

|  |  |  |
| --- | --- | --- |
| **Form** | | |
| **Recognition of MUMS status** | | |
| **Identification number:** | ZL102\_00\_003 |
| **Version:** | 1.3 |
| **Valid from:** | 29.06.2023 |

# Basic information

|  |
| --- |
| **Name of medicinal product:** …… |
| **Authorisation no.:** …… |
| **Active substance(s):** …… |
| **Pharmaceutical form:** …… |
| **Dosage strength(s):** …… |
| **ATCvet code:** …… |
| **Target animal species:** …… |
| **Precise wording of the proposed indication:** |

# Addresses

## Authorisation holder (distributor)

|  |  |
| --- | --- |
| 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: | …… |
| **Swissmedic has received power of attorney**  yes  no\*  *\*If no: Power of attorney is enclosed with this application (incl. original signature)* | |

# Further information

## Proposed procedure

|  |  |
| --- | --- |
|  | Minor Use according to Art. 8 para. 1 letter a TPLO |
|  | Minor Species according to Art. 8 para. 1 letter b TPLO |
|  | Recognition of foreign MUMS status according to Art. 8 para. 1 letter c TPLO  Reference country: …… |

## Timing of submission of the authorisation application

|  |  |
| --- | --- |
|  | At the same time as this application for recognition of the MUMS status |
|  | Later, expected on …… |
|  | Timing not yet known |

## MUMS status abroad

The status abroad should be stated at least for EU and EFTA countries.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Status granted | Country: …… | Date of recognition of status: ……  Date of authorisation of medicinal product: ……  ☐ *The copies of the decisions of the foreign authorities are enclosed (compulsory).* | Name of the medicinal product: …… |
|  | Submitted | Country: …… | Date of submission: …… | Name of the medicinal product: …… |
|  | Withdrawn | Country: …… | Date of withdrawal: …… | Name of the medicinal product: …… |
|  | Suspended | Country ……: | Date of suspension: …… | Name of the medicinal product: …… |

# Additional forms and documents to be submitted

|  |
| --- |
| Does a draft of the medicinal product information exist?  yes, the draft of the medicinal product information is enclosed.  no |
| Does an EU SmPC or draft of an EU SmPC exist?  yes, the EU SmPC is enclosed. It was approved on: ……  yes, the draft of the EU SmPC is enclosed.  no |
| Other documents (e.g. other SmPCs from other countries): …… |

# Consents and confirmations

## Confirmation of the recognition of the MUMS status by a foreign authority

|  |
| --- |
| The applicant confirms that the foreign medicinal product with MUMS status is the same medicinal product that forms the subject of this application.  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 | 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 |
| 1.0 | Implementation of TPO4 | dts |