European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Basel, 19 May 2021

Subject: Withdrawal of Type II Variation EMEA/H/C/002154/II/0069 for Esbriet (pirfenidone), 267 mg capsules and 267 mg, 534 mg and 801 mg film-coated tablets

Dear Dr Enzmann,

I would like to inform you that, at this point in time, Roche Registration GmbH has taken the decision to withdraw the application for a new therapeutic indication for Esbriet (pirfenidone) for the treatment of patients with unclassifiable interstitial lung disease.

This withdrawal is based on the CHMP requirement for further justification and data on the use of Esbriet in the proposed indication.

This withdrawal does not have any impact on any ongoing clinical trials with pirfenidone.

Roche Registration GmbH reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

Roche Registration GmbH would like to sincerely thank the (Co-)Rapporteurs, EMA, PRAC and CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

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

Yours sincerely,

On behalf of the Marketing Authorization Holder, Roche Registration GmbH

[redacted]

[redacted]

Roche Registration GmbH
(registered in Germany with registration number HRB 717155)

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