



26 January 2023
EMA/CHMP/37982/2023
Human Medicines Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product

Wakix (pitolisant)

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: Bioprojet Pharma
9 Rue Rameau
75002 Paris
FRANCE

Procedure

Procedure number: EMEA/H/C/002616/II/0030

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 P/0057/2021. All studies in the agreed paediatric investigation plan P/0057/2021 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 P/0057/2021 is included in the technical dossier.

