10 December 2020
EMA/45300/2021
Human Medicines Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Nplate/ romiplostim	
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:	Amgen Europe B.V. Minervum 7061 4817 ZK Breda NETHERLANDS

Procedure	
Procedure number:	EMEA/H/C/000942/II/0077

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 PIP P/0233/2017. All studies in the agreed paediatric investigation plan PIP P/0233/2017 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 PIP P/0233/2017 is included in the technical dossier.

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