Atazanavir 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, 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 IA_IN /	E.4 Change in the name and/or address of	05/05/2026		Annex II and	

[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/0000325156	the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank, manufacturing site for an active substance, intermediate or finished product, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier - E.4.b) The change in the name and/or address concerns a manufacturer(s)whose activities include batch release of the finished product - Accepted			PL	
Variation type IB / EMA/VR/0000268655	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e) Container closure system - B.II.e.z Other variation - Accepted	10/07/2025			
Variation type IB / EMA/VR/0000268126	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	14/05/2025		SmPC, Labelling and PL	To update sections 4.3 and 4.4 of the SmPC in order to clarify the contraindication for the co-administration of atazanavir with strong inducers of CYP3A4, based on the results from study AI424082. The changes follow assessment of the same

	new additional data is required to be submitted by the MAH - Accepted C.I.2.a - to update sections 4.3 and 4.4 of the SmPC in order to clarify the contraindication for the co-administration of atazanavir with strong inducers of CYP3A4, based on the results from study AI424082. This was an open-label, multiple-dose, randomised, drug-interaction study to assess the PK of ATV resulting from 3 regimens of ATV/RTV/RIF relative to those of ATV, with or without RTV. The changes follow assessment of the same changes for the reference product Reyataz. Also, the MAH took the opportunity to make editorial changes throughout the EN PI to correct for typographical errors, to align with the PI of the reference product and to amend the list of local representatives for CY. Additionally, the MAH took the opportunity to implement editorial changes to the PI in EL, ES, FR, HU, IS, IT, LV, MT, NL, NO, PT, RO, SK, SI and SV, to align with the counterpart PI of the reference product and to correct for spelling and typographical errors.				changes for the reference product Reyataz.
Variation type IA / EMA/VR/0000255132	This was an application for a group of variations. A.5 Change in the name and/or address of a manufacturer/importer of the finished	27/02/2025		Annex II and PL	

	product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted 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 B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.3 Updated certificate from an already approved manufacturer - Accepted B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.3 Updated certificate from an already approved manufacturer - Accepted B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active				

	substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.3 Updated certificate from an already approved manufacturer - Accepted				
Marketing Authorisation Transfer - H / EMA/T/0000178550	- Transfer of a marketing authorisation - Accepted Transfer of Marketing Authorisation from Mylan Pharmaceuticals Limited to Viatris Limited.	31/05/2024	29/07/2024	SmPC, Labelling and PL	
Variation type IA_IN / EMA/VR/0000174634	A.2 Change in the (invented) name of the medicinal product - A.2.a) for Centrally Authorised products - Accepted	18/04/2024	13/06/2024	SmPC, Labelling and PL	