Advate

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
Variation type IB /	C.I HUMAN AND VETERINARY MEDICINAL	21/05/2025		SmPC, Annex	

[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/0000254887	PRODUCTS - C.I.z Other variation - Accepted C.I.z - To update sections 4.2, 4.4, 4.5 and 4.8 of the SmPC to implement the recommendation of the CHMP based on Core SmPC for human plasma derived and recombinant coagulation factor VIII (Revision 3) products. In addition, the following changes are proposed as editorial within this variation application: · Combining the current 10 SmPCs into two: one SmPC for presentations with 2ml diluent and one for those with 5ml diluent in line with QRD recommendations. · The MAH is proposing to include the volume of dilution in the product name (eg. 250 IU/5 ml). · Update in line with the Annex to the European Commission guideline on `Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668) - Revision 4, regarding polysorbates. · Updates in line with guidelines for product information, including the current QRD template v10.4. · Minor rewording or reordering of text in order to enhance readability in all languages.			II, Labelling and PL	
Variation type II / EMA/VR/0000256654	B.II.g) Design Space and post approval change management protocol - B.II.g.2 Introduction of a post approval change management protocol related to the finished	15/05/2025	N/A		

	product - Accepted				