



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ADZYNMA

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 /	B.II.f.1 Change in the shelf-life or storage	20/01/2026			

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/0000316417	conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted				
Variation type IA / EMA/VR/0000320795	<p>This was an application for a group of variations.</p> <p>A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted</p> <p>B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.c Deletion of a non-significant in-process test - Accepted</p> <p>B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.b Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State - Accepted</p>	07/01/2026			
Annual reassessment - H / EMA/S/0000288329		13/11/2025			The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of ADZYNMA

					should be maintained.
Variation type II / EMA/VR/0000255553	<p>C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* - Accepted</p> <p>Submission of the final report from study 281102 listed as a Specific Obligation in the Annex II of the Product Information. This is a phase 3, prospective, randomized, controlled, open-label, multicentre study evaluating the safety and efficacy of TAK-755 (rADAMTS13) in the prophylactic and on-demand treatment of subjects with cTTP. In addition, results from the second interim analysis for Study 3002, which is a Phase 3b, prospective, open-label, multicenter, single treatment arm, continuation study of study 281102 was also submitted. The Annex II and the RMP version 1.1 are updated accordingly.</p>	13/11/2025	09/01/2026	Annex II	Not applicable
Variation type IA / EMA/VR/0000301800	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	07/10/2025			

	the information is not needed in the dossier CMDh recommends deletion of this information. - Accepted				
PASS / EMA/PASS/0000253115		04/09/2025			
Variation type IB / EMA/VR/0000284701	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p>	29/07/2025			
Variation type IB / EMA/VR/0000268228	<p>B.I.d.1.a Re-test period/storage period -</p> <p>B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real</p>	04/06/2025			

	time data - Accepted				
PSUR / EMA/PSUR/0000288290					Maintenance
PSUR / EMA/PSUR/0000248509					Maintenance