Amglidia

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	08/05/2026			

[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/0000340527	obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted Type IB, C.9.b - to update the RMP for Amglidia to take into account the request of the PRAC during the assessment of PSUSA/00010690/202505: the important identified risk “hypoglycaemia” and the important potential risks “transitory increased transaminases”, "neutropenia", "overdosing of preservative sodium benzoate", "bullous eruption, exfoliative dermatitis, erythema multiforme", "anaphylactic reaction including dyspnoea, hypotension, and shock", as well as the missing information "patients with renal or hepatic impairment" and "long-term use", should be removed from the RMP.				
Variation type IA / EMA/VR/0000328095	This was an application for a group of variations. Q.III.1.a) European Pharmacopoeial	04/03/2026			

	certificate of suitability to the relevant Ph. Eur. Monograph(*) - Q.III.1.a.2 Update of an approved certificate of suitability (CEP) - Accepted Q.II.d.2 Change to analytical procedure for the finished product - Q.II.d.2.a) Minor change to an approved analytical procedure - Accepted				
PSUR / EMA/PSUR/0000296601					Maintenance