|  |  |  |
| --- | --- | --- |
| **Form** | | |
| **Renewal of authorisation by notification procedure veterinary medicinal products** | | |
| **Identification number:** | ZL201\_00\_007 |
| **Version:** | 2.3 |
| **Valid from:** | 19.07.2023 |

# Basic information

|  |  |
| --- | --- |
| **External reference (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)

|  |  |
| --- | --- |
| 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 veterinary medicinal products authorised in the notification procedure in accordance with Art. 39 TPLO should be submitted, together with the required documents, 1 year at the earliest but **6 months at the latest** before expiry of the authorisation. * Authorisation renewals cannot be requested as a collective or multiple application. * The application for renewal of veterinary medicinal products authorised in the notification procedure 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*). |

# Application type

|  |  |  |
| --- | --- | --- |
| The applicant requests the renewal of the authorisation. | yes | 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: ……. * (Re)introduction on the Swiss market is planned on: ……. | yes | no |

|  |
| --- |
| 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.  yes |

# 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** |
| --- | --- | --- |
| 2.3 | New layout, no content adjustments to the previous version. | dei |
| 2.2 | Formal adjustments to the header and footer  No content adjustments to the previous version. | dei |
| 2.1 | Autor im System mit Autor in der Änderungshistorie synchronisiert. Freigabe durch Person im VM Team, da Dokument nicht in der VMS Suche angezeigt wird.  Keine inhaltlichen Änderungen | tsj |
| 2.0 | Supplement in the chapter Confirmation: It is not essential for renewal that all variation applications have already been completed by Swissmedic | ze |
| 1.0 | Implementation of TPO4 | dts |