

25 April 2014
EMA/339030/2014
Human Medicines Evaluation Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product

Invega/ PALIPERIDONE

Pharmaceutical form(s):	See Annex A of the CHMP Opinion
Strength(s):	See Annex A
Route(s) of administration:	See Annex A
Packaging and package size(s):	See Annex A
Number(s) in 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
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Procedure

Procedure number:	EMA/H/C/000746/II/0037
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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 PIP P/154/2011. For the purpose of the application of Article 45(3) of Regulation (EC) No° 1901/2006, all studies in the agreed paediatric investigation plan PIP P/154/2011 > 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.