EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2013
EMA/65572/2014
Human Medicines Evaluation Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Pandemic Influenza Vaccine H5N1 Baxter pandemic influenza vaccine (H5N1) (whole virion, inactivated, prepared in cell culture)	
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:	Baxter AG Industriestraße 67, Wien, 1221, Austria

Procedure	
Procedure number:	EMEA/H/C/001200/II/0015

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/67/2011. For the purpose of the application of Article 45(3) of Regulation (EC) No 1901/2006, all studies in the agreed paediatric investigation plan P/67/2011 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.

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