15 September 2022
EMA/690314/2022
Human Medicines Evaluation Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Repathat/ evolocumab	
Pharmaceutical form(s):	See Annex A
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:	Amgen Europe B.V. Minervum 7061 4817 ZK Breda NETHERLANDS

Procedure	
Procedure number:	EMEA/H/C/003766/IB/0059

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/0105/2018 .All studies in the agreed paediatric investigation plan P/0105/2018 were conducted after the entry into force of that Regulation,

-the Summary of Product Characteristics adopted by CHMP already reflected 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/0105/2018 is included in the technical dossier.

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