

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

Date: 17 September 2024

Subject: Withdrawal of Apremilast Viatris, 30 mg and Combination Pack (10 mg + 20 mg + 30 mg) Tablets - EMEA/H/C/006193

Dear CHMP Chairperson,

I would like to inform you that, at this point of time, **Viatris Limited** has taken the decision to withdraw the application for Marketing Authorisation of **Apremilast Viatris, 30 mg and Combination Pack (10 mg + 20 mg + 30 mg) Tablets**, which was intended to be used for Psoriasis, Psoriatic arthritis and Behçet's disease.

This withdrawal is based on the following reasons:

- The CHMP considers that the clinical data provided do not allow the committee to draw conclusions on the bioequivalence of the product.

We reserve the right to make further application for this Marketing Authorisation.

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

Yours faithfully,