Yttriga

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 /		21/05/2026		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/0000348646	Outcome: E.4 Change in the name and/or address of 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/0000327460	Outcome: Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.d) Replacement of a specification attribute with its corresponding analytical procedure - Accepted Q.II.e.4 Change in the specification attribute	07/04/2026			

	and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product -				

	Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted				

	Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted				
Variation type IB / EMA/VR/0000320290	Outcome: B.I.b.2 Change in test procedure for active	16/01/2026			

	substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted				
Variation type IA / EMA/VR/0000265509	Outcome: B.II.c.3 Change in source of an excipient or reagent with TSE risk - B.II.c.3.z Change in source of excipient unlikely to present any risk of TSE contamination - Accepted	28/04/2025			
PSUR / EMA/PSUR/0000282267	EURD: PSUSA/00003137/202503 Active substance: yttrium (90y) chloride Outcome: Maintenance	30/10/2025			Maintenance