10 January 2024
EMA/13649/2024
Human Medicines Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Brintellix	
vortioxetine	
Pharmaceutical form(s):	See Annex A of the CHMP Opinion
Strength(s):	See Annex A
Route(s) of administration:	See Annex A
Packaging and package size(s):	See Annex A
Number(s)in the Community Register of Medicinal Products:	See Annex A

Marketing Authorisation Holder (MAH):	
Name and address of the MAH:	H. Lundbeck A/S Ottiliavej 9 DK 2500 Valby DENMARK

Procedure	
Procedure number:	EMEA/H/C/002717/IB/0040

Further to the compliance check performed under Article 23 of Regulation (EC) No 1901/2006, and in accordance with Article 28(3) and Article 45(3) of the said Regulation it is concluded that:

-the development of this product has complied with all measures in the agreed paediatric investigation plan EMEA-C-000455-PIP02-10-M09. All studies in the agreed paediatric investigation plan EMEA-C-000455-PIP02-10-M09 were conducted after the entry into force of that Regulation,

-the Summary of Product Characteristics has been updated in section 5.1 to reflect the results of studies conducted in compliance with this agreed paediatric investigation plan.

In accordance with Article 23a of Regulation (EC) No 1234/2008, this statement indicating compliance with the agreed completed paediatric investigation plan EMEA-C-000455-PIP02-10-M09 is included in the technical dossier.