



21 May 2015  
EMA/325173/2015  
Procedure Management and Committees Support Division

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

21 May 2015

### Medicinal product

Kuvan/ SAPROPTERIN

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:	Merck Serono Europe Limited 56 Marsh Wall London E14 9TP UNITED KINGDOM
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### Procedure

Procedure number:	EMA/H/C/000943/II/0033
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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/0232/2013. 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/0232/2013 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.

