17 July 2018
EMA/492325/2018
Human Medicines Evaluation Division

# Statement indicating compliance with the agreed completed paediatric investigation plan

| Medicinal product | |
|---|---|
| Nucala/ mepolizumab | |
| | |
| 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: | GlaxoSmithKline Trading Services Limited<br>Currabinny<br>Carrigaline<br>County Cork<br>IRELAND |

| Procedure | |
|---|---|
| Procedure number: | EMEA/H/C/003860/II/0013/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/0239/2017. 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/0239/2017 were 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.

In accordance with Article 23a of Regulation (EC) No 1234/2008, this statement indicating compliance with the agreed completed paediatric investigation plan P/0239/2017 is included in the technical dossier.

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