Rasagiline Viatris

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
Marketing Authorisation	- Transfer of a marketing authorisation -	31/05/2024	29/07/2024	SmPC,	

[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).

Transfer - H / EMA/T/0000179065	Transfer of Marketing Authorisation from Mylan Pharmaceuticals Limited to Viatris Limited.			Labelling and PL	
Variation type IA_IN / EMA/VR/0000174634	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. A.2 Change in the (invented) name of the medicinal product - A.2.a) for Centrally Authorised products - Accepted	18/04/2024	17/06/2024	SmPC, Labelling and PL	