

26 April 2023 EMA/190289/2023 Human Medicines Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
OPDIVO/ nivolumab	
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	See Annex A
size(s):	
Number(s)in the Community	See Annex A
Register of Medicinal Products:	

Marketing Authorisation Holder (MAH):	
Name and address of the MAH:	Bristol-Myers Squibb Pharma EEIG Plaza 254
	Blanchardstown Corporate Park 2 Dublin 15 D15 T867 IRELAND

Procedure	
Procedure number:	EMEA/H/C/003985/II/0125/G

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/0432/2020. For the purpose of the application of Article 45(3) of Regulation (EC) No 1901/2006, significant studies in the agreed paediatric investigation plan P/0432/2020 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.

In accordance with Article 23a of Regulation (EC) No 1234/2008, this statement indicating compliance with the agreed completed paediatric investigation plan P/0432/2020 is included in the technical dossier.

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