14 January 2020
EMA/22261/2020
Human Medicines Evaluation Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Stelara	
ustekinumab	
Pharmaceutical forms:	See Annex A of the CHMP Opinion
Strengths:	See Annex A
Routes of administration:	See Annex A
Packaging and package sizes:	See Annex A
Numbers in the Community Register of Medicinal Products:	See Annex A

Marketing Authorisation Holder (MAH):	
Name and address of the MAH:	Janssen-Cilag International NV Turnhoutseweg 30 2340 Beerse BELGIUM

Procedure	
Procedure number:	EMEA/H/C/000958/II/0073

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/0003/2016. All studies in the agreed paediatric investigation plan PIP P/0003/2016 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/0003/2016 is included in the technical dossier.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union