23 June 2016
EMA/400035/2016
Procedure Management and Committees Support Division

# Statement indicating compliance with the agreed completed paediatric investigation plan

| Medicinal product | |
|---|---|
| Ryzodeg/ insulin degludec / insulin aspart | |
| 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: | Novo Nordisk A/S<br>Novo Allé<br>DK-2880 Bagsværd<br>Denmark |

| Procedure | |
|---|---|
| Procedure number: | EMEA/H/C/002499/II/0017 |

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/0034/2015. All studies in the agreed paediatric investigation plan P/0034/2015 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/0034/2015 is included in the technical dossier.

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