



25 April 2013  
EMA/246157/2013  
Human Medicines Development and Evaluation

## Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Menveo	
MENINGOCOCCAL GROUP A, C, W135 AND Y CONJUGATE VACCINE	
Pharmaceutical form:	See Annex A of the CHMP Opinion
Strengths:	See Annex A of the CHMP Opinion
Route of administration:	See Annex A of the CHMP Opinion
Packaging and package sizes:	See Annex A of the CHMP Opinion
Numbers in the Community Register of Medicinal Products:	See Annex A of the CHMP Opinion

Marketing Authorisation Holder (MAH):	
Name and address of the MAH:	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1 IT-53100 Siena Italy

Procedure	
Procedure number:	EMA/H/C/001095/II/0018

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/93/2011. 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/93/2011 have been completed after the entry into force of that Regulation,
- the Summary of Product Characteristics adopted by CHMP reflects the results of studies conducted in compliance with this agreed paediatric investigation plan.

