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 /	B.II.f.1 Change in the shelf-life or storage	28/08/2025		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/0000289520	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				
Variation type IA_IN / EMA/VR/0000293010	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		SmPC	
Variation type IB / EMA/VR/0000269129	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 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	23/05/2025		SmPC and PL	

	(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.				