19 March 2020
EMEA/H/C/000762/IB/0073
Human Medicines Evaluation Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Xelevia/ sitagliptin	
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:	Merck Sharp & Dohme B.V. Waarderweg 39 2031 BN Haarlem NETHERLANDS

Procedure	
Procedure number:	EMEA/H/C/000762/IB/73

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 PIP for Xelevia (EMEA-000470-PIP01-08-M11) was completed as requested during WS1727 finalised on 30 January 2020.

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