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| --- | --- | --- |
| **Form** | | |
| **Renewal of authorisation CHM** | | |
| **Identification number:** | ZL201\_00\_010 |
| **Version:** | 4.4 |
| **Valid from:** | 28.06.2023 |

# Basic information

|  |  |
| --- | --- |
| **External (company) reference:** …… | |
| **Authorisation no.: ……** | **Expiry date of the authorisation:** …… |
| **Name of medicinal product:** …… | |

# 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)

|  |  |
| --- | --- |
| Last 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) | |

# Notes

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| * The application for renewal of the authorisation in accordance with Art. 12 para. 1 TPO should be submitted together with the required documents and, where applicable, the discontinuation decision 1 year at the earliest but not later than 6 months before expiry of the authorisation. * Authorisation renewals cannot be requested as a collective or multiple application. * The application for renewal of the authorisation may not be associated with any variations. Variations according to Art. 21 to 24 TPO should be requested using a **separate** application (see guidance document *Variations and extensions HMV4*). * For medicinal products that are **not** considered to be homeopathics, complementary medicines with indication or complementary medicines without indication but with simplified authorisation, the Form *Renewal of authorisation HMV4* should be used for renewals. * The form *Renewal of authorisation by notification procedure for homeopathics and anthroposophic medicinal products HMV4* should be used for renewals for homeopathics and anthroposophics without indication in the notification procedure. * The form *Renewal of authorisation by notification procedure veterinary medicinal products HMV4* should be used for renewals of veterinary medicinal products authorised in the notification procedure in accordance with Art. 39 TPLO. * The form cannot be used for the renewal of a temporary authorisation. * If renewal of the authorisation is not requested, the questions under 5 do not need to be answered. * The texts of the medicinal product information and packaging are *not* to be submitted in connection with this application. * Where the application relates to homeopathic and anthroposophic medicines that have been approved with a reduced dossier, a *Full declaration HMV4* form is required. * If necessary, Swissmedic can request further supplements to the *Renewal of authorisation HMV4* form.   Additional information on the formal requirements can be found in the guidance document *Formal requirements HMV4*. |

# Application type

|  |  |  |
| --- | --- | --- |
| The applicant requests the renewal of the authorisation.  If “no”:  The medicinal product is a basic product and the authorisation holders of the co-marketing medicinal products have been informed of the negative decision. | yes  yes | no  no |
| The medicinal product is on the market in Switzerland.  If the medicinal product is not on the market in Switzerland:   * Distribution was stopped (temporarily) on: ……. A notification in accordance with Art. 11 para. 1 TPO was submitted on: …… * (Re)introduction on the Swiss market is planned on: ……. * This relates to an export licence | yes  yes  yes  yes | no  no  no  no |

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| Remarks: …… |

# Additional forms to be submitted

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| --- |
| Is the product in question a homeopathic or anthroposophic medicinal product that was authorised with a reduced dossier?  yes, the *form Full declarationHMV4* is enclosed  no |

# Further information

|  |  |  |
| --- | --- | --- |
| The latest version of the MPI consists of: | | |
| Information for healthcare professionals (IHP) Version: …… | yes | no |
| Patient information (PI) Version: …… | yes | no |
| Packaging texts (labels, carton, etc.) Approval date: …… | yes | no |

|  |  |  |
| --- | --- | --- |
| Is the product in question a co-marketing medicinal product?  If yes, auth. no. + medicinal product name of the basic product: …… | yes | no |
| IHP corresponds to the version dated: …… of the basic product | yes | no |
| PI corresponds to the version dated: …… of the basic product | yes | no |

|  |  |  |
| --- | --- | --- |
| For human medicinal products:  Have the labelling and product information requirements in accordance with the revised TPLRO (especially full declaration as per Annex 3, Warnings about excipients of particular interest as per Annex 3, fixed texts as per Annex 4 and 5) already been implemented or, as the case may be, has the corresponding application been submitted to Swissmedic? | yes | no |
| For veterinary medicinal products:  Have the labelling and product information requirements in accordance with the revised TPLRO (especially full declaration and adaptation of product information as per Annex 6) already been implemented or, as the case may be, has the corresponding application been submitted to Swissmedic? | yes | no |

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| Remarks: …… |

# Confirmation

|  |
| --- |
| By signing this form, the applicant confirms that the only variations made were either approved in advance by Swissmedic (in the case of *major type II variations* according to Art. 23 TPO) or were reported to Swissmedic in advance and were then not rejected within 60 days (in the case of *minor type IB variations that must be notified in advance* according to Art. 22 TPO) or within 30 days (in the case of *minor type IA/IAIN*  *variations to be reported subsequently* according to Art. 21 TPO). It is not essential for renewal that all variation applications have already been completed by Swissmedic. |

# 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** |
| --- | --- | --- |
| 4.4 | New layout, no content adjustments to the previous version. | dei |
| 4.3 | Formale Anpassung in Kapitel 7: Löschung Checkbox.  Keine inhaltlichen Anpassungen zur Vorversion. | lap |
| 4.2 | Formal adjustments to the header and footer  No content adjustments to the previous version. | dei |
| 4.1 | 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 |
| 4.0 | Further details in the chapter 3:   * The application for renewal of the authorisation in accordance with Art. 12 para. 1 TPO should be submitted together with the required documents and, where applicable, the discontinuation decision 1 year at the earliest but not later than 6 months before expiry of the authorisation.   Further details in the chapter 6:   * For human medicinal products: Have the labelling and product information requirements in accordance with the revised TPLRO (especially full declaration as per Annex 3, Warnings about excipients of particular interest as per Annex 3, fixed texts as per Annex 4 and 5) already been implemented or, as the case may be, has the corresponding application been submitted to Swissmedic? * For veterinary medicinal products: Have the labelling and product information requirements in accordance with the revised TPLRO (especially full declaration and adaptation of product information as per Annex 6) already been implemented or, as the case may be, has the corresponding application been submitted to Swissmedic? | ze |
| 3.0 | Supplement in the chapter Confirmation: It is not essential for renewal that all variation applications have already been completed by Swissmedic | ze |
| 2.0 | Chapter 3 “Explanations” and chapter 5 “Additional forms to be submitted”: reference to the form *Full declaration HMV4* for renewal of the authorisation of hom./anthr. medicinal products without any indication involving a reduced dossier. | spm |
| 1.0 | Implementation of HMV4 | dts |