Imatinib Accord

Procedural steps taken and scientific information after the authorisation*

*Due to Agency`s update of its procedure management systems, an additional document, capturing the historical lifecycle may be available in the 'Assesment history' section. For the complete 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

[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).

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	