GOBIVAZ

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 /	Outcome:	07/07/2026	15/07/2026	SmPC, Annex	

[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/0000339984	C.2 Change(s) in the summary of product characteristics, labelling or package leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.2.a) Implementation of change(s) for which no new additional data is required to be submitted by the holder - Accepted C.2.a (Type IB) - To extend the indication with the treatment of moderately to severely active ulcerative colitis in paediatric patients 2 years of age and older with a body weight of at least 15 kg, who have had an inadequate response to conventional therapy, including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. Consequently, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC and sections 1, 2 and 3 of the PL were updated. The change follows assessment of the same change for the reference product (Simponi). Furthermore, the RMP was updated to reflect the paediatric ulcerative colitis indication. In addition, the MAH took the opportunity to implement the following changes in the PI, consistent with those implemented in the PI of the reference product: • Inclusion of the E number for sorbitol (E420), in line with the Annex to the European Commission			II, Labelling and PL	

	guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' • Deletion of the Patient Reminder Card text from Annex II D • Changes in alignment with the latest QRD template • Minor editorial corrections				
Variation type IB / EMA/VR/0000355879	Outcome: Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.z Other variation - Accepted	06/07/2026			
Variation type IB / EMA/VR/0000349238	Outcome: Q.I.b.1 Change in the specification attribute and/or acceptance criteria of an active substance, starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.1.h) Change outside of the specification acceptance criteria for starting material/reagent/intermediate - Accepted	10/06/2026			
Variation type II / EMA/VR/0000333550	Outcome: This was an application for a group of variations. Q.I.b.1 Change in the specification attribute and/or acceptance criteria of an active substance, starting	07/05/2026			

	material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.1.f) Change outside of the specification acceptance criteria for the active substance - Accepted Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.d) Widening of the approved in-process control limits, which may have a significant effect on the overall quality of the active substance - Accepted Q.I.a.4 Change to in-process controls applied during the manufacture of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.4.d) Widening of the approved in-process control limits, which may have a significant effect on the overall quality of the active substance - Accepted				
Variation type IA / EMA/VR/0000323963	Outcome: This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance,	02/02/2026			

	starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.a Tightening of in-process limits - Accepted				