

From:

<MAH>
<Contact Person>
<Phone & Fax Numbers>
<Email address>

<Address>
<Post code> <Town>
<Country>

<Date>

To:

<National Competent Authority/EMA>

Subject: Submission of information about paediatric studies completed after 26 January 2007 in accordance with Article 46 of Regulation 1901/2006, as amended

Dear Sir or Madam,

According to Article 46 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006, **[Marketing Authorisation Holder]** is submitting information in the enclosed table on paediatric study completed after 26 January 2007.

- **Name of the medicinal product(s):**
- **INN/active substance(s):**
- **ATC Code(s):**
- **Current therapeutic indication(s):**

(Repeat per study)

Study Title:

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Study Type:

Phase 1 Phase 2 Phase 3 Phase 4 other

Scope of the Study:

Efficacy Safety Pharmacokinetic Pharmacodynamic

Others

If others, please specify:

Is this study linked to other paediatric studies which have been or will be the subject of other Article 46 submissions?

No

Yes

If yes, please specify which studies:

Is this study going to be submitted as part of a future variation/extension?

No

Yes

If yes, please specify:

- when is this variation planned for submission
 - in which Member States will the variation be submitted
-

<Potential regulatory activities planned by the MAH and other information>

Best regards,

<Signature>

<Name>

<Title>