25 July 2019
EMA/CHMP/406684/2019
Human Medicines Evaluation Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Lucentis/ ranibizumab	
Pharmaceutical form:	See Annex A of the CHMP Opinion
Strength:	See Annex A
Route 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:	Novartis Europharm Limited Vista Building Elm Park, Merrion Road Dublin 4 IRELAND

Procedure	
Procedure number:	EMEA/H/C/000715/II/0074/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/0010/2017. 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/0010/2017 were 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.

In accordance with Article 23a of Regulation (EC) No 1234/2008, this statement indicating compliance with the agreed completed paediatric investigation plan P/0010/2017 is included in the technical dossier.