1 How and when is it possible to apply for confirmation of complete fulfilment of a PIP? By when can such an application be submitted?

If a PIP approved in another country is completely fulfilled, and if all the knowledge obtained has been incorporated in the Swiss product information in the appropriate form, an application for confirmation can be submitted in accordance with Art. 9 para. 5 TPO. Part C of the Paediatric Investigation Plan should be used for this purpose.

Applications can be submitted until further notice, no restrictions are planned.

2 Do paediatric investigation plans also need to be submitted for complementary medicines?

No, only for authorisations according to Art. 11 TPA and for Orphan Drugs. The scope is described in greater detail in the Guidance document *Paediatric investigation plan*.

3 Do waivers and deferrals need to be requested from Swissmedic? If so, when?

If a paediatric investigation plan is prepared separately for Switzerland, Swissmedic advises applicants to clarify critical points (such as possible waivers or deferrals) at an early stage in the context of a Scientific Advice procedure.

The application for approval of a Swiss PIP can be submitted either before the submission of the authorisation application or in connection with the authorisation application.

4 If not all the measures of an EU-PIP are fulfilled, should those EU measures fulfilled to date be submitted now to Swissmedic, followed later by the successive submission of the outstanding measures, incl. any adaptations?

In the event of a new authorisation application, Swissmedic expects to receive all currently available information on the medicinal product, incl. all available study results from an EU PIP or US PSP.

For PIPs approved by foreign authorities with comparable medicinal product control, the measures according to the foreign PIP are ordered cumulatively in a single condition. If all measures according to the PIP are completed, the corresponding documentation on the complete fulfilment of the conditions should be submitted to Swissmedic.

However, the applicant is obliged to keep the product information constantly updated based on the paediatric study results (Art. 28 TPO in conjunction with Art. 13 TPLRO). To this end, applications to modify the product information should be submitted accordingly. Both positive and negative study results should be included in the product information.

5 Does Swissmedic also issue confirmations on the complete fulfilment of a PIP according to Art. 9 para. 5 TPO for medicinal products included in an authorisation application submitted before 2019?

Yes, the application for confirmation of fulfilment of all conditions of a foreign PIP and the incorporation of the knowledge obtained in the Swiss product information is also possible for medicinal products covered by an authorisation application submitted to Swissmedic before 1 January 2019. It does not matter whether a PIP was already voluntarily submitted or not with the original authorisation application in Switzerland.

6 How long does it take to check a Swiss PIP and how long to recognise a foreign PIP?

Foreign PIPs are accepted without a separate assessment by Swissmedic. The corresponding application time limits apply to the review of a Swiss PIP in connection with an application. An extended Scientific Advice procedure is available for an advance assessment of a PIP before the authorisation application. The duration of this assessment is yet to be established for this situation.

7 What eCTD Envelope should be used for applications for “Confirmation of complete fulfilment of a PIP" according to Art. 9 para. 5 TPO?

"fum" (follow up measures) should be used as the envelope.

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8 In the event of an additional indication for a medicinal product for which an authorisation application was submitted before 1 January 2019, a PIP (typically an EU PIP) is submitted for review on a voluntary basis. PIP measures are accordingly ordered by Swissmedic as a condition. In this scenario, does the Information for healthcare professionals need to be continually updated in suitable form to reflect the latest results on paediatric use?

Yes, in this case the Information for healthcare professionals does need to be continually updated in suitable form with the findings from paediatric studies.

9 If PIP measures have been ordered by Swissmedic as a condition, is the marketing authorisation holder then obliged, for example, to include a paediatric indication or paediatric pharmaceutical form in the Information for healthcare professionals, or does the inclusion of the results relate solely to other sections in the Information for healthcare professionals (e.g. Clinical efficacy, Undesirable effects, etc.)?

If the PIP measures have been ordered by Swissmedic as a condition, the company is obliged to include a paediatric indication and, if applicable, the use of a paediatric pharmaceutical form in the Information for healthcare professionals. The application type to be used and the scope and content of the relevant Information for healthcare professionals sections should be determined on a case-by-case basis.

10 Paediatric data from a foreign EU PIP or US PSP are available a medicinal product for which an authorisation application was submitted before 1 Jan. 2019. Is the authorisation holder obliged to submit these data to Swissmedic?

The authorisation holder is not obliged to submit these data to Swissmedic.

The aspect of safety is the key criterion in deciding whether an application to modify the product information needs to be submitted in the specific case. If the new scientific findings from paediatric studies relate to aspects of the product that are considered to be relevant to safety in connection with the existing authorisation, an application to modify the product information would need to be submitted. This might apply, for example, in the case of new scientific findings that would rule out use in the age group under 12 years old even though paediatric use has not been explicitly ruled out to date in the Information for healthcare professionals.

However, in line with the aim of the current therapeutic products legislation, a pharmaceutical company itself decides which medicinal products it wishes to have authorised for distribution in Switzerland and for which indications.

11 The Paediatric Investigation Plan form can be used to explain why the submitted foreign PIP is applicable to the medicinal product proposed for authorisation in Switzerland. What is expected in this explanation (same composition, same indication, same formulation, prevalence data for Switzerland, other)?

The foreign PIP can be applied to the medicinal product notified in Switzerland only if the latter corresponds, in respect of its essential properties, to the foreign medicinal product for which the PIP was produced.

In the justification Swissmedic expects a critical assessment of the implications of any deviations on the applicability of the PIP study results to the medicinal product notified in Switzerland. Whether the deviations are permitted or are no longer acceptable cannot be established in general terms, but is assessed by Swissmedic on a case-by-case basis. If applicable, additional guidelines may be issued as a later date when a review practice has become established at Swissmedic.

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