EMA/273414/2015

Statement indicating compliance with the agreed completed paediatric investigation plan

10 April 2015

Medicinal product	
Orfadin	
nitisinone	
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:	Swedish Orphan Biovitrum International AB SE-112 76 Stockholm Sweden

Procedure	
Procedure number:	EMEA/H/C/000555/X/0041

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/0065/2012. 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/0065/2012 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.

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