Sugammadex Mylan

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 /	This was an application for a group of	12/03/2025		SmPC, Annex	

[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/0000253871	variations. C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted 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 for which the manufacturer/importer is responsible include batch release - Accepted C.I.2.a (IB) - To update section 4.8 of the SmPC to add information on hypersensitivity reactions for sugammadex-rocuronium complex, following approval of the same changes in the reference product. A.5.a (IAIN) - To change the name of the site responsible for quality control testing and batch release of the finished product from Eurofins Analytical Services Hungary Kft (Anonymus Utca 6, Kerulet, Budapest IV, 1045, Hungary) to Eurofins BioPharma Product Testing Budapest Kft. The address remains unchanged. Furthermore, the Marketing Authorisation Holder has taken			II and PL	

	the opportunity to remove the United Kingdom (Northern Ireland) from the list of local representatives.				