26 July 2024
EMA/324532/2024
Human Medicines Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product	
Spevigo	
Spesolimab	
Pharmaceutical form):	See Annex A of the CHMP Opinion
Strengths:	See Annex A
Routes of administration:	See Annex A
Packaging and package sizes:	See Annex A
Numbers in the Community Register of Medicinal Products:	See Annex A

Marketing Authorisation Holder (MAH):	
Name and address of the MAH:	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein GERMANY

Procedure	
Procedure number:	EMEA/H/C/005874/X/0006/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/0049/2022. All studies in the agreed paediatric investigation plan P/0049/2022 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/0049/2022 is included in the technical dossier.