|  |  |  |
| --- | --- | --- |
| **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

|  |
| --- |
| 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.

|  |
| --- |
| 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

|  |  |
| --- | --- |
|  | 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 footer  No 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 form  Chapter 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)