|  |  |  |
| --- | --- | --- |
| **Form** | | |
| **New authorisation variation innotification procedure KPTPO** | | |
| **Identification number:** | ZL103\_00\_003 |
| **Version:** | 1.3 |
| **Valid from:** | 29.06.2023 |

# Basic information

|  |
| --- |
| External reference (Company Reference): …… |
| Number of basic company dossier: ……  *(if known)* |

# Addresses

## Marketing authorisation holder

|  |  |
| --- | --- |
| 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: | …… |
| **Has Swissmedic received the power of attorney?**  yes  no, the power of attorney is enclosed with this application (incl. original signature) | |

# Application type

## Homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy

|  |  |
| --- | --- |
|  | Basic company dossier for homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy  new authorisation (5019)  variation (5321)  *🡪 proceed to chap. 4.1, 5, 6* |
|  | Master dossier for homeopathic or anthroposophic medicinal products  new authorisation (5022)  variation (5324)  *🡪 proceed to chap. 4.2, 5, 6* |
|  | Individual notifications for homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy (5024) *🡪 proceed to chap. 4.3, 5, 6* |

## Asian medicinal products

|  |  |
| --- | --- |
|  | Basic company dossier for Asian medicinal products  new authorisation (5020)  variation (5322)  *🡪 proceed to chap. 4.4, 5, 6* |
|  | New authorisation of sample quality documentation for Asian medicinal products (5023) *🡪 proceed to chap. 4.5, 5, 6* |
|  | Individual notifications for Asian medicinal products (5025) *🡪 proceed to chap. 4.6, 5, 6* |

## Individual teas and cough and throat sweets and pastilles

|  |  |
| --- | --- |
|  | Basic company dossier for individual teas  new authorisation (5021)  variation (5323)  *🡪 proceed to chap. 4.7, 5, 6* |
|  | Basic company dossier for cough and throat sweets and pastilles  new authorisation (5021)  variation (5323)  *🡪 proceed to chap. 4.7, 5, 6* |
|  | Note regarding notification of individual teas and notification of cough and throat sweets and pastilles: Submit only the form *New authorisation of human medicinal products HMV4*. |

# Information on notification and additional forms to be submitted

## Basic company dossier for homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy

### Basic information

*Check all appropriate boxes*

|  |  |
| --- | --- |
| **The medicinal products are**  Human medicinal products  Veterinary medicinal products | **Pharmaceutical forms**  Oral  Globules  Granules  Tablets  Drinkable ampoules  Triturations / Powders  Drops / Sprays  Other oral pharmaceutical forms  ……  External  Ointments  Tinctures for external use  Other external pharmaceutical forms:  ……  Other  Ophthalmic  Ampoules for injection (s.c., i.c.)  Nasal drops / sprays  Suppositories  Other pharmaceutical forms:  …… |
| **Medicinal product category(ies)**  Homeopathic medicinal products  Homeopathic-spagyric / Spagyric medicinal products  Anthroposophic medicinal products  Medicinal products for Schüssler therapy / Schüssler salts  Medicinal products for gemmotherapy |
| **Type of medicinal products**  Single products  Combined products  Homaccords |
| **Type of starting materials contained in the medicinal products**  Chemical origin  Botanic origin  Mineral origin  Zoological origin (excluding organ preparations and  nosodes)  Organ preparations  Nosodes (animal and/or human origin)  Other |

### Additional forms and documents

|  |
| --- |
| Evidence that the authorisation requirements are fulfilled according to Art. 10 para. 1 letters b and c TPA.  already exists at Swissmedic.  enclosed. |

The list is not exhaustive. Please also consult directory *Overview of documents to be submitted HMV4.*

|  |
| --- |
| The form *Manufacturer information HMV4* is enclosed. (For new authorisations and variations that concern the manufacturer information.)  The form Manufacturer information HMV4 is enclosed. (must be submitted)  *A Form Declaration by the Responsible Person for foreign manufacturers HMV4 should be submitted for each proposed foreign manufacturer.*  *🡪 Guidance document GMP compliance by foreign manufacturers HMV4*  **Exception:** A *Manufacturer information TPO* form is not needed for teas in the notification procedure (Art. 12 KPTPO) or for cough and throat sweets and pastilles in the notification procedure (Art. 13 KPTPO).  The form *Manufacturer information HMV4* already exists at Swissmedic.. (Only for variations that do not concern the manufacturer information.)  A Form *Declaration by the Responsible Person for foreign manufacturers HMV4* should be submitted for each proposed foreign manufacturer. *🡪* Guidance document *GMP compliance by foreign manufacturers HMV4* |
| Are active substances or excipients used that contain, or may contain, substances derived from GMO?  Yes; the form *Confirmation regarding substances from GMO HMV4* is enclosed.  Yes; the form *Confirmation regarding substances from GMO HMV4* already exists at Swissmedic. (Only for variations that do not concern substances derived from GMO.)  No. |
| Are homeopathic medicinal products manufactured that contain substances subject to the Narcotics Control Ordinance (NarcCO; SR 812.121.1) and with a dilution up to, and including, D8/C4?  Yes; the licence according to NarcCO is enclosed.  Yes; the licence according to NarcCO already exists at Swissmedic. (Only for variations that do not concern substances subject to the NarcCO.)  No. |

### Confirmations

#### Packaging material / Labelling

|  |
| --- |
| We confirm that, following authorisation, the homeopathic and anthroposophic medicinal products and the medicinal products for gemmotherapy will be labelled according to Annex 1a TPLRO, and that the labelling will not include any information concerning indication or dosage, including in the scientific name, and that any warnings, contraindications or side effects in the HAS List or Gemmotherapy List are taken into account according to Annexes 6 and 8, respectively, of KPTPO and listed on the packaging material on the applicant's own initiative.  yes |

#### Precondition for the notification procedure

|  |
| --- |
| We confirm that all the preconditions for the notification procedure according to Art. 25 para. 1 and Art. 27 and 28 KPTPO are fulfilled.  yes |

## Master dossier for homeopathic or anthroposophic medicinal products

### Basic information

Master dossier for:

*Only one answer possible*

|  |  |  |
| --- | --- | --- |
|  | Active substances or excipients manufactured using material of animal or human origin (Art. 39 para. 1 letter a KPTPO) | Number of master dossier:  …… |
|  | Medicinal products for parenteral administration for use on/in the eye (Art. 39 para. 1 letter b KPTPO) | Number of master dossier:  …… |
|  | Manufacturing instructions not included in the pharmacopoeia according to Art. 23 para. 3; (Art. 39 para. 1 letter c KPTPO) | Number of master dossier:  …… |
|  | Spagyric active substances, if required according to the HAS List (Annex 6). (Art. 39 para. 1 letter d KPTPO) | Number of master dossier:  …… |
|  | Other (Art. 39 para. 1 KPTPO) | Number of master dossier:  …… |

## Individual notifications for homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy

### Other information

|  |
| --- |
| NuNumber2 of individual notifications exported from HOMANT Offline (preparations): ……  NuNumber2 of master dossiers exported from HOMANT Offline: ……  *2 See Export report in HOMANT Offline.* |

|  |
| --- |
| 1. Is TSE risk material used for manufacture? 2. Is other material of animal origin used for manufacture? 3. Is human material used for manufacture?   yes, TSE risk material and/or animal and/or human material is used; according to Art. 39 para. 1 letter a KPTPO a master dossier is required. Number(s) of master dossier(s): ……  no |

|  |
| --- |
| Are medicinal products for parenteral administration or use or/in the eye manufactured?  yes; the master dossier required by Art. 39 para. 1 letter b KPTPO exists. Number(s) of master dossier(s): ……  no |

|  |
| --- |
| Are manufacturing instructions used which are not included in the pharmacopoeia according to Art. 23 para. 3 KPTPO?  yes; the master dossier required by Art. 39 para. 1 letter c KPTPO exists. Number(s) of master dossier(s): ……  no |

|  |
| --- |
| Are spagyric active substances used for which a master dossier is required according to the HAS List (Annex 6 KPTPO)?  yes; the master dossier required by Art. 39 para. 1 letter d KPTPO exists. Number(s) of master dossier(s): ……  no |

|  |
| --- |
| Do other master dossiers required for notification exist?  yes; number(s) of master dossier(s): ……  no |

### Confirmations

#### Evidence of notification of the use of a genetic resource or related traditional knowledge in accordance with the Nagoya Ordinance

|  |  |  |  |
| --- | --- | --- | --- |
| According to Art. 3 para. 2 of the Therapeutic Products (TPO; SR 812.212.21), a new application for authorisation of a medicinal product whose development is based on the utilisation of genetic resources or related traditional knowledge must include the registration number pursuant to Art. 4 para. 3 or 8 para. 5 of the Nagoya Ordinance (NagO, SR 451.61). The registration number serves as evidence that the obligation to notify pursuant to Articles 4, 5 or 8 of the NagO is satisfied, and is a prerequisite for authorisation according to Art. 9 para. 2 TPO. The obligation to notify according to Art. 4 NagO must be complied with if access to the genetic resource was gained after 12 October 2014 (see Art. 25*d* of the Federal Act on the Protection of Nature and Cultural Heritage (NCHA]; SR 451). If the use of traditional knowledge relating to genetic resources pursuant to Article 23*p* NCHA is involved, the obligation to notify according to Art. 4 NagO is similarly applicable. If the use of a genetic resource from Switzerland pursuant to Art. 8 NagO is involved, evidence that the obligation to notify has been met is to be provided once Art. 8 NagO has taken effect from 1 January 2017. | | | |
| Are individual notifications subject to the obligation to notify pursuant to Art. 4, 5 or 8 of the NagO? | yes | no | n/a |
| If yes, the registration number(s) issued by the FOEN as evidence that the obligation to notify has been met is/are as follows: | …… | | |

#### Nanoparticles

|  |
| --- |
| We confirm that no synthetic nanoparticles1 are used for manufacture.  yes  *1* *The particles have at least one dimension on the nanoscale (1-1000nm) plus a function and/or mode of action based on nanotechnology characteristics.* |

#### Packaging material / Labelling

|  |
| --- |
| We confirm that, following authorisation, the products will be labelled according to Annex 1a TPLRO, and that the labelling will not include any information concerning indication or dosage, including in the scientific name, and that any warnings, contraindications or side effects in the HAS List or Gemmotherapy List are taken into account according to Annexes 6 and 8, respectively, of KPTPO and listed on the packaging material on the applicant's own initiative.  yes |

#### Quality and safety

|  |
| --- |
| We confirm that the products are manufactured in compliance with GMP according to Art. 4 para. 2 and 3 and/or Art. 11 para. 1 letter i MPLO and in strict accordance with the manufacturing instructions applicable to the respective preparations and  that the precondition for authorisation stated in Art. 10 para. 1 letter abis TPA is fulfilled.  yes |
| We confirm that the primary containers are defined (dimensions and material, including confirmations on safety in respect of contact with foodstuffs).  yes |
| We confirm that the shelf lives (including use-by periods after opening, where necessary) and storage instructions have been verified by corresponding investigations.  yes |

#### Precondition for the notification procedure

|  |
| --- |
| We confirm that all the preconditions for the notification procedure according to Art. 25 para. 1 and Art. 27 and 28 KPTPO are fulfilled.  yes |

## Basic company dossier for Asian medicinal products

### Additional forms and documents

|  |
| --- |
| Evidence that the authorisation requirements are fulfilled according to Art. 10 para. 1 letters b and c TPA.  already exists at Swissmedic.  enclosed. |

The list is not exhaustive. Please also consult VZ Overview of documents to be submitted HMV4

|  |
| --- |
| The form *Manufacturer information HMV4* is enclosed. (For new authorisations and variations that concern the manufacturer information.)  The form Manufacturer information HMV4 is enclosed. (must be submitted)  *A Form Declaration by the Responsible Person for foreign manufacturers HMV4 should be submitted for each proposed foreign manufacturer.*  *🡪 Guidance document GMP compliance by foreign manufacturers HMV4*  **Exception:** A *Manufacturer information TPO* form is not needed for teas in the notification procedure (Art. 12 KPTPO) or for cough and throat sweets and pastilles in the notification procedure (Art. 13 KPTPO).  The form *Manufacturer information HMV4* already exists at Swissmedic. (Only for variations that do not concern the manufacturer information.)  A Form *Declaration by the Responsible Person for foreign manufacturers HMV4. 🡪* Guidance document *GMP compliance by foreign manufacturers HMV4* |

|  |
| --- |
| 1. Is TSE risk material used for manufacture? 2. Is other material of animal origin used for manufacture? 3. Is human material used for manufacture?   Yes, TSE risk material and/or animal and/or human material is used; the form *Substances of animal and human origin* *HMV4* is enclosed.  Yes, TSE risk material and/or animal and/or human material is used; the form *Substances of animal and human origin* *HMV4* already exists at Swissmedic. (Only for variations that do not concern substances of animal or human origin.)  No. |

|  |
| --- |
| Does the medicinal product contain excipients that contain, or may contain, substances derived from GMO?  Yes; the form *Confirmation regarding substances from GMO HMV4* is enclosed.  Yes; the form *Confirmation regarding substances from GMO HMV4* already exists at Swissmedic. (Only for variations that do not concern substances derived from GMO.)  No. |

### Confirmations

#### Packaging material / Labelling

|  |
| --- |
| We confirm that, following authorisation of the Asian medicinal products, the information and texts will be stated on the containers and packaging materials according to Annex 1b TPLRO, and that the required Patient information will be prepared according to Annex 5.4 TPLRO and will be made available to  patients.  yes |

#### Precondition for the notification procedure

|  |
| --- |
| We confirm that all the preconditions for the notification procedure according to Art. 30 and 31 KPTPO are fulfilled.  yes |

## Sample quality documentation for Asian medicinal products

### Basic information

*Only one answer possible*

|  |  |
| --- | --- |
| **Product category**  Chinese medicinal product  Ayurvedic medicinal product  Tibetan medicinal product | **Pharmaceutical form**  Oral  Powder (single doses / multiple doses with measuring device)  Granules (single doses / multiple doses with measuring device)  Tablets  Capsules  Liquid preparations  External  Ointment |
| **Type of medicinal products**  Single products  Combined products |
|  |

### Additional forms and documents

The list is not exhaustive. Please also consult VZ Overview of documents to be submitted HMV4

|  |
| --- |
| The form Manufacturer information HMV4 is enclosed. (must be submitted)  *A Form Declaration by the Responsible Person for foreign manufacturers HMV4 should be submitted for each proposed foreign manufacturer.*  *🡪 Guidance document GMP compliance by foreign manufacturers HMV4*  **Exception:** A *Manufacturer information TPO* form is not needed for teas in the notification procedure (Art. 12 KPTPO) or for cough and throat sweets and pastilles in the notification procedure (Art. 13 KPTPO). |

|  |
| --- |
| 1. Is TSE risk material used for manufacture? 2. Is other material of animal origin used for manufacture? 3. Is human material used for manufacture?   yes, TSE risk material and/or animal and/or human material is used; the form *Substances of animal and human origin* *HMV4* is enclosed.  no |

## Individual notifications for Asian medicinal products

### Basic information

|  |
| --- |
| Sample quality document number(s) for Asian medicinal products …… |

### Confirmations

#### Evidence of notification of the use of a genetic resource or related traditional knowledge in accordance with the Nagoya Ordinance

|  |  |  |  |
| --- | --- | --- | --- |
| According to Art. 3 para. 2 of the Therapeutic Products (TPO; SR 812.212.21), a new application for authorisation of a medicinal product whose development is based on the utilisation of genetic resources or related traditional knowledge must include the registration number pursuant to Art. 4 para. 3 or 8 para. 5 of the Nagoya Ordinance (NagO, SR 451.61). The registration number serves as evidence that the obligation to notify pursuant to Articles 4, 5 or 8 of the NagO is satisfied, and is a prerequisite for authorisation according to Art. 9 para. 2 TPO. The obligation to notify according to Art. 4 NagO must be complied with if access to the genetic resource was gained after 12 October 2014 (see Art. 25*d* of the Federal Act on the Protection of Nature and Cultural Heritage (NCHA]; SR 451). If the use of traditional knowledge relating to genetic resources pursuant to Article 23*p* NCHA is involved, the obligation to notify according to Art. 4 NagO is similarly applicable. If the use of a genetic resource from Switzerland pursuant to Art. 8 NagO is involved, evidence that the obligation to notify has been met is to be provided once Art. 8 NagO has taken effect from 1 January 2017. | | | |
| Are individual notifications subject to the obligation to notify pursuant to Art. 4, 5 or 8 of the NagO? | yes | no | n/a |
| If yes, the registration number(s) issued by the FOEN as evidence that the obligation to notify has been met is/are as follows: | …… | | |

#### Nanoparticles

|  |
| --- |
| We confirm that no synthetic nanoparticles1 are used for manufacture.  yes  *1* *The particles have at least one dimension on the nanoscale (1-1000nm) plus a function and/or mode of action based on nanotechnology characteristics.* |

#### Substances derived from GMO

|  |
| --- |
| We confirm that the product does not contain active substances that contain, or may contain, substances derived from GMO?  yes |

#### Packaging material / Labelling

|  |
| --- |
| We confirm that, following authorisation, the information and texts will be stated on the containers and packaging materials according to Annex 1b TPLRO, and that the required Patient information will be prepared according to Annex 5.4 TPLRO and will be made available to patients.  yes |

#### Quality and safety

|  |
| --- |
| We confirm that the products are manufactured in compliance with GMP according to Art. 4 para. 2 and 3 and/or Art. 11 para. 1 letter i MPLO and in strict accordance with the manufacturing instructions applicable to the respective preparations and that the precondition for authorisation stated in Art. 10 para. 1 letter abis TPA is fulfilled.  yes |

#### Precondition for the notification procedure

|  |
| --- |
| We confirm that all the preconditions for the notification procedure according to Art. 30 and 31 KPTPO are fulfilled.  yes |

## Basic company dossier for individual teas and basic company dossier for cough and throat sweets and pastilles

### Additional forms and documents

|  |
| --- |
| Evidence that the authorisation requirements are fulfilled according to Art. 10 para. 1 letters b and c TPA.  already exists at Swissmedic.  enclosed. |

The list is not exhaustive. Please also consult VZ Overview of documents to be submitted HMV4

|  |
| --- |
| The form *Manufacturer information HMV4* is enclosed. (For new authorisations and variations that concern the manufacturer information.)  The form *Manufacturer information HMV4* is enclosed. (must be submitted)  *A Form Declaration by the Responsible Person for foreign manufacturers HMV4 should be submitted for each proposed foreign manufacturer.*  *🡪 Guidance document GMP compliance by foreign manufacturers HMV4*  **Exception:** A *Manufacturer information TPO* form is not needed for teas in the notification procedure (Art. 12 KPTPO) or for cough and throat sweets and pastilles in the notification procedure (Art. 13 KPTPO).  The form *Manufacturer information HMV4* already exists at Swissmedic. (Only for variations that do not concern the manufacturer information.)  A Form *Declaration by the Responsible Person for foreign manufacturers HMV4*. *🡪* Guidance document *GMP compliance by foreign manufacturers HMV4* |

### Confirmations

#### Company dossier for individual teas

|  |
| --- |
| We confirm that all the preconditions for the notification procedure according to Art. 12 KPTPO are fulfilled.  yes |

#### Company dossier for cough and throat sweets and pastilles

|  |
| --- |
| We confirm that all the preconditions for the notification procedure according to Art. 13 KPTPO are fulfilled.  yes |

# Other confirmations

## Confirmation of compliance with the requirements for the application documents

|  |
| --- |
| We confirm that the requirements of guidance document *Formal requirements HMV4* and the Directory *Overview of documents to be submitted HMV4* were satisfied during the compilation of application documents.  yes |

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

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

# 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** |
| --- | --- | --- |
| 1.3 | New layout, no content adjustments to the previous version. | dei |
| 1.2 | Formal adjustments to the header and footer  No content adjustments to the previous version. | dei |
| 1.1 | Chapters 4.1.2, 4.4.1, 4.5.2, 4.7.1: Explanation regarding the list of forms to be submitted in addition | ze |
| 1.0 | Implementation of TPO4 | dts |