Imatinib Teva

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 /	This was an application for a variation	05/03/2026		SmPC and 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/VR/0000314304	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 C.I.2.a - to update section 4.5 of SmPC with new paragraph related to interaction with Methotrexate. Following changes of reference product texts Glivec (EMA/VR/0000290092) sections 4.2, 4.8 and 5.1 of the SmPC (reordering of text) and Sections 3 and 6 of PL were updated. The MAH took also the opportunity to apply the following additional changes: • Adaption to the latest QRD-template; • Minor editorial changes (format changes, e.g. spacing or indentation, correcting typos, reordering of text) For EMEA/H/C/002585 only: • Changes within list of local representatives in section 6 of the PL for: MT, ES and deletion of UK(NI); • Minor editorial changes in translations for EL, HU and MT.				

Variation type IA / EMA/VR/0000314612	This was an application for a group of variations. 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 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	26/11/2025			
Variation type IA / EMA/VR/0000314213	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	26/11/2025			
Variation type IB / EMA/VR/0000278121	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.z Other changes -	04/09/2025			

	Accepted				
Variation type IA / EMA/VR/0000253469	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	18/02/2025			