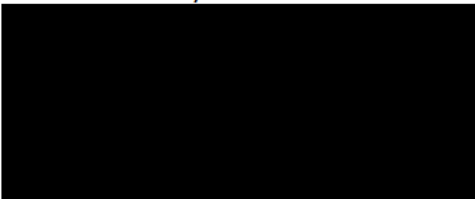
I would like to inform you that, at this point of time, Amgen Technology (Ireland) Unlimited Company has taken the decision to withdraw the application for the duplicate Marketing Authorisation (MAA) of UPSTELDA, (ustekinumab), which was intended to be used for treatment of plaque psoriasis, paediatric plaque psoriasis, psoriatic arthritis and Crohn's disease.

This withdrawal is based on a change to the applicant's strategy for this duplicate MAA and is not related to product's quality or safety.

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

I agree for this letter to be published on the European Medicines Agency website.

Yours sincerely



On behalf of Amgen Technology (Ireland) Unlimited Company, the applicant