# **Suggested MAH Cover letter template**

From:

<Contact Person>

<Marketing Authorisation Holder>

<Address>

<Town> <Post code>

<Country>

<Email address>

<Phone number>

To:

Paediatrics Unit Manager

Medicines and Healthcare products Regulatory Agency

10 South Colonnade

Canary Wharf

London E14 4PU

United Kingdom

paediatricstudies@mhra.gov.uk

Submission of information about paediatric studies completed after 26 January 2007 in accordance with *Reg. 78A* of the Human Medicines Regulations (HMR) 2012*, as inserted*

Dear Sir or Madam,

In accordance with regulation 78A(14) of the Human Medicines Regulations 2012, as inserted by *the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019,* **<Marketing Authorisation Holder>** is submitting below information of the following paediatric studies completed within the last six months.

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(Repeat per study)*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study Title:** | | | | | | | | |
|  | | | | | | | | |
| **Study Number / Reference:** | | | |  | | | | |
| **Study Completion date[[1]](#footnote-1):** | | | | Click or tap to enter a date. | | | | |
| **Study Type:** | | | | | | | | |
|  | Phase 1 |  | Phase 2 | |  | Phase 3 |  | Phase 4 |
|  | Other, please specify: | | | | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Scope of the Study:** | | | | | | | |
|  | Efficacy |  | Safety |  | Pharmacokinetic |  | Pharmacodynamic |
|  | Other, please specify: | | | | | | |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| **Has this study been submitted for assessment as an EU PdWS procedure under Article 46 of Reg. 1901/2006?** | |
|  | No |
|  | Yes |
| If yes, please provide a copy of the final assessment report if available.  If not available, please inform us of expected date of when the final assessment report will be available. Also, inform us of any urgent safety or efficacy updates identified during the EU assessment if on-going. |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Is this study linked to other paediatric studies which have been or will be the subject of other submissions under:**  **- *Reg. 78A(14) of the Human Medicines Regulations 2012*, *as inserted?* Or**  **- *Article 46 of Reg. 1901/2006*?** | | |
|  | No | |
|  | Yes | |
| If yes, the MAH should provide: - the study title(s), approximate date of completion - any other relevant UK completed paediatric study procedure and if applicable, the UK PIP number.       - if applicable, the EU *Art. 46* procedure and/or EU PIP procedure number with the latest PIP opinion as appropriate.       - if relevant, any paediatric study data under Art. 45 of Reg. 1901/2006 that are not yet assessed. | |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | **As a result of this data, is there a need to update the product information?** | | |  | No  If no, please specify the reason(s):  the same data have been reviewed in another regulatory procedure by MHRA  or another competent authority and the review has not led to product information  (PI) changes  the study was conducted mainly in adult patients with limited paediatric patients included  the drug is already licensed in the paediatric population and the study does not provide new PK, efficacy or safety data  the study, due to its design, limited number of paediatric patients, discontinuation or other reason does not allow drawing conclusions on efficacy or safety that would impact on the drug’s benefit:risk ratio or be useful to prescribers and patients  only interim results from an ongoing study are available which will be assessed  later in their totality  the study has been conducted in populations and/or diseases that are not  applicable to UK (for example hay fever to specific seasonal pollen found in non-UK countries)  other reason | |  | Yes | | If yes, please specify: |   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   |  |  | | --- | --- | | **Please confirm that, based on the results of the study, no urgent safety nor efficacy update of the product information is required** | | |  | no urgent safety nor efficacy update of the product information is required based on the data of this study <add short free txt box for justification of statement> | |  | < short justification of statement selected above> | |  | urgent safety and/or efficacy update of the product information is required based on the data of this study <add short free txt box for justification of statement> | |  | < short justification of statement selected above> |   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Has the study been or would be submitted in the UK or EU as part of a variation/extension or any other application including paediatric data?** | |
|  | No |
|  | Yes |
| If yes, please: - specify the UK or EU procedure number, if available or the type of application this will be submitted under.       - confirm that the application will be submitted within the next 6 months.       - inform us of the planned route of submission of any updates to PI (e.g. reliance route) and the planned date of the submission to the MHRA. |
| If the MAH, plans to omit the initial appraisal step and directly submit the study data as a variation, the MAH should commit by providing an estimated date of planned submission as well as the route of submission e.g. via reliance route. | |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Kind regards,

<Signature>

<Name>

Click or tap to enter a date.

1. Study completion date is defined as last visit of last subject undergoing the trial, unless otherwise justified in the protocol. [↑](#footnote-ref-1)