Sapropterin Dipharma

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_IN /		13/05/2026		Annex II and	

[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/0000347620	Outcome: Q.II.b.2.c) Addition or replacement of a site responsible for batch release (QP certification) - Q.II.b.2.c.1 Not including batch control/testing - Accepted			PL	
Variation type IB / EMA/VR/0000337408	Outcome: This was an application for a group of variations. Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.d) Minor change to the restricted part of an Active Substance Master File - Accepted	10/04/2026			
Variation type IA_IN / EMA/VR/0000319636	Outcome: 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	18/12/2025		Annex II and PL	

Variation type IB / EMA/VR/0000301290	Outcome: 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.z Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.11.z (Type IB) – To update the RMP by removing all safety concerns in alignment with the RMP of the reference product, Kuvan. In addition, the MAH updated the RMP to reflect the change in the MAH's name and to align with the GVP Module V Rev. 2 template.	17/10/2025			To update the RMP by removing all safety concerns in alignment with the RMP of the reference product, Kuvan.
Variation type IA / EMA/VR/0000300572	Outcome: B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.a Up to 10-fold increase compared to the originally approved batch size - Accepted	24/09/2025			
Variation type IB / EMA/VR/0000247063		20/02/2025	10/11/2025	SmPC and PL	

	Outcome: This was an application for a group of variations. B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.z Other changes - Accepted				