



Amsterdam, 20 March 2026
EMADOC-1700519818-3014087
PIP compliance
EMA/VR/0000335941

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product

RXULTI / Brexpiprazole

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: Otsuka Pharmaceutical Netherlands B.V.
Herikerbergweg 292 1101 CT Amsterdam Noord-Holland
Netherlands

Procedure

Procedure number: EMA/VR/0000335941

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 EMA/PE/0000183866. All studies in the agreed paediatric investigation plan EMA/PE/0000183866 were conducted after the entry into force of that Regulation,

-the Summary of Product Characteristics reflects 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 EMA/PE/0000183866 is included in the technical dossier.