25 July 2013
EMA/631299/2013
Human Medicines Development and Evaluation

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Prezista	
Darunavir	
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
Numbersin the Community Register of Medicinal Products:	See Annex A

Marketing Authorisation Holder (MAH):	
Name and address of the MAH:	Janssen-Cilag International N.V. Turnhoutseweg 30 B-2340 Beerse BELGIUM

Procedure	
Procedure number:	EMEA/H/C/000707/II/0054

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/138/2010. 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/138/2010 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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