Rukobia

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Renewal - 5 year / EMA/R/0000264656	- Renewal - Renewal of marketing authorisation with	24/07/2025	08/09/2025	SmPC, Annex II and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Rukobia in the approved indication

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	unlimited validity				remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
Variation type IB / EMA/VR/0000253073	C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II - Accepted C.I.11.z (IB) - To provide a revised RMP version to update the final study report milestone of "A Clinical Trial to Investigate the Efficacy and Safety of Fostemsavir in HTE Subjects Infected with Multi-drug Resistant HIV-1 (BRIGHTE Study)" from 31 December 2025 to 31 December 2026.	31/03/2025	N/A		To provide a revised RMP version to update the final study report milestone of "A Clinical Trial to Investigate the Efficacy and Safety of Fostemsavir in HTE Subjects Infected with Multi-drug Resistant HIV-1 (BRIGHTE Study)" from 31 December 2025 to 31 December 2026.
Variation type IB / EMA/VR/0000244295	B.I ACTIVE SUBSTANCE - B.I.z Other variation - Accepted	28/03/2025	N/A		