30 May 2013
EMA/161384/2013
Human Medicines Development and Evaluation

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Glivec/ IMATINIB	
Pharmaceutical forms:	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:	Novartis Europharm Ltd Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM

Procedure	
Procedure number:	EMEA/H/C/000406/II/0080

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/0028/2012. 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/0028/2012 were 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union