Mepact

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_IN /	B.II.b.2.c Replacement or addition of a	18/12/2025		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/0000319446	manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted			PL	
Marketing Authorisation Transfer - H / EMA/T/0000301999	- Transfer of a marketing authorisation - transfer of marketing authorisation from Takeda France S.A.S. to Esteve Pharmaceuticals S.A.	17/10/2025	26/11/2025	SmPC, Labelling and PL	
Variation type IB / EMA/VR/0000286228	This was an application for a group of variations. B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.z Other changes - Accepted B.II.c.1 Change in the specification parameters and/or limits of an excipient - B.II.c.1.z Other changes - Accepted B.II.c.1 Change in the specification parameters and/or limits of an excipient - B.II.c.1.z Other changes - Accepted	20/08/2025	N/A		
Variation type IB / EMA/VR/0000287273	B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process	07/08/2025	N/A		

	of the active substance - B.I.b.1.z Other changes - Accepted				
Variation type IB / EMA/VR/0000287022	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted	04/08/2025	N/A		
Variation type IA_IN / EMA/VR/0000282421	A. ADMINISTRATIVE CHANGES - A.1 Change in the name and/or address of the marketing authorisation holder - Accepted	11/07/2025	26/11/2025	SmPC, Labelling and PL	
Variation type IA / EMA/VR/0000284952	B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.d Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Refused	10/07/2025	N/A		