



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Scemblix

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 IA / EMA/VR/0000261219	A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant	25/03/2025	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).



	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				
Variation type IB / EMA/VR/0000246322	<p>This was an application for a group of variations.</p> <p>B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.z Reduction in the testing frequency of an analysis, from routine testing to skip or periodic testing (microbial testing of finished product). - Accepted</p> <p>B.II.g.5 Implementation of changes foreseen in an approved change management protocol - B.II.g.5.a The implementation of the change requires no further supportive data - Accepted</p>	25/02/2025	N/A		