ADYNOVI

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 /	Outcome:	22/06/2026			

[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/0000356666	B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted				
Variation type II / EMA/VR/0000268348	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.2, 4.4, 4.8, 5.1, and 5.2 of the SmPC in order to update clinical pharmacokinetic, efficacy, and safety information based on final results from study 261203, listed as a category 3 study in the RMP; this is a phase 3, prospective, multi-center, open label study to investigate safety, immunogenicity, and hemostatic efficacy of PEGylated Factor VIII (BAX 855) in previously untreated patients (PUPs); the Package Leaflet is updated accordingly. The RMP version 5.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet, to introduce editorial changes, and to bring the PI in line with the latest QRD template.	26/02/2026	07/04/2026	SmPC, Annex II, Labelling and PL	Submission of the final results from an open-label study (trial 261203) in 120 dosed paediatric (below 6 years) previously untreated patients (PUPs) with severe haemophilia A. This trial showed that Adynovi is effective in controlling and preventing bleeding episodes in PUPs. Most bleeding episodes were effectively managed with one or two infusions. The incidence of FVIII inhibitor formation in PUPs is very common (i.e. frequency ≥1/10 patients), within the expected ranges for PUPs.

Variation type IB / EMA/VR/0000274174	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.2 Change in test procedure for active 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	15/01/2026			
Variation type II / EMA/VR/0000262248	Outcome: 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 product - Accepted	17/07/2025			
Variation type IB / EMA/VR/0000278005	Outcome: This was an application for a group of variations. B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted	08/07/2025			

	B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.a Change in the name of a supplier of a packaging component. If the information is not needed in the dossier CMDh recommends deletion of this information. - Accepted				
PSUR / EMA/PSUR/0000248511	EURD: PSUSA/00010663/202411 Active substance: rurioctocog alfa pegol Outcome: Maintenance	05/06/2025			Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing rurioctocog alfa pegol remains unchanged and therefore recommends the maintenance of the marketing authorisation(s).