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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 IB /	C.I.11 Introduction of, or change(s) to, the	21/11/2025	N/A		

[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/0000309493	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 with the updated due dates of PASS DAISY as per agreed protocol and updated list of countries where PASS will be conducted (France no longer part of PASS but Poland included). The due date for the final report is extended from December 2029 to December 2030.				To update the RMP with the updated due dates of PASS DAISY as per agreed protocol and updated list of countries where PASS will be conducted (France no longer part of PASS but Poland included). The due date for the final report is extended from December 2029 to December 2030
Variation type IB / EMA/VR/0000294313	B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Change in the holding time of an intermediate - Accepted	16/09/2025	N/A		
PSUR / EMA/PSUR/0000248513	- -	05/06/2025			Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing linzagolix choline remains unchanged and therefore recommends the maintenance of the marketing authorisation.
Variation type IA_IN / EMA/VR/0000247510	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.a The activities	30/01/2025	N/A		

	for which the manufacturer/importer is responsible include batch release - Accepted				