Evrysdi

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 /	C.9 Introduction of, or change(s) to, the	17/04/2026			

[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/0000338688	obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted C.9.b (Type IB) – To change the due dates for the provision of the final study reports for two Category 3 studies, BN44619 (PUPFISH) from Q1 2026 to Q1 2027, and BN42833 (risdiplam pregnancy surveillance study) from Q4 2031 to Q4 2032, in the Evrysdi Risk Management Plan. In addition, the MAH took the opportunity to update the product overview; the carcinogenicity information based on the final study report 1103092 for the 2 year rat carcinogenicity study; the clinical trial and post authorisation exposure data; the narrative on Important Potential Risks and Missing Information to reflect up to 5 years of clinical follow up; the list of required additional pharmacovigilance activities and the post authorisation development plan by removing completed studies; the current status and milestones for the PAES study				

	BN43428; and the template in line with the latest RMP format guidance (Rev. 2.0.1).				
Variation type IB / EMA/VR/0000320478	This was an application for a group of variations. B.I.d.1.a Re-test period/storage period - B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real time data - Accepted B.I.d.1 Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - B.I.d.1.c Change to an approved stability protocol - Accepted	10/03/2026			
Variation type IB / EMA/VR/0000325586	C. Safety, efficacy, pharmacovigilance changes - C.11 Submission of results of assessments carried out on target patient groups in order to comply with Article 59(3) of Directive 2001/83/EC and any resulting change(s) to the package leaflet. - Accepted C.11 - A user testing bridging report has been submitted to address the layout difference between the package leaflet that was approved in the procedure EMEA/H/C/005145/X/0024/G and the package leaflet that is in production.	03/03/2026			

Variation type II / EMA/VR/0000310762	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 - - Accepted Update of section 4.2 of the SmPC in order to modify administration instructions to allow the administration of Evrysdi 5 mg film-coated tablet disperse in water via a nasogastric or gastrostomy tube based on the compatibility data for the dispersed Evrysdi tablet and nasogastric or gastrostomy tube; the Package Leaflet (including the Instructions for Use) is updated accordingly. In addition, the MAH took the opportunity to make some minor editorial changes to the product information.	26/02/2026		SmPC and PL	Update of section 4.2 of the SmPC in order to modify administration instructions to allow the administration of Evrysdi 5 mg film-coated tablet disperse in water via a nasogastric or gastrostomy tube based on the compatibility data for the dispersed Evrysdi tablet and nasogastric or gastrostomy tube; the Package Leaflet (including the Instructions for Use) is updated accordingly. In addition, the MAH took the opportunity to make some minor editorial changes to the product information.
Variation type IA / EMA/VR/0000313401	B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted	20/11/2025			
Renewal - 5 year / EMA/R/0000275338	- Renewal - Accepted	13/11/2025	08/01/2026	SmPC, Annex II and PL	Renewal of marketing authorisation. Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Evrysdi in the approved indication remains favourable and therefore recommended the renewal

					of the marketing authorisation with unlimited validity.
Variation type II / EMA/VR/0000287985	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted Submission of the final report from study BP39054 (JEWELFISH) listed as a category 3 study in the RMP. This is an open-label phase 2 study to investigate the safety, tolerability, and pharmacokinetics/pharmacodynamics of risdiplam (RO7034067) in adult and pediatric patients with spinal muscular atrophy.	09/10/2025			
Variation type IB / EMA/VR/0000293709	B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.d Change in storage conditions of the finished product or the diluted/reconstituted product - Accepted	26/09/2025	08/01/2026	SmPC, Labelling and PL	
Article 61(3) / EMA/N/0000281001	- Notification acc. Article 61(3) - Accepted Update of the Annex IIIA to include the update to section 16 of the labelling to reflect accurate information in Braille, an amendment to section 2 regarding composition and packaging details, and a revision to Section 5 of the package leaflet	26/06/2025	08/01/2026	Labelling and PL	

	to align the storage requirements.				
Variation type IA / EMA/VR/0000280817	A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted	23/06/2025			
Variation type IA / EMA/VR/0000269671	B.II.e.6 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - B.II.e.6.b Change that does not affect the product information - Accepted	16/05/2025			
PSUR / EMA/PSUR/0000311153					Maintenance
PSUR / EMA/PSUR/0000268972					Maintenance