Efavirenz/Emtricitabine/Tenofovir disoproxil Krka

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, please 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
Article 61(3) /	- Notification acc. Article 61(3) -	16/01/2025		PL	

[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).

EMA/N/0000241468	Update of the package leaflet to delete 'United Kingdom (Northern Ireland)' from the list of local representatives in line with the QRD template v10.4. Additionally, the marketing authorisation holder took the opportunity to introduce minor linguistic amendments in the Greek and Icelandic translations.				
Article 61(3) / EMA/N/0000182187	- Notification acc. Article 61(3) - Update of the package leaflet with revised contact details of local representatives. Additionally, the MAH took the opportunity to introduce minor linguistic amendments to some of the translations.	11/07/2024		PL	