# **MAH Cover letter template**

From:

<Contact Person>

<Marketing Authorisation Holder>

<Address>

<Town> <Post code>

<Country>

<Email address>

<Phone number>

To:

Head of Paediatrics Unit

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 amended*

Dear Sir or Madam,

In accordance with regulation 78A(14) of the Human Medicines Regulations 2012, as amended by *the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 and the Human Medicines (Amendments relating to the Windsor Framework) Regulations 2024 (HMRs),* **<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):** |  |
| * **Product licence number (PL)** |  |

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*(Repeat per study)*

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

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

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| **Has this study been submitted for assessment as a paediatric review procedure via a non UK-regulator (such as EU Article 46 of Reg. 1901/2006)?** | |
|  | No |
|  | Yes |
| If yes, please specify the non UK-regulator and provide a copy of the final assessment report if available.  If not available, please inform us of the expected date of when the final assessment report will be available. Also, inform us of any urgent safety or efficacy updates identified in the on-going final assessment. |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **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**  **- Non UK regulator procedures such as EU *Article 46 of Reg. 1901/2006*?** | | |
|  | No | |
|  | Yes | |
| If yes, the MAH must provide: - the study title(s), approximate date of completion.       - any other relevant UK completed paediatric study procedure and if applicable, the adopted or agreed UK PIP procedure number with the latest PIP opinion as appropriate.       - if applicable, the relevant non UK regulator paediatric procedure such as EU *Art.* *46* procedure of Reg. 1901/2006.       - if relevant, any paediatric study data under non UK regulator such as EU *Art 46* of Reg. 1901/2006 that are not yet assessed. | |

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| |  |  | | --- | --- | | **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 regulatory 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 as part of a variation/extension, or any other application which includes this paediatric data?** | |
|  | No |
|  | Yes |
| If yes, please: - specify the UK 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 type of submission, of any proposed updates to PI 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 type of submission. | |

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| <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-2)