



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ovitrelle

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, please 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 /	B.IV.1.a Addition or replacement of a device	23/05/2025		PL	

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/0000267272	which is not an integrated part of the primary packaging - B.IV.1.a.1 Device with CE marking - Accepted				
Variation type II / EMA/VR/0000238672	B.II.g) Design Space and post approval change management protocol - B.II.g.2 Introduction of a post approval change management protocol related to the finished product - Accepted	06/03/2025			
Variation type IA / EMA/VR/0000239038	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 - - Accepted	13/12/2024	N/A		