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| **Form** |
| **Paediatric investigation plan** |
| **Identification number:** | ZL000\_00\_034 |
| **Version:** | 2.3 |
| **Valid from:** | 21.09.2023 |

# Basic information

|  |
| --- |
| Name of medicinal product: …… |
| Authorisation no: ……*If known* |
| Application ID: ……*If known* |

# Further information

* The form is divided into Parts A to C:
* **Part A:** Submission of a PIP approved by a foreign reference authority
* **Part B:** Submission of a Swiss PIP (CH-PIP)
* **Part C:** Application for confirmation of complete fulfilment of PIP conditions
* Only section 1 "Basic information" and the respective Part A, B or C needs to be submitted. The parts of the form that are not applicable should be deleted.
* Part C can be submitted separately or at the same time as the documents on the complete fulfilment of the PIP condition(s).
* For waivers / partial waivers and deferrals, the text fields "Description" and "Description and justification" must always be completed. A reference to the application documentation is not sufficient.
* Further information on the requirements pertaining to the PIP and waivers/partial waivers and deferrals can be found in the guidance document *Paediatric investigation plan HMV4*.

# PART A - Submission of a PIP approved by a foreign reference authority

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| Foreign authority: …… |
| Date of first approval of the PIP: …… |
| Date of most recently approved update of the PIP: …… |
| If EMA PIP: PIP ID: …… EMA decision ID: …… |
| If FDA PSP: …… |

## Documentation to be supplied

***If EU PIP***

* Initial EMA/PDCO Summary Report on the Paediatric Investigation Plan (PIP)
* EMA Decision on the last approved update of the PIP, including waivers and deferrals

***If FDA PSP***

* Initial Pediatric Study Plan approved by the FDA (agreed iPSP)
* Overview of the measures last approved by the FDA as per the PSP, including waivers and deferrals (amended agreed iPSP)

Before a foreign PIP can be accepted, comparability of the medicinal product authorised abroad with the medicinal product proposed for authorisation in Switzerland must be demonstrated.

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| Justification for stating that the submitted foreign PIP is applicable to the medicinal product proposed for authorisation in Switzerland: …… |

# PART B - Submission of a Swiss PIP

The scientific documentation on the CH-PIP should be prepared according to the following EMA template: "Template for scientific document (part B-F)".

Please check all items included in the submitted PIP and justify this where necessary:

|  |
| --- |
|[ ]  **Paediatric investigation plan** |
|  | **Summary of main aspects of the PIP** |
|  | Authorised indication(s) in adults and/or children:…… |
|  | Planned indication(s) in adults: |
|  | Proposed indication(s) in children:…… |
|  | Possible therapeutic benefit for children:…… |
|  | Clinical development programme:…… |
|  | Development programme for paediatric formulation:…… |
|  | Administration route:…… |
|  | Non-clinical development programme:…… |
|  | Extrapolation:…… |

|  |
| --- |
|[ ]  **Application for waiver / partial waiver** |
|  | [ ]  Class waiver |
|  | [ ]  Preparation-specific waiver [ ]  based on reasons of lack of safety or efficacy in the paediatric target population [ ]  disease does not occur in the paediatric target population [ ]  lack of significant therapeutic benefit in the paediatric target population[ ]  other reasons: …… |
|  | Description of/justification for proposed waiver / partial waiver:…… |

|  |
| --- |
|[ ]  **Application for deferral / partial deferral** |
|  | Description of/justification for proposed deferral / partial deferral:…… |

# PART C – Application for confirmation of complete fulfilment of PIP conditions

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| --- |
|[ ]  All the conditions in the PIPs below are fulfilled, and the approved Swiss medicinal product information suitably reflects the results of studies conducted in accordance with the respective PIP. |

*🡪 Please delete inapplicable table*

**For CH-PIP**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| PIP study no. | Swissmedic official decision on the fulfilment of the condition(Date and ID) | Adaptation in Information for healthcare professionals in brief | Adaptation in Patient information in brief | Remarks[[1]](#footnote-1) |
| …… | …… | …… | …… | …… |
| …… | …… | …… | …… | …… |
| …… | …… | …… | …… | …… |

**For a PIP approved by a foreign authority**

Date of Swissmedic official decision on the fulfilment of the PIP condition[[2]](#footnote-2) …… Swissmedic Application ID2: ……

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| PIP study no. | Date of fulfilment of condition acc. to the foreign authority | Swissmedic official decision on the adaptation of the medicinal product information(Date and ID) | Adaptation in Information for healthcare professionals, briefly | Adaptation in PI, briefly | Remarks |
| …… | …… | …… | …… | …… | …… |
| …… | …… | …… | …… | …… | …… |
| …… | …… | …… | …… | …… | …… |

If the application for new authorisation of the medicinal product was submitted to Swissmedic before 1 January 2019, please include with the application an official confirmation that it fully complies with the foreign PIP requirements.

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 2.3 | New layout, no content adjustments to the previous version. | dei |
| 2.2 | Formal adjustments to the header and footerNo content adjustments to the previous version. | dei |
| 2.1 | Autor im System mit Autor in der Änderungshistorie synchronisiert. Freigabe durch Person im VM Team, da Dokument nicht in der VMS Suche angezeigt wird.Keine inhaltlichen Änderungen | tsj |
| 2.0 | Part A of the formChapter 3.1: Further detail on the documentation to be supplied if EMA PIP or US PSP | dts |
| 1.1 | Part C of the form* Addition to note: If the application for new authorisation of the medicinal product was submitted before 1 January 2019, please include with the application an official confirmation that it fully complies with the foreign PIP requirements.

Explanation of what is to be confirmed by checking the box | dts |
| 1.0 | Implementation of TPO4 | dts |

1. If IHP or PI did not require adaptation, please describe study results briefly [↑](#footnote-ref-1)
2. Only indicate a date if the medicinal product is the subject of a new application for authorisation submitted to Swissmedic after 1 Jan. 2019. [↑](#footnote-ref-2)