Lenalidomide 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
IB/0011	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	04/10/2022		SmPC and PL	
IAIN/0010/G	This was an application for a group of variations.	15/08/2022	n/a		

[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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	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/07/2022		Labelling and PL	
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/02/2022	08/07/2022	PL	
IA/0007	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	06/10/2021	n/a		
PSUSA/1838/202012	Periodic Safety Update EU Single assessment - lenalidomide	22/07/2021	16/09/2021		Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/1838/202012.
IB/0006	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	13/09/2021	08/07/2022	SmPC	To update section 6.3 of the Summary of Product Characteristics.
IAIN/0005/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer	13/08/2021	08/07/2022	Annex II and PL	

	responsible for importation and/or batch release - Not including batch control/testing B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
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 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	19/07/2021	12/08/2021	SmPC, Annex II and PL	
IB/0003/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside	17/05/2021	12/08/2021	SmPC, Labelling and PL	Change in the pack size of the finished product outside the range of the currently approved pack size to add 7 x 1 capsules in (PVC/Aclar/alu) unit dose blister for the 5 mg, 10 mg & 15 mg strengths, new pack sizes of 7 x 1 capsules (unit dose) for the 2.5 mg, 7.5 mg, 20 mg & 25 mg strengths (EU/1/20/1490/019, EU/1/20/1490/021, EU/1/20/1490/025 and EU/1/20/1490/026) and new pack size of 7 capsules in blister (PVC/Aclar/alu) for the 10 mg strength (EU/1/20/1490/022).

	the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes				The marketing authorisation holder took the opportunity to align the PI to the latest QRD template (version 10.2) and to include editorial changes are in the linguistic versions of the Annexes for ES, HR and SK.
IA/0001	A.7 - Administrative change - Deletion of manufacturing sites	05/03/2021	12/08/2021	SmPC, Annex II and PL	