# Basic information[[1]](#footnote-1)

|  |  |
| --- | --- |
| Active substance(s), preferably INN: | …… |
| Name of medicinal product: | …… |
| Dosage form: | …… |
| Administration route: | …… |
| Therapeutic indication: | …… |
| ATC code: *If not yet allocated, state first 3 characters* | …… |
| IT no.: | …… |

# Addresses

## Applicant\*

|  |  |
| --- | --- |
| Company name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| P.O. Box: | …… |
| Postcode, town/city: | …… |
| Canton: | …… |
| Telephone: | …… |
| E-mail | …… |

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

## Address for correspondence (if not the same as 2.1)

|  |  |
| --- | --- |
| Company name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| P.O. Box: | …… |
| Postcode, town/city: | …… |
| Telephone: | …… |
| E-mail | …… |

## Legal representative (if not the same as 2.1)

|  |  |
| --- | --- |
| Name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| P.O. Box: | …… |
| Postcode, town/city: | …… |
| Telephone: | …… |
| **Does Swissmedic already possess the power of attorney?**  yes  no, the power of attorney is enclosed with this application (incl. original signature) | |

# Authorisation status

|  |  |
| --- | --- |
|  | Authorisation applied for |
|  | Authorised |
|  | Authorisation revoked  Authorisation no.: …… |
|  | Authorisation application withdrawn or rejected  Application ID: …… |
|  | Authorisation not yet applied for |

## Authorisation status of the medicinal product or of the variation abroad

|  |  |
| --- | --- |
|  | Authorised in: …… |
|  | Authorisation revoked in: …… |
|  | Authorisation application withdrawn or rejected in: …… |
|  | Authorisation application pending in: …… |
|  | Authorisation not yet applied for |

If an indication was approved in the foreign country with wording that differs from that in Switzerland, this should be stated (English or correspondence language):

|  |  |
| --- | --- |
| **Country** | **Wording of the approved indication** |
| …… | …… |
| …… | …… |
| …… | …… |
| *Note: For the requested meeting, if applicable please submit relevant details on the authorisation status in other countries in Annex 2.* | |

# Requested meeting

**Type of meeting**

|  |  |  |
| --- | --- | --- |
|  | Scientific Advice Meeting (in the development phase) | see **section 5** |
|  | Accelerated Application Hearing (candidates for FTP/temporary auth.) | see **section 6** |
|  | Presubmission Meeting (before application submission) | see **section 7** |
|  | Early Clarification Meeting (on the LoQ) | see **section 8** |
|  | Pipeline Review | see **section 9** |

**Proposal for form of interaction**

|  |  |
| --- | --- |
|  | Meeting on the premises of Swissmedic |
|  | Teleconference |
|  | Video conference |
|  | Swissmedic replies in writing to questions (AAA: n.a.) |

# Scientific Advice Meetings

The subject areas checked below must correspond to the list of questions in Annex 1.

|  |  |
| --- | --- |
|  | Pharmaceutical quality |
|  | Biological quality |
|  | Biotechnological quality |
|  | Preclinical |
|  | Clinical |
|  | Biometrics |
|  | Pharmacovigilance, Risk Management Plan |
|  | Procedural issues |
|  | Other, please specify: …… |
| Reason for the application: …… | |
| Proposal for meeting dates in the period of 4–8 weeks after application: …… | |

# Accelerated Application Hearing (AAA)

Application for the authorisation procedure:

|  |  |
| --- | --- |
|  | **Fast-track authorisation procedure (FTP)** |
| Enclosures: | |
|  | Cover letter |
|  | Draft decision minutes (sections 1–3 completed) |
|  | Explanation (for each requested indication, if applicable) |
|  | Relevant top-line results |
|  | Overview of the data scheduled for the future authorisation application |
|  | Draft version of the Information for healthcare professionals or the *Summary of Product Characteristics* |
| Proposal for meeting dates within 4-6 weeks after application: …… | |
|  | |
|  | **Temporary authorisation of human medicinal products** |
| Enclosures: | |
|  | Cover letter |
|  | Draft decision minutes (sections 1–3 completed) |
|  | Explanation (for each requested indication, if applicable) |
|  | Relevant top-line results |
|  | Overview of the data package scheduled for the future authorisation application |
|  | Confirmation that the complete data for pharmaceutical quality (module 3) are available and will be submitted with the application for temporary authorisation. |
|  | Draft version of the risk management plan (RMP) |
|  | Draft version of the Information for healthcare professionals or the *Summary of Product Characteristics* |
| Proposal for meeting dates within 4-6 weeks after application: …… | |

\* see guidance documents *Fast-track authorisation procedure HMV4* or *Temporary authorisation of human medicinal products HMV4*

# Presubmission Meetings

The subject areas checked below must correspond to the list of questions in Annex 1.

|  |  |
| --- | --- |
|  | Legal basis for the application |
|  | Dossier structure and content |
|  | Aspects of the Information for healthcare professionals and Patient information / packaging elements (labelling) |
|  | Procedure and timetable |
|  | Technical aspects of submission |
|  | Other, please specify: …… |
| Reason for the application: …… | |
| Proposal for meeting dates in the period of 4–8 weeks after application: …… | |
| Planned date of submission of the authorisation application: …… | |

# Early Clarification Meetings

The subject areas checked below must correspond to the list of questions in Annex 1.

|  |  |
| --- | --- |
|  | Discussion and explanation of Major Objections that are not clearly understood incl. on labelling |
|  | Clarification of questions on the applicant's scheduled response strategy |
|  | Other, please specify: …… |
| Reason for the application: …… | |
| Proposal for meeting dates in the period of approx. 3 weeks after application: …… | |
| Relates to the LoQ letter dated: ……  Application ID: …… | |

# Pipeline Review

|  |
| --- |
| Proposal for meeting dates within 4–8 weeks after application: …… |
| Subject: …… |

# Additional documents to be submitted

|  |  |
| --- | --- |
|  | Cover letter |
|  | List of questions according to Annex 1 (compulsory; AAA: n.a.) |
|  | Documentation and background information (compulsory) |
|  | List of scheduled participants at the requested meeting (compulsory) |
|  | Agenda with the points to be discussed (compulsory; AAA: n.a.) |
|  | Records of advice procedures with other authorities |
|  | Details of the authorisation status in other countries (Annex 2) |

# Fees

|  |
| --- |
| The scientific and procedural advice provided by Swissmedic in Scientific Advice Meetings, Accelerated Application Hearings, Presubmission Meetings and Clarification Meetings is subject to fees payable by the applicant and may be associated with conditions. The invoice will be issued on completion of the advice procedure or hearing. The fees are charged in accordance with the Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic, SR 812.214.5).  This rule does not apply to the Pipeline Review, for which no fees are charged.  The applicant confirms its awareness of this fact and agrees to pay the fees associated with Scientific Advice, Accelerated Application Hearings, Presubmission Meetings and/or Early Clarification Meetings. |

# Signature

|  |  |  |  |
| --- | --- | --- | --- |
| **All the entries made in this form are certified to be complete and accurate:**  *(company stamp of the applicant, optional)*  ……  ……  …… | | | |
| *Authorised signatory* | | *Other responsibilities (Optional signature)* | |
| Place, date: ……  Signature: …………………………….. | | Place, date: ……  Signature: …………………………….. | |
| Last name: | …… | Last name: | …… |
| First name: | …… | First name: | …… |
| Position: | …… | Position: | …… |
| Telephone: | …… |  | |
| E-mail | …… |
|  | | | |
| **The application should be sent to** | | **For enquiries contact** | |
| Swissmedic  Swiss Agency for Therapeutic Products  Operational Support Services  Hallerstrasse 7  3012 Bern | | Telephone +41 58 462 02 11  Fax +41 58 462 02 12  E-mail Anfragen@swissmedic.ch | |

# Annex 1 – List of questions

For each question, the applicant's position should be explained.

|  |  |
| --- | --- |
| 1 | …… |
| 2 | …… |
| 3 | …… |
| 4 | …… |
| 5 | …… |

**If necessary, please add further rows to the table**

# Annex 2 – Details of the authorisation status in other countries

……

Change history

| Version | Valid and binding as of | Description, comments (by author) | Author’s initials |
| --- | --- | --- | --- |
| 4.0 | 01.07.2021 | Further details in section 6 and in section 10 (AAA) | fg |
| 3.0 | 15.12.2020 | Further details on company meetings / Inclusion of Accelerated Application Hearing | fg |
| 2.1 | 04.06.2020 | 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 | 08.08.2019 | Inclusion of Pipeline Review | dts |
| 1.0 | 01.01.2019 | Implementation of TPO4 | dts |

1. If the application relates to more than one medicinal product, the basic information should be reproduced based on the number of medicinal products concerned and stated accordingly. [↑](#footnote-ref-1)