Columvi

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 II /	This was an application for a group of	24/07/2025		SmPC,	For more information, please refer to the Summary

[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/0000270570	variations. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted A grouped application consisting of three Type II variations, as follows: C.I.4: Update of sections 4.2 and 4.4 of the SmPC in order to add information regarding opportunistic infections based on a review of data from clinical trials, post-marketing surveillance, and literature. The Package Leaflet is updated accordingly. C.I.4: Update of sections 4.8 of the SmPC in order			Labelling and PL	of Product Characteristics.

	to add colitis as an adverse reaction with frequency uncommon based on a review of data from clinical trials, post-marketing surveillance, and literature. The Package Leaflet is updated accordingly. C.I.4: Update of sections 4.8 of the SmPC in order to add information regarding cytomegalovirus infection/reactivation based on a review of data from clinical trials, post-marketing surveillance, and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the PI, and to update section 6.6. of the SmPC.				
Variation type IB / EMA/VR/0000249350	B.IV.1 Change of a measuring or administration device - B.IV.1.z Other variation - Accepted	26/03/2025		SmPC, Labelling and PL	