EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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
Variation type IA /	A. ADMINISTRATIVE CHANGES - A.7	22/09/2025		Annex II 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).

EMA/VR/0000296778	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			PL	
Variation type IB / EMA/VR/0000292271	B.II.e) Container closure system - B.II.e.z Other variation - Accepted	11/09/2025	N/A		
Variation type IB / EMA/VR/0000256926	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 Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.11.z (Type IB) - To update the RMP in accordance with the published RMP of the reference product Efient, following the adoption of the same changes applied for. Annex II of the Product Information has been updated accordingly. The MAH took the opportunity to update the contact details of the local representative in Cyprus in section 6 of the Package Leaflet.	30/05/2025		Annex II and PL	
Article 61(3) / EMA/N/0000247565	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised	20/03/2025		PL	

	contact details of local representatives and deletion of 'United Kingdom (Northern Ireland)' from the list of local representatives in line with the QRD template v10.4.				
Variation type IA / EMA/VR/0000248723	A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted	07/02/2025	N/A		