

|  |  |  |
| --- | --- | --- |
| **Form** | | |
| **Import of a human medicinal product according to Art. 14 para. 2 and 3 TPA (parallel import)** | | |
| **Identification number:** | ZL106\_00\_002 |
| **Version:** | 3.0 |
| **Valid from:** | 01.01.2024 |

# Basic information

|  |  |  |  |
| --- | --- | --- | --- |
| **External reference (Company Reference): ……** | | | |
| **Name of medicinal product:** …… | | | |
| **Active substance(s):** ……  *(Published on receipt of the application))* | | | |
| **Pharmaceutical form:** …… | | | |
| **Indication:** ……  *(Published on receipt of the application)* | | | |
| **Basic company dossier no.: ……**  *(Mandatory for teas in the notification procedure and for cough and throat sweets and pastilles in the notification procedure)* | | | |
| **Pharmaco-therapeutic group** | **ATC code[[1]](#footnote-1):** …… | | **IT no.:** …… |
| **Dosage strength(s)** | **Primary container**  *(e.g. blister))* | | **Secondary container**  *(All pack sizes incl.clinic packs)* |
| …… | …… | | …… |
| …… | …… | | …… |
| …… | …… | | …… |
|  | | | |
| **Medicinal product category**  Select an option.  For antivenins please use only the form *New authorisation variation antivenin* | | | |
| **Dispensing category**  Select an option. | | | |
| **Original medicinal product** | | **Parallel imported medicinal product** | |
| **Designation:** …… | | **Designation:** …… | |
| **Authorisation no.:** …… | | **Authorisation no.:** …… | |
|  | | **Country of export:** …… | |
| **Name and address of the authorisation holder:**  …… | | **Name and address of the authorisation holder abroad:**  …… | |
|  | | *(For authorisation holders not domiciled in the country of export)*  **Name and address of the local representative of the authorisation holder in the country of export:**  …… | |
|  | | **Name(s) and address(es) of the foreign source(s) of supply (manufacturers or wholesalers):** *(Address(es) in the country of export or a third country)*  …… | |
|  | | **Name and address of the repackaging company:**  …… | |

# Addresses

## Marketing authorisation holder (importer) in Switzerland

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

## 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) | |

# Confirmation

## Completeness of documentation and compliance with formal requirements

|  |
| --- |
| The applicant confirms that the requirements stated in Art. 14 para. 2 and 3 TPA are fulfilled.  yes |

## eDok confirmation of identity (paper-based applications with eDok copy)

|  |
| --- |
| The applicant confirms that the electronic copy and the paper documentation are complete and identical. The applicant hereby consents to the review being conducted by Swissmedic exclusively on the basis of the electronic documents.  yes  n/a |

## Confirmation of procedure according to Art. 14 para. 2 and 3 TPA

|  |
| --- |
| The applicant confirms that it is in a position to fulfil its reporting obligation as part of vigilance throughout the authorisation of its medicinal product (Art. 61 ff. TPO).  yes |

## Conformity of Information for healthcare professionals and Patient information

|  |
| --- |
| The applicant confirms that the medicinal product information for the parallel imported medicinal product conforms to the currently published text of the Information for healthcare professionals and Patient information for the original medicinal product …… (name of original medicinal product) dated …… (month/year), apart from any deviations permitted according to section 5.6 of the guidance document *Import of a human medicinal product according to Art. 14 para. 2 and 3 TPA (parallel import)*.  yes |

## Secondary packaging/laser colour prints

|  |
| --- |
| **On submission of specific Swiss secondary packaging for the parallel imported medicinal product:**  The applicant confirms that the enclosed laser colour prints for the above-mentioned product are completely identical to the original print of the packaging materials in terms of both text and graphic design.  yes  n/a |
| **On submission of a label that is applied to the foreign packaging:**  The applicant confirms that the enclosed laser colour prints for the above-mentioned medicinal product are completely identical to the original print of the packaging materials in terms of both text and graphic design. The applicant also confirms that the relevant information according to TPLRO is included on the packaging with the information on the label.  yes  n/a |

## Sending of sample packs

|  |
| --- |
| The applicant confirms that 2 sample packs each per dosage strength will be sent to the following address, while ensuring correct transportation in accordance with the product specifications (e.g. cold chain):  Swissmedic OMCL Department (Laboratory)  Freiburgstrasse 139  3008 Bern  yes |
| Batch details of sample pack:  LOT: ……  EXP: …… |
| Does the cold chain need to be maintained?  yes  no |

# Further information

## Company meetings

|  |  |  |
| --- | --- | --- |
| Was a company meeting conducted for this application? | | |
| Presubmission Meeting | no | Yes, date: ……  Application ID: …… |
| Scientific Advice Meeting | no | Yes, date: ……  Application ID: …… |

## Narcotics

|  |  |  |
| --- | --- | --- |
| Does the medicinal product contain a narcotic substance? | yes | no |
| |  |  | | --- | --- | | 🡪 If yes, the narcotic substance is classified as list | Select an option. | | Select an option. | |

## Combination products

|  |  |  |
| --- | --- | --- |
| Is the product in question a combination product (medicinal product with medical device component)? | yes *🡪 Questions a) to c)* | no |
| 1. Is it an **integral** combination product and is the medical device component an integral part of the combination (physically inseparable)?  yes  no | | |
| 1. Is it an **integral** combination product with the medical device component enclosed in the packaging (use-specific non-separability, co-packaged)?  yes  no | | |
| 1. Is it a **non-integral** combination product with the medical device component **not** enclosed in the packaging, but referred to for combined use (referenced)?  yes  no | | |

## Mobile technologies

|  |
| --- |
| Is a QR code being added to the medicinal product information and/or the packaging?  yes, the *Mobile technologies* form is enclosed.  no |

# 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 | | Telephone +41 58 462 02 11  Fax +41 58 462 02 12  E-mail anfragen@swissmedic.ch | |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 3.0 | Changes due to new paragraph 3 in Article 14 TPA | nma, cho, vit, hv |
| 2.1 | New layout, no content adjustments to the previous version. | dei |
| 2.0 | Amendment concerning wholesaler | mik, hv |
| 1.3 | Formal adjustments to the header and footer  No content adjustments to the previous version. | dei |
| 1.2 | Autor im System mit Autor in der Änderungshistorie synchronisiert. Freigabe durch Person im VM Team, da Dokument nicht in der VMS Suche angezeigt wird.  No content adjustments to the previous version. | tsj |
| 1.1 | Basic information: Deletion of the eCTD sequence no. | dts |
| 1.0 | Implementation of TPO4 | ze |

1. If the WHO has not yet issued a valid ATC code, or a new ATC code has only just been applied for, the ATC code applied for must be specified (with a note to that effect) stating the level up to which the code is already clear. [↑](#footnote-ref-1)