Imatinib 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, please 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
Article 61(3) /	- Notification acc. Article 61(3) -	05/05/2025		PL	

[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/N/0000268278	Update of the package leaflet to introduce a list of local representatives.				
Variation type IB / EMA/VR/0000262007	This was an application for a group of variations. B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	05/05/2025			
Variation type IA_IN / EMA/VR/0000267387	This was an application for a group of variations.	30/04/2025		Annex II and PL	

	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 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 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 IB / EMA/VR/0000223492	This was an application for a group of variations. B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished	16/10/2024	N/A		

	product - B.II.d.1.z Other changes - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.z Other changes - Accepted				
Variation type IB / EMA/VR/0000180960	This was an application for a group of variations. B.II.a.3.a Changes in components of the flavouring or colouring system - B.II.a.3.a.1 Addition , deletion or replacement - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.d Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) - Accepted	06/09/2024		SmPC and PL	

Variation type IB / EMA/VR/0000181149	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 The in-process limits for hardness are proposed to be widened from 65-85 N to 45-85 N. The lower limits will be at 45N and therefore closer to the limits in the finished product specifications (25-85 N) - 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 The in-process limits for hardness are proposed to be widened from 65-85 N to 45-85 N. The lower limits will be at 45N and therefore closer to the limits in the finished product specifications (25-85 N) - Accepted	17/07/2024	N/A		
Variation type IA / EMA/VR/0000184073	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 dossier)* - Accepted	16/07/2024	N/A		

Variation type IA / EMA/VR/0000183778	B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted	04/07/2024	N/A		
Variation type IB / EMA/VR/0000179363	C.I.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.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted To update section 4.4 of the SmPC and section 4 of the PL in line with the reference product Glivec, following approval of EMEA/H/C/000406/II/133. In addition, the marketing authorisation holder has taken the opportunity to implement editorial changes in the PI annexes in alignment with the reference product, in Annex IIIA in alignment to QRD, and in the linguistic version in HU in alignment to changes approved with procedure IB/0032.	20/06/2024		SmPC, Labelling and PL	