26 February 2015
EMA/285905/2015
Procedure Management and Committees Support Division

# Statement indicating compliance with the agreed completed paediatric investigation plan

| Medicinal product | |
|---|---|
| Procoralan | |
| Ivabradine | |
| 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: | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>FRANCE |

| Procedure | |
|---|---|
| Procedure number: | EMEA/H/C/000598/II/0034 |

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/0101/2013. For the purpose of the application of Article 45(3) of Regulation EC (No 1901/2006, all studies in the agreed paediatric investigation plan P/0102/2013 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.

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