Degarelix Accord

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 /	Outcome:	04/08/2026		Annex II and	

[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/0000365502	This was an application for a group of variations. E.4 Change in the name and/or address of the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank, manufacturing site for an active substance, intermediate or finished product, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier - E.4.c) The change in the name and/or address does not concern a manufacturer(s) whose activities include batch release of the finished product nor the marketing authorisation holder - Accepted E.4 Change in the name and/or address of the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank, manufacturing site for an active substance, intermediate or finished product, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the			PL	

	dossier - E.4.c) The change in the name and/or address does not concern a manufacturer(s) whose activities include batch release of the finished product nor the marketing authorisation holder - Accepted E.4 Change in the name and/or address of the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank, manufacturing site for an active substance, intermediate or finished product, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier - E.4.c) The change in the name and/or address does not concern a manufacturer(s) whose activities include batch release of the finished product nor the marketing authorisation holder - Accepted E. Administrative Changes - E.5 Deletion of manufacturing sites for an active substance, intermediate or finished product, storage of master and/or working cell bank, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the				

	dossier) - Accepted Q.II.b.1 Change in the manufacturing site for part or all of the manufacturing process of the finished product (except for batch release and batch control testing sites) - Q.II.b.1.a) Addition or replacement of a site responsible for secondary packaging - Accepted				
Variation type IA_IN / EMA/VR/0000340501	Outcome: Q.IV.1 Changes to a device co-packaged with the medicinal product or referenced in the product information - Q.IV.1.a) Addition or replacement of a co-packaged device or referenced device - Accepted	23/04/2026			
Variation type IB / EMA/VR/0000337954	Outcome: This was an application for a group of variations. Q.I.b.2 Change to analytical procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.2.a) Minor change to an analytical procedure for the active substance - Accepted 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	21/04/2026			

	substance - Q.I.b.1.d) Deletion of a non-significant or an obsolete specification attribute - Accepted 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.d) Deletion of a non-significant or an obsolete specification attribute - Accepted Q.I.d.1 Change in the re-test period/storage period or storage conditions of the active substance or intermediates used in the manufacturing process of the biological active substance - Q.I.d.1.c) Change to an approved stability protocol - Accepted Q.I.a.1 Change in the manufacturing site of a starting material/intermediate used in the manufacturing process of the active substance or change in the manufacturing site (including where relevant quality control testing sites) of the active substance - Q.I.a.1.c) Addition or replacement of a manufacturing site of a starting material used in the manufacture of the active substance or reagent required to be mentioned in the dossier - Accepted Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.d) Minor				

	change to the restricted part of an Active Substance Master File - Accepted				
Variation type IB / EMA/VR/0000292461	Outcome: B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted	10/09/2025			