Thalidomide Lipomed

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.I.11 Introduction of, or change(s) to, the	11/09/2025	N/A		To update the RMP to reflect safety changes, after

[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/0000279194	obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.11.z (Type IB) – To update the RMP to reflect safety changes, after assessment of the same changes for the reference product Thalidomide BMS. In addition, the MAH took the opportunity to implement editorial changes to the RMP, to replace "Celgene" by "BMS" for the originator product throughout the document, to update the Post authorisation experience to reflect the current marketing situation, to update the wording for the Important potential risk "Medication error", and to add the Thalidomide Lipomed EPAR link.				assessment of the same changes for the reference product Thalidomide BMS.
PSUR / EMA/PSUR/0000248471	- -				Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing thalidomide remains unchanged and therefore recommends the maintenance of the marketing authorisation(s).