Lenalidomide Mylan

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 /	C.9 Introduction of, or change(s) to, the	11/05/2026		Annex II,	

[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/0000334301	obligations and conditions of a marketing authorisation, including the risk management plan - C.9.z Other variation - Accepted C.9.z - To update the RMP to version 1.6 to remove Tumour Flare Reaction (TFR) related to indication for Mantle cell lymphoma (MCL) and Follicular lymphoma (FL), previously classified as important identified risk, from the list of safety concerns in line with the RMP for the reference product Revlimid. Annex II is updated accordingly. - To reclassify "Cardiac failure, cardiac arrhythmias and ischaemic heart disease (including myocardial infarction)", previously classified as important potential risk, as important identified risk due to changes in the level of scientific evidence for the causal association or risk-benefit impact, following the RMP for the reference product Revlimid. - To update Part V and Part VI of the RMP to mention only the “Educational Healthcare Professional brochure” as additional risk minimisation measures for the risk of SPM. Furthermore, the MAH has taken the opportunity to introduce the following minor changes to the PI: - To update Annex IIIA by grey-shading the name of the active substance Lenalidomide in section 1 of the immediate packaging. - To update the package leaflet by adding the patient-			Labelling and PL	

	friendly term of the pharmaceutical form "(capsules)" in section 6 as in line with the QRD template.				
Article 61(3) / EMA/N/0000309298	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives. Additionally, the MAH took the opportunity to add the latest renewal Commission Decision in section 9 of the SmPC.	06/11/2025		PL	
Variation type IB / EMA/VR/0000268655	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e) Container closure system - B.II.e.z Other variation - Accepted	10/07/2025			
Renewal - 5 year / EMA/R/0000257483	- Renewal - Accepted Renewal of marketing authorisation.	19/06/2025	21/08/2025	SmPC	
Variation type IA / EMA/VR/0000256112	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	03/03/2025	21/08/2025	Annex II and PL	

	dossier)* - Accepted				
Variation type IA / EMA/VR/0000245155	This was an application for a group of variations. B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.3 Updated certificate from an already approved manufacturer - Accepted B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.3 Updated certificate from an already approved manufacturer - Accepted B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.2 New certificate for a starting material/reagent/ intermediate/or excipient from a new or an already approved manufacturer - Accepted	27/01/2025			