6 March 2023

EMA/97317/2023
Human Medicines Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Artesunate Amivas/ artesunate <common name>	
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:	Amivas Ireland Ltd 7 Durands Court Parnell Street Waterford X91 P381 IRELAND

Procedure	
Procedure number:	EMEA/H/C/005550/IB/0002

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 decision number P/0328/2020 with the full compliance check PIP EMEA-C-002710-PIP01-19: all studies in the agreed paediatric investigation plan P/0328/2020 were conducted 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.