EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Gefitinib Mylan

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
R/0008	Renewal of the marketing authorisation	26/04/2023	23/06/2023	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Gefitinib Mylan in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

[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).

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IAIN/0007	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	15/06/2022	23/06/2023	Annex II and PL	
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/04/2022	23/06/2023	PL	
T/0005	Transfer of Marketing Authorisation	24/09/2021	19/10/2021	SmPC, Labelling and PL	
IB/0004/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH A.6 - Administrative change - Change in ATC Code/ATC Vet Code	09/09/2021	19/10/2021	SmPC, Annex II, Labelling and PL	
IA/0003/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	09/07/2020	n/a		

N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/04/2019	19/10/2021	Labelling and PL	
IAIN/0001	B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	15/03/2019	n/a		