



24 July 2014  
EMA/661059/2019  
Human Medicines Evaluation Division

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

### Medicinal product

Resolor	
prucalopride	
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:	Shire Pharmaceuticals No.5 Riverwalk Citywest Business Campus Dublin 24 Ireland
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### Procedure

Procedure number:	EMA/H/C/001012/II/0031
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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 P/0293/2012. 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/0293/2012 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.

