10 April 2019
EMA/552323/2019
Human Medicines Evaluation Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Vimpat/ lacosamide	
Pharmaceutical form(s):	See Annex A
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:	UCB Pharma S.A. Allee de la Recherche 60 B-1070 Brussels BELGIUM

Procedure	
Procedure number:	EMEA/H/C/000863/IB/0079

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/0183/2015 .All studies in the agreed paediatric investigation plan P/0183/2015 were conducted after the entry into force of that Regulation,

-the Summary of Product Characteristics adopted by CHMP already reflected the results of studies conducted in compliance with this agreed paediatric investigation plan.

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