Kisplyx

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
Variation type IB /	This was an application for a variation	26/03/2026		SmPC	

[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/VR/0000328217	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.3 Change(s) in the summary of product characteristics, labelling or package leaflet intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Article 45 or 46 of Regulation (EC) No 1901/2006, or the outcome of a PRAC signal recommendation, or to adapt to a joint recommendation of EU competent authorities (e.g. a Core SmPC, or following the assessment of an Urgent Safety Restriction etc.) - C.3.b) Implementation of the agreed wording that requires additional minor assessment (e.g. translations are not yet agreed upon) - Accepted Type IB, C.3.b - to update section 4.8 of the EN SmPC, resulting from the final assessment report, dated 11 December 2025, for paediatric study E7080-G000-231, which was submitted in accordance with Article 46 of regulation (EC) No 1901/2006 (Procedure no.: EMA/PAM/0000279817 and EMA/PAM/0000279841).				
Variation type IA_IN / EMA/VR/0000322522	C.3 Change(s) in the summary of product characteristics, labelling or package leaflet	04/02/2026			

	intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Article 45 or 46 of Regulation (EC) No 1901/2006, or the outcome of a PRAC signal recommendation, or to adapt to a joint recommendation of EU competent authorities (e.g. a Core SmPC, or following the assessment of an Urgent Safety Restriction etc.) - C.3.a) Implementation of the agreed wording - Refused				
Variation type IA_IN / EMA/VR/0000254997	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment - Accepted	17/04/2025		SmPC and PL	