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| **Form** | | |
| **Decision minutes Accelerated Application Hearing** | | |
| **Identification number:** | ZL104\_00\_001 |
| **Version:** | 3.1 |
| **Valid from:** | 29.06.2023 |

# Basic information

|  |  |
| --- | --- |
| Name of medicinal product: | …… |
| Active substance(s), preferably INN: | …… |
| Pharmaceutical form: | …… |
| Administration route: | …… |
| Therapeutic indication: | …… |
| ATC code: *If not yet allocated, state first 3 characters* | …… |
| IT no.: | …… |
| Date/time: | …… |
| Place: | …… |
| Type of hearing: | Select an option. |

# Further information

## Applicant\*

|  |  |
| --- | --- |
| Company name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| P.O. Box: | …… |
| Postcode, place: | …… |
| Canton: | …… |
| Tel.: | …… |
| E-mail: | …… |

\* The applicant must have a registered office in Switzerland or a legal representative with a registered office in Switzerland.

## Accelerated Application Hearing (AAA) participants

|  |  |  |
| --- | --- | --- |
| Applicant:(marketing authorisation holder)  if applic. CRO  (Regulatory Consultancy) | NAME | FUNCTION |
|  | NAME | FUNCTION |
| FOPH | NAME | FUNCTION |
| Swissmedic: | NAME | FUNCTION |
|  | NAME | FUNCTION |

# Requested procedure (multiple options possible)

|  |  |
| --- | --- |
|  | Fast-track authorisation procedure (FTP)[[1]](#footnote-1) planned submission date: …… |
|  | Temporary authorisation of human medicinal product[[2]](#footnote-2) planned submission date: …… |
|  | Application for temporary authorisation if FTP rejected planned submission date |
|  | Application for PPN if FTP rejected[[3]](#footnote-3): planned submission date: |

\* multiple options possible

# Comparison with therapies available in Switzerland

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| --- | --- |
| Tabular comparison of study findings on efficacy and safety of the medicinal product/indication for which authorisation is being requested with the available therapies with authorised medicinal products in Switzerland. | See page(s) …… Module(s): …… |

# Preconditions for authorisation procedure

(Delete inapplicable procedure)

## Fast-track authorisation procedure (FTP)\*

|  |  |  |
| --- | --- | --- |
| 1. **It provides promising prevention against, or treatment for, a severe, disabling or life-threatening disease.** | | |
| Result of the evaluation by Swissmedic of the submitted documentation | Criterion fulfilled | Criterion **not** fulfilled |
| Rationale for fulfilment of the criterion:  Based on the latest findings, the disease of …… in stage …… leads to severe disability or the death of the patient.  Remark: …… | | |
| Reason for non-fulfilment of the criterion:  …… | | |
| Reasons presented by the applicant: …… | | |
| Relevant discussion items: …… | | |
| **Swissmedic decision:**  Criterion fulfilled  Criterion **not** fulfilled | | |
| 1. **Treatment using currently authorised medicinal products is either unavailable or unsatisfactory.** | | |
| Result of the evaluation by Swissmedic of the submitted documentation | Criterion fulfilled | Criterion **not** fulfilled |
| Rationale for fulfilment of the criterion:  No medicinal product is currently authorised in Switzerland for the indication …….  or (delete inapplicable statements)  The currently available medical treatment for the indication …… is unsatisfactory, and more effective or safer treatments are needed.  Remark: …… | | |
| Reason for non-fulfilment of the criterion:  …… | | |
| Reasons presented by the applicant:  …… | | |
| Relevant discussion items: …… | | |
| **Swissmedic decision:**  Criterion fulfilled  Criterion **not** fulfilled | | |

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| 1. **A high therapeutic benefit is expected from using this new medicinal product/the new indication of the medicinal product.** | | |
| Result of the evaluation by Swissmedic of the submitted documentation | Criterion fulfilled | Criterion **not** fulfilled |
| Rationale for fulfilment of the criterion:  The medicinal product to be authorised …… shows a high therapeutic benefit in the prevention or treatment of patients with ……, which exceeds the benefit of existing authorised treatments for this indication. Already on the basis of the top-line results from the submitted clinical trial(s), this benefit …… can be rated as probable.  Remark: …… | | |
| Reason for non-fulfilment of the criterion:  …… | | |
| Reasons presented by the applicant:…… | | |
| Relevant discussion items:  …… | | |
| **Swissmedic decision:**  Criterion fulfilled  Criterion **not** fulfilled | | |
| **The criteria a), b) and c) are all fulfilled for each proposed indication.** | | |
| **Swissmedic decision:**  The criteria a) to c) are fulfilled. The application for an FTP procedure is approved.  The criteria a) to c) are **not** fulfilled. The application for an FTP procedure is rejected. | | |
| **If FTP application rejected**  **Application for procedure for temporary authorisation**  ☐ yes  ☐ no | | |
| **If FTP application rejected**  **Application for PPN procedure**  ☐ yes  ☐ no | | |

(Delete inapplicable procedure)

## Procedure for temporary authorisation

1. **The medicinal product/new indication of the medicinal product is used to identify, prevent or treat a disease that can lead to serious invalidity, severe suffering possibly resulting in death, or to the death of a patient in the short term.**

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| --- | --- | --- |
| Result of the evaluation by Swissmedic of the submitted documentation | Criterion fulfilled | Criterion **not** fulfilled |
| Rationale for fulfilment of the criterion:  Based on the latest findings, the disease of …… in stage …… leads to severe disability, severe suffering or the death of the patient in the short term.  Remark: …… | | |
| Reason for non-fulfilment of the criterion:  …… | | |
| Reasons presented by the applicant:…… | | |
| Relevant discussion items:  …… | | |
| **Swissmedic decision:**  Criterion fulfilled  Criterion **not** fulfilled | | |
| 1. **No alternative and equivalent medicinal product is authorised in Switzerland.** | | |
| Result of the evaluation by Swissmedic of the submitted documentation | Criterion fulfilled | Criterion **not** fulfilled |
| Rationale for fulfilment of the criterion:  No medicinal product is currently authorised in Switzerland for the prevention or treatment of the disease …….  or (delete inapplicable statements)  The currently available medical treatment for the indication …… is unsatisfactory, and more effective or safer treatments are needed.  Remark: …… | | |
| Reason for non-fulfilment of the criterion:  …… | | |
| Reasons presented by the applicant:  …… | | |
| Relevant discussion items: …… | | |
| **Swissmedic decision:**  Criterion fulfilled  Criterion **not** fulfilled | | |
| 1. **Major therapeutic benefit is expected from the use of the medicinal product/the new indication for which authorisation is requested.** | | |
| Result of the evaluation by Swissmedic of the submitted documentation | Criterion fulfilled | Criterion **not** fulfilled |
| Rationale for fulfilment of the criterion:  The medicinal product to be authorised …… shows a high therapeutic benefit in the prevention or treatment of patients with ……, which exceeds the benefit of existing authorised treatments for this indication. Already on the basis of the top-line results from the submitted clinical trial(s), this benefit …… can be rated as probable.  Remark: …… | | |
| Reason for non-fulfilment of the criterion:  …… | | |
| Reasons presented by the applicant:…… | | |
| Relevant discussion items:  …… | | |
| **Swissmedic decision:**  Criterion fulfilled  Criterion **not** fulfilled | | |
| 1. **The applicant is expected to be able to supply the necessary data per section 2 of the TPLRO before the temporary authorisation expires with a view to achieving ordinary authorisation.** | | |
| Result of the evaluation by Swissmedic of the submitted documentation | Criterion fulfilled | Criterion **not** fulfilled |
| Rationale for fulfilment of the criterion:  The applicant is able to submit additional data from study(studies) …… in order to ensure a transfer to an ordinary authorisation before the temporary authorisation expires. | | |
| Reason for non-fulfilment of the criterion:  …… | | |
| Reasons presented by the applicant:…… | | |
| Relevant discussion items:  …… | | |
| **Swissmedic decision:**  Criterion fulfilled  Criterion **not** fulfilled | | |

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| 1. **It takes so long to compile all the required data and to process and evaluate the data under letter d) in an ordinary authorisation procedure as per Art. 11 TPA that irreversible damage in patients would result or worsen, or this would be associated with severe suffering.** | | |
| Result of the evaluation by Swissmedic of the submitted documentation | Criterion fulfilled | Criterion **not** fulfilled |
| Rationale for fulfilment of the criterion:  According to the latest findings, the patients suffering from …… are at immediate risk of invalidity or imminent death.  Remark: …… | | |
| Reason for non-fulfilment of the criterion:  …… | | |
| Reasons presented by the applicant:…… | | |
| Relevant discussion items:  …… | | |
| **Swissmedic decision:**  Criterion fulfilled  Criterion **not** fulfilled | | |
| **The criteria a), b), c), d) and e) are all fulfilled for each proposed indication.** | | |
| **Swissmedic decision:**  The criteria a) to e) are fulfilled. The application for temporary authorisation is approved.  The criteria a) to e) are **not** fulfilled. The application for temporary authorisation is rejected. | | |

# Remarks

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# Binding decision

Based on the scientific review of the documentation on the planned procedure submitted with the application, and after discussing the data with the applicant, the following decision is issued:

|  |  |
| --- | --- |
| **Fast-track authorisation procedure** | approved  rejected  n.a. |
| Remarks  **……** | |
| **Procedure for temporary authorisation** | approved  rejected  n.a. |
| Remarks  **……** | |
| **Procedure with prior notification** | approved  rejected  n.a. |
| Remarks  **……** | |

## Confirmation

|  |  |
| --- | --- |
|  | The applicant confirms that it has been informed of all the reasons for Swissmedic's decision during the AAA. |
|  | The applicant confirms that it has orally presented its position statement on the intended decision during the AAA and has therefore been granted an appropriate fair hearing in accordance with the law; it thus dispenses with the subsequent submission of a written position statement on Swissmedic's intended decision. |

# Fees

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| Fees are payable by the applicant for the scientific and procedural evaluation by Swissmedic during Accelerated Application Hearings. The invoice will be sent to the applicant following the Accelerated Application Hearing. The costs are based on Art. 4 of the Therapeutic Products Fees Ordinance (FeeO-Swissmedic; SR 812.214.5).  The applicant confirms its awareness of this fact and agrees to pay the costs associated with the implementation of the AAA. |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 3.1 | New layout, no content adjustments to the previous version. | dei |
| 3.0 | Section 3: Information on planned submission date Section 4: Information on comparison with existing therapies Section 9: Signature block deleted | fg/zsa/pfc/rc/ru |
| 2.0 | Clarification of options if FTP rejected  Addition re. expansion of scope for temporary authorisation: temporary additional indications | fg |
| 1.1 | Editorial adjustment (tick boxes) | fg |
| 1.0 | New document | fg |

1. See Guidance document *Fast-track authorisation procedure* [↑](#footnote-ref-1)
2. See Guidance document *Temporary authorisation for human medicinal products* [↑](#footnote-ref-2)
3. See Guidance document *Procedure with prior notification* [↑](#footnote-ref-3)