Enzalutamide 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 IB /	Outcome:	18/06/2026		SmPC and 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/0000350515	C.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.2.a) Implementation of change(s) for which no new additional data is required to be submitted by the holder - Accepted C.2.a (Type IB) – To update sections 4.8 and 5.1 of the SmPC and section 4 of the PL to (1) include the adverse reaction for headache under very common frequency, (2) provide updated information on the Ischemic heart disease findings, and (3) provide updated clinical safety and efficacy data based on final results from 9785-CL 0335 (EMBARK) study. The changes follow approval of the same change for the reference product, Xtandi. In addition, the MAH took the opportunity to implement editorial changes across the product information to update the local representative for BG and implement further editorial changes to the translated product information to align with the reference product and correct typographical errors.				
Variation type IA_IN / EMA/VR/0000333469	Outcome: Q.II.b.2.c) Addition or replacement of a site responsible for batch release (QP certification) - Q.II.b.2.c.1 Not including	23/02/2026		Annex II and PL	

	batch control/testing - Accepted				
Variation type IB / EMA/VR/0000289520	Outcome: B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.z To increase the shelf-life in accordance with ICH guidelines and amend storage conditions (e.g. decrease in temperature to preserve longer shelf-life) - Accepted	28/08/2025	21/11/2025	SmPC and PL	
Variation type IA_IN / EMA/VR/0000293010	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH - Accepted	25/08/2025	21/11/2025	SmPC	
Variation type IB / EMA/VR/0000269129	Outcome: 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	23/05/2025	17/10/2025	SmPC and PL	

	C.I.2.a - To update sections 4.2, 4.4 and 4.8 of the SmPC to add a new warning on Dysphagia and to add dysphagia to the list of adverse drug reactions (ADRs) with frequency Not known, and to add decreased appetite to the list of adverse drug reactions (ADRs) with frequency Not known. The PL is updated accordingly. The changes follow assessment of the same changes for the reference product Xtandi. In addition, the MAH took the opportunity to update the PI with editorial changes to align with the QRD template, including the removal of the local representative for the UK. Furthermore, the MAH took the opportunity to implement editorial changes to the PI for DE, EL, HU, NL and SL, to align with the PI of the reference product and the QRD template.				