EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Humalog

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 IA_IN /	A. ADMINISTRATIVE CHANGES - A.1 Change	21/01/2026		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/0000315488	in the name and/or address of the marketing authorisation holder - Accepted			Labelling and PL	
Variation type IA / EMA/VR/0000302558	B.II.d.2 Change in test procedure for the finished product - B.II.d.2.b Deletion of a test procedure if an alternative method is already authorised - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.e Update of the test procedure to comply with the updated general monograph in the Ph. Eur. - 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 B.II.d.2 Change in test procedure for the finished product - B.II.d.2.b Deletion of a test procedure if an alternative method is already authorised - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.f To reflect compliance with the Ph.Eur. and remove reference to the outdated internal test method and test method number - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.e Update of the	09/10/2025	N/A		

	test procedure to comply with the updated general monograph in the Ph. Eur. - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted				
Variation type IB / EMA/VR/0000281212	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted	04/09/2025	N/A		

Variation type IB / EMA/VR/0000278799	This was an application for a group of variations. B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.f The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line) - Accepted	15/07/2025	N/A		
Variation type IB / EMA/VR/0000262180	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.1 Replacement or addition of a	22/05/2025	N/A		

	manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted				
Variation type IB / EMA/VR/0000253644	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.f The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line) - Accepted	25/04/2025	N/A		
