19 November 2015
EMA/850660/2015
Procedure Management and Committees Support Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
ILARIS	
canakinumab	
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:	Novartis Europharm Ltd Frimley Business Park Camberley GU16 7SR UNITED KINGDOM

Procedure	
Procedure number:	EMEA/H/C/001109/II/0040/G

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/208/2011. For the purpose of the application of Article 45(3) of Regulation (EC) No 1901/2006, significant studies in the agreed paediatric investigation plan P/208/2011 have been completed 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.

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