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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
PSUR / EMA/PSUR/0000296554	In view of available data on limbal stem cell deficiency risk from the literature,	29/01/2026	07/04/2026	SmPC and PL	Variation

[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).

	spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between hydroxycarbamide and limbal stem cell deficiency is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing hydroxycarbamide should be amended accordingly.				
Variation type IB / EMA/VR/0000306487	C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II - Accepted C.I.11.z - to provide and updated RMP to propose a change of due date for a Category 3 PRECISE PASS study protocol (NOVDD-001), from 'March 2029' to 'June 2030'. In addition, the MAH submitted the updated version of the PASS study Protocol, v3.0, which now contains new contact details (including the new QPPV details) as well as the updated milestones.	03/11/2025			
Variation type IB / EMA/VR/0000303946	B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.3 New certificate	03/11/2025			

	from a new manufacturer (replacement or addition) - Accepted				
Variation type IA_IN / EMA/VR/0000278741	This was an application for a group of variations. B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	12/06/2025	22/05/2025	Annex II and PL	
Marketing Authorisation Transfer - H / EMA/T/0000266220	transfer of marketing authorisation from Nova Laboratories Ireland Limited to Lipomed GmbH	28/04/2025	22/05/2025	SmPC, Labelling and PL	