Icatibant 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 IB /	C.9 Introduction of, or change(s) to, the	19/03/2026			To update the RMP in line with the approved safety

[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/0000333262	obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted C.9.b (Type IB) – To update the RMP in line with the approved safety concern updates for the reference product Firazyr by removing all important identified risks, all important potential risks, and one missing information (use in children below 2 years of age).				concern updates for the reference product Firazyr by removing all important identified risks, all important potential risks, and one missing information (use in children below 2 years of age).
Renewal - 5 year / EMA/R/0000300686	Renewal of marketing authorisation	26/02/2026	13/04/2026		Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Icatibant Accord in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
Variation type IA / EMA/VR/0000297152	This was an application for a group of variations. A.5 Change in the name and/or address of a manufacturer/importer of the finished	02/10/2025			

	product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted				
Variation type IA_IN / EMA/VR/0000293287	This was an application for a group of variations. B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.2 Including batch control/testing - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the	26/08/2025	13/04/2026	Annex II and PL	

	dossier)* - Accepted				