Kuvan

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 II / EMA/VR/0000301983	Outcome: C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet	07/05/2026		SmPC	

[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).

	of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH - Accepted Update of section 4.6 of the SmPC in order to update pregnancy information based on a cumulative pregnancy data analysis, following the PRAC request in the PSUR assessment for PSUR/0000257835. In addition, the MAH took the opportunity to introduce a minor editorial change to the PI.				
Variation type IA_IN / EMA/VR/0000320742	Outcome: This was an application for a group of variations. B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	07/01/2026		Annex II and PL	

Variation type IB / EMA/VR/0000244880	Outcome: 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	03/02/2025			
PSUR / EMA/PSUR/0000257835	EURD: PSUSA/00002683/202412 Active substance: sapropterin Outcome: Maintenance	10/07/2025			Maintenance