9 December 2014
EMA/759531/2014

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
TOBI Podhaler	
Tobramycin	
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:	Novartis Europharm Ltd Wimblehurst Road Horsham West Sussex RH12 5AB UNITED KINGDOM

Procedure	
Procedure number:	EMEA/H/C/002155/II/0027/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/0177/2014. 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/0177/2014 have been 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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