20 December 2019
EMA/CHMP/3022/2020
Human Medicines Evaluation Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Dacogen/ decitabine	
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:	Janssen-Cilag International N.V. Turnhoutseweg 30 B-2340 Beerse Belgium

Procedure	
Procedure number:	EMEA/H/C/0002221/IB/0041

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 DACOGEN (P/0234/2017) consisted of 5 studies, 4 non-clinical studies (PIP Measures 1 to 4) and 1 clinical study (PIP Measure 5):

  Reports of compliance were adopted by the PDCO on 15 July 2011 for PIP Measure 1 and on 18 October 2019 for PIP Measures 2 to 5.

  Results of the PIP measures were assessed by the CHMP at time of the marketing authorisation application (PIP Measure 1), the renewal application (PIP Measures 2 to 4) and the variation procedure II-33 (PIP Measure 5).

  Results from the study conducted in the paediatric population have been reflected in the EUPI as part of the procedure EMEA/H/C/002221/II/33.

  The outcomes of the compliance checks with PIP are provided within this application, as follow:
  - Partial compliance check (PIP Measure 1) granted on the 15 July 2011
  - Full compliance check (PIP Measure 2-5) granted on the 18 October 2019

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