Zebinix

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	05/08/2025	N/A		To update the RMP to extend the due date of final

[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/0000275829	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 To update the RMP to extend the due date of final report for the pregnancy exposure registry from December 2024 to February 2026. In addition the format was updated to comply with GVP module V (rev. 2).				report for the pregnancy exposure registry from December 2024 to February 2026. In addition the format was updated to comply with GVP module V (rev. 2).
Variation type IB / EMA/VR/0000285690	This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.3 New certificate from a new manufacturer (replacement or addition) - Accepted	25/07/2025	N/A		

Variation type IA_IN / EMA/VR/0000261032	B.IV.1.a Addition or replacement of a device which is not an integrated part of the primary packaging - B.IV.1.a.1 Device with CE marking - Accepted	31/03/2025		SmPC and PL	