EMA/261748/2015

Statement indicating compliance with the agreed completed paediatric investigation plan

26 February 2015

Medicinal product	
Humira/ adalimumab	
Pharmaceutical form:	See Annex A of the CHMP Opinion
Strengths:	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:	AbbVie Ltd. Maidenhead, SL6 4XE United Kingdom

Procedure	
Procedure number:	EMEA/H/C/000481/II/0134

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/0324/2013. 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/0324/2013 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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