Amglidia

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
IAIN/0017	A.1 - Administrative change - Change in the name and/or address of the MAH	05/12/2023		SmPC and PL	
IAIN/0016	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	25/09/2023		Annex II and PL	

[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).

II/0015	Update of section 5.1 of the SmPC in order to update information regarding sulphonylurea effects on neurological abnormalities in children and adults with KCNJ11- and ABCC8-related neonatal diabetes based on literature. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/05/2023		SmPC	
R/0014	Renewal of the marketing authorisation.	10/11/2022	09/02/2023	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Amglidia in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10690 /202205	Periodic Safety Update EU Single assessment - glibenclamide (for centrally authorised products only)	12/01/2023	n/a		PRAC Recommendation - maintenance
IB/0012	B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation	06/07/2022	n/a		
PSUSA/10690 /202105	Periodic Safety Update EU Single assessment - glibenclamide (for centrally authorised products only)	13/01/2022	n/a		PRAC Recommendation - maintenance
IAIN/0010/G	This was an application for a group of variations. 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	25/02/2021	16/02/2022	Annex II and PL	

	control/testing takes place B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer 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 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 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 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 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 responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging				

	site				
PSUSA/10690 /202005	Periodic Safety Update EU Single assessment - glibenclamide (for centrally authorised products only)	14/01/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10690 /201911	Periodic Safety Update EU Single assessment - glibenclamide (for centrally authorised products only)	11/06/2020	n/a		PRAC Recommendation - maintenance
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/02/2020	n/a		
PSUSA/10690 /201905	Periodic Safety Update EU Single assessment - glibenclamide (for centrally authorised products only)	16/01/2020	n/a		PRAC Recommendation - maintenance
II/0004	Update of section 4.2 and 5.1 of the SmPC to reconcile posology instructions with the actual use of the product in clinical practice in order to avoid overdosing, to harmonise sections related to "Dosage adjustments and long-term treatment management" and remove reference to the off-label use of crushed tablets. This update is based on recently published literature, the ISPAD consensus guideline, and in line with the NEOGLI CSR. In addition, the applicant took the opportunity to make editorial corrections. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	04/07/2019	03/09/2019	SmPC and PL	Update based on recently published literature, the ISPAD consensus guideline, and in line with the NEOGLI Clinical Study Report. The SmPC section 4.2 has been updated to reconcile posology instructions with the actual use of the product in clinical practice and to improve clarity and readability. The segment "Dosage adjustments and long-term management" is initiated by a new paragraph summarising information on observed average daily doses. In the recommendation for blood glucose and HbA1c monitoring after insulin discontinuation it was added that, once insulin independence is achieved and steady state of glibenclamide is reached, capillary blood glucose does no longer need to be daily monitored except in clinical situations at risk of metabolic unbalance. In all cases, HbA1c must be monitored every three months. Reference to the off-label use of crushed tablets was removed.

					The SmPC section 5.1 has been updated with reference to the success rate, the average doses, and most recent data.
IA/0005	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	16/07/2019	n/a		
PSUSA/10690 /201811	Periodic Safety Update EU Single assessment - glibenclamide (for centrally authorised products only)	14/06/2019	n/a		PRAC Recommendation - maintenance
IAIN/0002	A.1 - Administrative change - Change in the name and/or address of the MAH	18/12/2018	03/09/2019	SmPC, Labelling and PL	
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	31/07/2018	03/09/2019	Labelling	