



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 June 2023  
EMA/CHMP/286711/2023  
Human Medicines Division

## Statement indicating compliance with the agreed completed paediatric investigation plan

### Medicinal product

methoxy polyethylene glycol-epoetin beta

Mircera

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: Roche Registration GmbH  
Emil-Barell-Strasse 1  
79639 Grenzach-Wyhlen  
GERMANY

### Procedure

Procedure number: EMEA/H/C/000739/II/0092

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/0317/2017. All studies in the agreed paediatric investigation plan P/0317/2017 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.

In accordance with Article 23a of Regulation (EC) No 1234/2008, this statement indicating compliance with the agreed completed paediatric investigation plan P/0317/2017 is included in the technical dossier.

