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| --- | --- | --- |
| **Form** | | |
| **Information for application Art.13 TPA** | | |
| **Identification number:** | ZL101\_00\_004 |
| **Version:** | 4.0 |
| **Valid from:** | 15.01.2024 |

# Basic information

|  |  |
| --- | --- |
| **Name of medicinal product:** …… |  |
| **Authorisation no.:** …… | **Application ID:** ……  *Will be allocated upon receipt* |
| **Dosage strength:** …… | **Dosage form:** …… |
| *A separate form must be completed for each dosage form.* | |

# Procedure as per Art. 13 TPA

## Reference authority whose evaluation results form the basis for the applicant's authorisation application in Switzerland

|  |
| --- |
| EMA  EU MRP / Reference Member State: °°°°° Concerned Member State: °°°°°  EU DCP / Reference Member State: °°°°° Concerned Member State: °°°°°  EU / EFTA Member State / national regulatory authority: °°°°° |
| FDA / USA  Japan  New Zealand  Australia  Canada  Singapore |

## Decision of foreign authority

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **2.2** | **Decisions of foreign authorities[[1]](#footnote-1)** | | Available? | | |  |
| yes | no[[2]](#footnote-2) | n.a.[[3]](#footnote-3) | Remarks |
| **2.2.1** | **Responses to questions** *(always incl. LoQ)* | |  |  |  | …… |
| **EMA CP:** | Answer to Day 180 LoOI *(incl. Day 180 LoOI)* |  |  |  | …… |
| Answer to Day 120 LoQ *(incl. Day 120 LoQ)* |  |  |  | …… |
| **All other countries**: | Answer to LoQ *(incl. LoQ)* |  |  |  | …… |
| **2.2.2** | **Assessment Reports[[4]](#footnote-4) (=AR)** | |  |  |  | …… |
| **EMA CP** | Day 210 AR |  |  |  | …… |
| Day 80 AR  Veterinary medicinal products: Day 70 AR |  |  |  | …… |
| EU  **DCP / MRP** | Day 70 Preliminary AR *(for DCP)* |  |  |  | …… |
| Day 90 RMS AR *(for MRP)* |  |  |  | …… |
| Final AR *(MRP =Day 90, DCP ≥ Day 105)* |  |  |  | …… |
| In the event of arbitration to CHMP/CVMP 🡪 Opinion of EMA |  |  |  | …… |
| **EU / EFTA** | Final AR |  |  |  | …… |
| **FDA** | Final AR *(=Standard or Priority Review)* |  |  |  | …… |
| Summary Basis of Approval SBA (if available) |  |  |  | …… |
| **Canada** | Final AR |  |  |  | …… |
| Summary Basis of Decision (*if available*) |  |  |  | …… |
| **Japan** | Review Report PMDA |  |  |  | …… |
| Review Summary |  |  |  | …… |
| Overall Summary – Basis of Decision |  |  |  | …… |
| **All other countries:** | Final AR |  |  |  | …… |
| **2.2.3** | **EU Decision of reference authority** | |  |  |  | …… |
| **EMA CP** | CHMP/HMPC/CVMP Opinion |  |  |  | …… |
| EU Commission decision (*to be submitted as soon as it is available*) |  |  |  | …… |
| **EU DCP/MRP:** Marketing Authorisation of RMS (Letter of approval or Letter end of procedure) | |  |  |  | …… |
| **EU/EFTA:** Marketing Authorisation RMS (Letter of approval or Letter end of procedure) | |  |  |  | …… |
| **2.2.4** | **FDA Decision**: Approval Letter | |  |  |  | …… |
| **2.2.5** | **Decision of other foreign authorities:** | |  |  |  | …… |
| **Canada:** Notice of Compliance (NOC) | |  |  |  | …… |
| **All other countries**: Marketing authorisation RMS (Letter of approval or Letter end of procedure) | |  |  |  | …… |

## Specifications for authorisation as per Art. 13 TPA in conjunction with Art. 16–20 TPO to be met by the authorisation holder

|  |  |  |
| --- | --- | --- |
|  | yes[[5]](#footnote-5) | Remark |
| **For new applications: The medicinal product is identical with that submitted and authorised abroad**[[6]](#footnote-6). (Except in the case of deviations as defined in the Guidance documents *Authorisation of human medicinal products in accordance with Art. 13 TPA* / *Authorisation of veterinary medicinal products in accordance with Art. 13 TPA.* Reasons must be stated and documented together with a critical appraisal.) |  | …… |
| **For new applications: The documentation submitted is identical with that on which the reference authority based its authorisation**[[7]](#footnote-7)**.**  (Except in the case of deviations as defined in the Guidance documents *Authorisation of human medicinal products in accordance with Art. 13 TPA* / *Authorisation of veterinary medicinal products in accordance with Art. 13 TPA.* |  | …… |
| **For new applications:** Any changes since authorisation **by the** reference authority have been submitted (differences tracked) and mentioned in the covering letter[[8]](#footnote-8) (old/new, Module 1.7.6 Paragraph 13 Additional Documentation or, for veterinary medicinal products, in binder Part 1a3 doc foreign authorities).  An additional Assessment Report has been compiled for the changes submitted. Where appropriate, reasons must be stated and documented together with a critical appraisal.) |  | …… |
| **Authorisation extensions and variation applications**: If applicable to medicinal products that were **authorised by Swissmedic with reference to Art. 13 TPA**:  The documentation for the reference authority (prior to the approval of the variation/authorisation extension) and that for Switzerland are identical (Modules 2.4, 2.5, 2.6, 2.7, 4 and 5) for variation applications and authorisation extensions. Any Module 2.3 and Module 3 deviations correspond to the deviations outlined in full in the Guidance document *Authorisation of human medicinal products under Art. 13 TPA*. |  | …… |
| **Authorisation extensions and variation applications**: If applicable to medicinal products that were **authorised by Swissmedic without reference to Art. 13 TPA**:  The documentation for the reference authority (prior to the approval of the variation/authorisation extension) and that for Switzerland are identical (Modules 2.4, 2.5, 2.6, 2.7, 4 and 5) for variation applications/authorisation extensions. Any Module 2.3 and Module 3 deviations correspond to the deviations outlined in full in the Guidance document *Authorisation of human medicinal products under Art. 13 TPA*.  The documentation and the corresponding documents for the first authorisation have also been submitted for applications for extensions (Modules 1-5), if they are the main source of reference. |  |  |
| **For new applications:** The authorisation procedure in the reference country corresponds to the authorisation procedure applied for in Switzerland. |  | …… |
| **For all applications:** The **foreign authorisation / variation** or **Repeat Use in MRP/DCP procedure** is **not more than 5 years old** *(date of official decision on the new authorisation or the approval of the extension/variation is to be given under “Remarks”)* |  | …… |
| **For all applications:** The documentation listed in the Guidance documents *Authorisation of human medicinal products in accordance with Art. 13 TPA / Authorisation of veterinary medicinal products in accordance with Art. 13 TPA* has been submitted in full. Where applicable: the DMF Holder has been informed that the complete Assessment Report of the Restricted Part, LoQ and the company's answers to the Restricted Part must be submitted to Swissmedic. |  | …… |
| **For new applications and other applications if applicable:**  The current requirements of Ph.Eur. / Ph.Helv. have been complied with and the corresponding documents submitted.  *(Where Ph. Eur. / Ph. Helv. methods are not applied, equivalence must be documented)* |  | …… |

# Manufacture

*(For new applications and other applications if applicable)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | yes | no[[9]](#footnote-9) | n.a. | Remarks[[10]](#footnote-10) |
| **Flowchart exists** *(up-to-date flowchart for the medicinal product authorised by the reference authority; state filing location under Remarks)* |  |  |  | …… |

## Details of active substance (Drug Substance)

*Please complete the following details separately for each manufacturer.* Additional lines for entering manufacturer information can be inserted by copying and pasting:

|  |  |
| --- | --- |
| Active substance manufacturer (name, address), including specification details (pharmacopoeia or manufacturer monograph)  …… | |
| **Details of CEP** *(if applicable)* | **Details of DMF (ASMF)** *(if applicable)* |
| No.: …… | Applicant's part: Date of documentation: ……  Version no.: …… |
| Holder: …… |
| Manufacturer: …… | Restricted part: Date of documentation: ……  Version no.: ……  *(if known)* |
| Last updated: …… |

## Details of finished product (Drug Product)

*Please complete the following details separately for each manufacturer.* *Additional lines for entering manufacturer information can be inserted by copying and pasting*

|  |  |
| --- | --- |
| Manufacturer of finished product (name, address): | …… …… …… |
| Primary container(s) (type and material): | ……. |
| Details of application and measuring devices *(if applicable):* | …… |
| Are the tablets divisible? | yes  no  not applicable |
| Is divisibility documented in accordance with Ph. Eur.? | yes  no  not applicable |
| Storage instructions proposed for Switzerland *(absolute requirement: see Guidance document Product information for human medicinal products)* | …… |
| Storage instructions approved abroad | …… |
| Shelf-life proposed  (in months): | …… |
| Proposed storage conditions and shelf-life, in hours (h) / days (d) / months (m): | after first opening: ……  after dilution: ……  after reconstitution: ……  not applicable |
| **Finished product with solvent included**  yes  not applicable | |
| Type of solvent: | …… |
| Manufacturer of solvent (name, address): | …… …… …… |
| Primary container (type and material): | …… |
| Storage instructions proposed for Switzerland *(absolute requirement: see Guidance document Product information for human medicinal products)* | …… |
| Storage instructions approved abroad | …… |
| Shelf-life proposed (in months): | …… |

## Additional details for vaccines or blood products (human medicinal products only)

|  |  |  |
| --- | --- | --- |
| Method of administration (oral, i.v., i.m., s.c., etc.): | …… | |
| *Please supply the following details separately for each intermediate (definition: no immediate further processing; is stored)* | | |
| Name of intermediate: | …… | |
| Manufacturer (name, address): | …… | |
| Intended primary container (type and material): | …… | |
| Storage instructions and shelf-life (in months): | …… | …… |
| With this basic information, please enclose one copy each of the valid specifications for the active substance and the finished product (if applicable: approved release and end-of-shelf-life specifications). | | |

# Discrepancy/discrepancies between the product authorised by the reference authority and the medicinal product notified in Switzerland

|  |
| --- |
| **For new applications:** The applicant confirms that there are no discrepancies between the medicinal product approved by the reference authority and the medicinal product notified in Switzerland. |
| yes |
| ☐ no; the discrepancies are set out in the following table. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Do discrepancies exist concerning the following points?** | | | **Remarks** |
| Manufacturer of the active substance(s) | Authorised abroad:  ……  Date of authorisation:  …… | Applied for in Switzerland:  …… | °°°°° |
| Manufacturer of the finished product | Authorised abroad:  ……  Date of authorisation:  ……. | Applied for in Switzerland:  …… | °°°°° |
| Batch release | Authorised abroad:  ……  Date of authorisation:  …… | Applied for in Switzerland:  …… | °°°°° |
| Quality control(s) | Authorised abroad  ……  Date of authorisation  …… | Applied for in Switzerland:  …… | °°°°° |
| Secondary packaging or Secondary packer | Authorised abroad  ……  Date of authorisation  …… | Applied for in Switzerland:  …… | °°°°° |
| Primary packaging or primary packer | Authorised abroad  ……  Date of authorisation  …… | Applied for in Switzerland:  …… | °°°°° |
| Additional/different pack sizes[[11]](#footnote-11) | Authorised abroad  ……  Date of authorisation  …… | Applied for in Switzerland:  …… | °°°°° |
| Dosage strengths11 | Authorised abroad  ……  Date of authorisation  …… | Applied for in Switzerland:  …… | °°°°° |
| Name of the medicinal product | Authorised abroad  ……  Date of authorisation  …… | Applied for in Switzerland:  …… | °°°°° |
| Dispensing category | Authorised abroad  ……  Date of authorisation  …… | Applied for in Switzerland:  …… | °°°°° |
| Other discrepancies | Authorised abroad  ……  Date of authorisation  …… | Applied for in Switzerland:  …… | °°°°° |

# Details of vaccines

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **yes** | **no** | **n/a** | **Remarks** |
| Is the product a vaccine? |  |  |  |  |
| Has it been authorised by the EU Commission or US FDA? |  |  |  |  |
| Is it an NAS? |  |  |  |  |
| The medicinal product is intended to prevent a transmissible infectious disease that may cause severe harm or serious suffering with potentially fatal consequences. |  |  |  | °°°°° |
| The medicinal product’s indication is identical to the indication approved by the reference authority. |  |  |  | °°°°° |
| Is it a non-innovative medicinal product in the categories listed in Art. 12 para. 5 TPLO? |  |  |  | °°°°° |
| All active substances are contained in at least one medicinal product that is or used to be authorised by Swissmedic.  *(State authorisation no.)* |  |  |  | °°°°° |
| Swissmedic has already approved the active substance manufacturers’ production sites.  *(State application ID for manufacturers’ locations)* |  |  |  | °°°°° |
| Swissmedic has already approved the manufacturing process (active substance and finished product).  *(State application ID for manufacturing process)* |  |  |  | °°°°° |
| The requested indication is identical to the indication approved by the reference foreign authority. |  |  |  | °°°°° |
| The requested administration route for the medicinal product submitted for authorisation must be identical to the administration route authorised by the foreign reference authority. |  |  |  | °°°°° |
| The new components are produced using the same/approved manufacturing process. |  |  |  | °°°°° |

# Additional information

*(For new applications)*

|  |  |  |  |
| --- | --- | --- | --- |
|  | **yes** | **no** | **Remarks** |
| Was a decision for the proposed medicinal product issued on the basis of an earlier assessment? |  |  | °°°°° |

# Pharmacokinetic data (human medicinal products only)

*(For new applications and other applications if applicable)*

|  |
| --- |
| *Please state all key pharmacokinetic results (“key results”) from the individual studies incl. study number, preferably in a table. For KAS and biosimilars, all relevant pharmacokinetic results must be stated, especially those relevant for bridging issues*.  ……  …… |

# Process documentation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | Yes | No[[12]](#footnote-12) | n.a.[[13]](#footnote-13) | Remarks |
| **GLP** | The principles of Good Laboratory Practice are observed where applicable. |  |  |  | …… |
| **GCP** | Clinical trials shall be conducted in conformity with the current legal provisions and must meet the ethical and scientific requirements of the Good Clinical Practice (GCP) guidelines. The safety and personal rights of participating persons must be guaranteed, and the results of the clinical trials must satisfy scientific criteria in respect of quality and integrity. |  |  |  | …… |
| **Pharmacovigilance** | The extension of authorisation or type II variation does not require any amendments in the RMP with regard to:   * risk aspects of the medicinal product * pharmacovigilance activities * risk mitigation measures. |  |  |  | …… |

# 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 must be sent to** | | **For enquiries contact** | |
| Swissmedic  Swiss Agency for Therapeutic Products  Operational Support Services  Hallerstrasse 7  3012 Bern | | Tel. +41 58 462 02 11  Fax +41 58 462 02 12  E-mail Anfragen@swissmedic.ch | |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 4.0 | Additions in section 2.2 in line with section 11.3 of the guidance document and addition of RUP,  Addition in section 2.3 regarding authorisation procedure, identity of the documentation and RUP,  Deletion of the specific requirements for the implementation of spontaneous recording of ADRs in section 6, editorial clarifications | cho/hv/fg |
| 3.5 | New layout, no content adjustments to the previous version. | dei |
| 3.4 | Section 1: Update to submission of form. | cho/fg |
| 3.3 | Adjustment to subsection in section 2.2. | nma |
| 3.2 | Clarification in section 2.3 regarding variations for medicinal products that were authorised in accordance with Art. 13. | nma |
| 3.1 | Clarification in section 2.3 regarding variations for medicinal products that were originally not authorised in accordance with Art. 13. Editorial clarifications. | nma |
| 3.0 | New section on details of vaccines added. | nma |
| 2.1 | Explanation in section 4 “Discrepancy/discrepancies between the medicinal product authorised by the reference authority and the medicinal product notified in Switzerland”. | nma |
| 2.0 | Addendum to section 5 and new section on process documentation added. | nma |
| 1.0 | Implementation of HMV4 | dts/fg |

1. in an official Swiss language or in English. Translations into one of these languages are also accepted, provided that the applicant confirms in writing that the translations are correct. [↑](#footnote-ref-1)
2. Please explain why these documents are not being submitted [↑](#footnote-ref-2)
3. not applicable [↑](#footnote-ref-3)
4. unredacted, legible throughout (redacted ARs are accepted but may incur a time surcharge and thus higher fees) [↑](#footnote-ref-4)
5. If not submitted, please explain [↑](#footnote-ref-5)
6. If no, please explain in section 4 [↑](#footnote-ref-6)
7. If no, please explain in section 4 [↑](#footnote-ref-7)
8. If no, please explain in section 4 [↑](#footnote-ref-8)
9. Please explain why these documents are not being submitted. [↑](#footnote-ref-9)
10. State location in reference dossier [↑](#footnote-ref-10)
11. must not conflict with the use of the product or dosage recommendation [↑](#footnote-ref-11)
12. explain under “Remarks” [↑](#footnote-ref-12)
13. not applicable – explain under “Remarks” [↑](#footnote-ref-13)