|  |  |  |
| --- | --- | --- |
| **Form** | | |
| **Renewal of authorisation by notification procedure homeopathic and anthroposophic medicinal products** | | |
| **Identification number:** | ZL201\_00\_009 |
| **Version:** | 1.4 |
| **Valid from:** | 19.07.2023 |

|  |  |
| --- | --- |
| Basic information **Company reference: ……** | |
| **Basic company dossier No. (BCD):** **……** | **Expiry date of marketing authorisation: ……** |
| **Name of BCD:** **……** | **Number of authorised medicinal products (AMP):** …… |
| **Application No.:** **……** *(as shown in the Annex to the official decision)* |  |

# Addresses

## Marketing authorisation holder

|  |  |
| --- | --- |
| Company name: | …… |
| Additional title: | …… |
| Street, building no.: | …… |
| Postcode, place: | …… |
| Canton: | …… |
| Telephone: | …… |
| E-mail | …… |

## Address for correspondence (if not identical to 2.1)

|  |  |
| --- | --- |
| Company name: | …… |
| Additional title: | …… |
| Street, building no.: | …… |
| P.O. Box | …… |
| Postcode, place: | …… |
| Telephone: | …… |
| E-mail | …… |

## Legal representative (if not identical to 2.1)

|  |  |
| --- | --- |
| Name: | …… |
| Additional title: | …… |
| Street, building no.: | …… |
| P.O. Box | …… |
| Postcode, place: | …… |
| Telephone: | …… |
| **Does Swissmedic already have the power of attorney?**  Yes  No, the power of attorney in enclosed with this application (with an original signature) | |

# Notes

|  |
| --- |
| * The application to renew homeopathic and anthroposophic medicinal products authorised under the notification procedure must be sent with the required documents no sooner than 1 year but **not later than 6 months** before the authorisation period expires. * Authorisation renewals cannot be requested in collective or multiple applications. * Enclosures: A copy of the official authorisation decision with a list of the authorised medicinal products (as an annex) must be submitted with each application. The applicant should delete from this list those medicinal products for which authorisation renewal is **not** required (discontinuation of the renewal). The deletions should additionally be highlighted using coloured markings to make them easier to find. All documents should be stamped by the marketing authorisation holder.   Additional information on the formal requirements can be found in the guidance document *Formal requirements HMV4*. |

# Application type

|  |  |  |
| --- | --- | --- |
| 1. The applicant requests renewal of the marketing authorisation | Yes; number of AMP: …… | no |
| 1. The applicant is not requesting renewal of the marketing authorisation | Yes; number of AMP: …… | no |
| 1. The medicinal products for which renewal was requested under point 1 are on the market in Switzerland or the Principality of Liechtenstein | yes | no |
| **If NO**: The *No marketing / interruption of distribution HMV4* form has been submitted. | yes | no |

|  |
| --- |
| Remarks: …… |

# Confirmation

|  |
| --- |
| Conformity of medicinal products with approved information by the application of the renewal of the authorisation We confirm,   * that the medicinal products for which their authorisation shall be renewed is sought conform with:   the most recently approved basic company dossier which forms the basis of the marketing authorisations,  the most recently approved master dossier which forms the basis of the marketing authorisations, and  the approved preparation-specific information.   * that there are no variations associated with the application for renewal of homeopathic and anthroposophic medicinal products authorised under the notification procedure.  yes   New medicinal product notifications and variations of the basic company dossier (e.g. manufacturer information) must be applied for in a separate application using a *New authorisation of human medicinal products HMV4* form or a *Variations and extensions HMV4* form. |

### 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 the current Annex 1a TPLRO including the full declaration 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 |

# Signature

|  |  |  |  |
| --- | --- | --- | --- |
| **The completeness and correctness of all the information provided in this form and in the additional documents appended to the application is confirmed by:**  *(Official stamp of the applicant – optional)*  ……  ……  …… | | | |
| *Authorised signatory* | | *Other competencies (optional signature)* | |
| Place, date: ……  Signature: …………………………….. | | Place, date: ……  Signature: …………………………….. | |
| Surname: | …… | Surname: | …… |
| First name: | …… | First name: | …… |
| Function: | …… | Function: | …… |
| 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** |
| --- | --- | --- |
| 1.4 | New layout, no content adjustments to the previous version. | dei |
| 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.  Keine inhaltlichen Änderungen | tsj |
| 1.1 | Chapter 5: Completion of the confirmation | lap |
| 1.0 | Implementation of TPO4 | dts |