Inbrija

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
Marketing Authorisation Transfer - H / EMA/T/0000303317	- Transfer of a marketing authorisation - transfer of marketing authorisation from	16/10/2025	21/11/2025	SmPC, Labelling and	

[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).

	Acorda Therapeutics Ireland Limited to Merz Therapeutics GmbH			PL	
Variation type II / EMA/VR/0000275645	This was an application for a group of variations. B.II.c.2 Change in test procedure for an excipient - B.II.c.2.d Other changes to a test procedure (including replacement or addition) - Accepted B.II.c.2 Change in test procedure for an excipient - B.II.c.2.d Other changes to a test procedure (including replacement or addition) - Accepted B.II.c.1 Change in the specification parameters and/or limits of an excipient - B.II.c.1.d Change outside the approved specifications limits range - Accepted	09/10/2025	N/A		
Variation type IB / EMA/VR/0000266340	This was an application for a group of variations. B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.z Other changes - Accepted	04/06/2025	N/A		

	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted				
PSUR / EMA/PSUR/0000257892	- -				Maintenance