

|  |  |  |
| --- | --- | --- |
| **Form** | | |
| **New authorisation by notification procedure veterinary medicinal products** | | |
| **Identification number:** | ZL112\_00\_002 |
| **Version:** | 3.1 |
| **Valid from:** | 30.06.2023 |

# Basic information

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of the medicinal product; ……**  **Marketing authorisation no. where applicable: ……** | | | |
| **Are active pharmaceutical ingredients listed in Annex 2 of the TPLO involved?**  Yes  No, inclusion of the following active pharmaceutical ingredient(s) in Annex 2 is requested: …… \* | | | |
| **Active substance(s) in the finished product by type and quantity:** | | | |
| **Excipient(s) in the finished product by type and quantity:** | | | |
| **Dosage form: ……** | | | |
| **Indications:** **……** | | | |
| **Pharmacotherapeutic group (ATCvet code):** **……** | | | |
| **Dosage strength(s):** | **Presentations (primary container)**  *(e.g. blisters)* | | **Packaging (secondary container)**  *(e.g. folding cartons)* |
| …… | …… | | …… |
| …… | …… | | …… |
| …… | …… | | …… |
| …… | …… | | …… |
| …… | …… | | …… |
|  | | | |
| **Target animal species:**  Ornamental fish  Ornamental and songbirds  Carrier pigeons | | Reptiles  Amphibians  Small mammals | |
| **Dispensing category:**  **D** Dispensed after expert advice  **E** Dispensed without expert advice | | | |

# Addresses

## Marketing authorisation holder

|  |  |
| --- | --- |
| Company name: | …… |
| Additional title: | …… |
| Street, building no.: | …… |
| Postcode, place: | …… |
| 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) | |

# Application type

|  |  |  |
| --- | --- | --- |
| **Application type** | | **Code**  *(SMC internal)* |
|  | New authorisation under the notification procedure | 5026 |
|  | Variation of an existing authorisation under the notification procedure  (type Variation with assessment, time limit “Reduced”) in accordance with the guidance document *Variations VMP HMV4;)*   |  |  | | --- | --- | | **Description of / reason for variation** | | | …… | | | **Currently approved** | **Requested** | | …… | …… | | 6271 |

# Further information

## Manufacturer of the ready-to-use medicinal product

|  |  |  |
| --- | --- | --- |
| A copy of the GMP certificate or the manufacturing licence must be submitted for each manufacturer (for details, see the guidance document *GMP compliance by foreign manufacturers HMV4*). | | |
| **Processing steps**  *If one manufacturer performs all steps in galenical production, enter “all” below.* | **Manufacturer**  *Full address of the operating sites (not addresses for correspondence)* | *(Please leave blank)* |
| **Dosage strength(s)** ……  **Step(s)** …… | **Manufacturer** …… | *GMP*  *Manufacturing licence* |
| **Dosage strength(s)** ……  **Step(s)** …… | **Manufacturer** …… | *GMP*  *Manufacturing licence* |
| **Dosage strength(s)** ……  **Step(s)** …… | **Manufacturer** …… | *GMP*  *Manufacturing licence* |

## Confirmation that the following requirements are met

|  |  |  |
| --- | --- | --- |
| 1. The manufacturing process is defined and validated | Yes | No |
| 1. The quality and the manufacturer of the active substance are defined | Yes | No |
| 1. The primary container is defined (dimensions and materials) | Yes | No |
| 1. The specifications and test methods for batch release are defined | Yes | No |
| 1. The shelf life (including shelf life after opening or reconstitution) and storage instruction have been verified by corresponding investigations | Yes | No |

## Information about the packaging texts

|  |  |  |
| --- | --- | --- |
| The preparation is intended for distribution in Switzerland with foreign packaging texts and additional labels in accordance with the guidance document *Notification procedure for veterinary medicinal products HMV4*. | Yes | No |
| The preparation is intended for distribution with packaging texts produced specifically for Switzerland. | Yes | No |

## Documents to be submitted

|  |
| --- |
| * Accompanying letter demonstrating compliance with the requirements of Article 39 of the TPLO |
| * Proof of authorisation if the preparation is authorised in another country |
| * \*If the notified medicinal product contains an active pharmaceutical substance that is neither listed in Annex 2 of the TPLRO nor contained in a medicinal product already authorised in Switzerland under the notification procedure: additional documents in accordance with the guidance document *Notification procedure for veterinary medicinal products HMV4* |

## 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 Ordinance (TPO; SR 812.212.21), a new application for authorisation of a medicinal product whose development is based on the use 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 of the 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.  Additional information on the requirements can be found in the guidance document *Formal requirements HMV4*.  Is the new application for authorisation subject to the obligation to notify pursuant to Art. 4, 5 or 8 of the NagO?  Yes  No  If yes, the registration number issued by the FOEN as evidence that the obligation to notify has been met is as follows: …… |

# Signature

|  |  |  |  |
| --- | --- | --- | --- |
| **The completeness and correctness of all the information provided in this form is confirmed by:**  *(Official stamp of the applicant, optional)*  ……  ……  …… | | | |
| Authorised signatory | | Other competencies *(optional signature)* | |
| Place, date: ……  Signature: …………………………….. | | Place, date: ……  Signature: …………………………….. | |
| Name: | …… | Name: | …… |
| 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 Berne | | Telephone +41 58 462 02 11  Fax +41 58 462 02 12  E-mail Anfragen@swissmedic.ch | |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 3.1 | New layout, no content adjustments to the previous version. | dei |
| 3.0 | Editorial change in section 3 (Swissmedic code) | ps/fg |
| 2.0 | Clarification regarding changes to reporting procedure (section 3); adaptations due to new structure of VMP variations (early revision of VMP regulations) | lac, ps |
| 1.4 | Formal adjustments to the header and footer  No content adjustments to the previous version. | dei |
| 1.3 | Author in system synchronised with author in change history. Release by person in VM Team, as document is not displayed in VMS search.  No changes to content. | tsj |
| 1.2 | Chapter 4.4: Deletion of the list of forms to be submitted in addition. | lac |
| 1.1 | Chapter 4.4: Explanation regarding the list of forms to be submitted in addition. | ze |
| 1.0 | Implementation of TPO4 | dts |