Brintellix

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 /	C.I HUMAN AND VETERINARY MEDICINAL	07/08/2025		SmPC and PL	To update Section 4.8 of the SmPC and Section 4 of

[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/0000290437	PRODUCTS - C.I.z Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment - Accepted				the PL to implement the signal recommendation on 'Vortioxetine – Hallucinations, not related to serotoninergic syndrome' (EPITT no 20152) adopted at the 5 June 2025 PRAC.