Dr. Harald Enzmann
CHMP Chairman
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

[redacted]

Date: 22 February 2023

Subject: Withdrawal of Raltegravir Viatris (Raltegravir) 600 mg film-coated tablets – EMEA/H/C/005813

Dear Dr. Enzmann,
[redacted]

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 Raltegravir Viatris (Raltegravir) 600 mg film-coated tablets, which was intended to be used in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults, and paediatric patients weighing at least 40 kg.

This withdrawal is based on the following reason:
- the CHMP considers that the clinical data provided do not allow the committee to draw conclusions on the bioequivalence of the product

We confirm that this withdrawal has no consequences on on-going clinical trials or compassionate use programmes.

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 EMEA website.

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