Benepali

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	10/07/2025	N/A		

[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/0000263971	variations. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted A grouped application consisting of: C.I.13: Submission of the final report from study (ARTIS) listed as a category 3 study in the RMP. This is a national prospective, observational, uncontrolled cohort study whose objectives are to evaluate the risk of selected AEs in RA, juvenile idiopathic arthritis, and other rheumatic disease patients treated with etanercept. The RMP version 10.0 has also been submitted. C.I.13: Submission of the final report from study (BSRBR-RA) listed as a category 3 study in the RMP. This is an established nationwide register for patients with rheumatological disorders treated with biologic agents.				

Variation type IB / EMA/VR/0000263549	B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted	12/05/2025	N/A		
Variation type IB / EMA/VR/0000253630	B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.z Other changes - Accepted	20/03/2025	N/A		
Article 61(3) / EMA/N/0000255572	- Notification acc. Article 61(3) - Update of the package leaflet with revised contact details of local representatives.	05/03/2025		PL	