

|  |  |  |
| --- | --- | --- |
| **Form** | | |
| **New authorisation of veterinary medicinal products** | | |
| **Identification number:** | ZL100\_00\_002 |
| **Version:** | 3.1 |
| **Valid from:** | 29.06.2023 |

# Basic information

|  |  |  |
| --- | --- | --- |
| **External reference (Company Reference):** …… | | |
| **Name of medicinal product:** …… | | |
| **Active substance(s):** …… | | |
| **Dosage form:** …… | | |
| **Short form of the area of application incl. proposed targeted animal species:** ……  *(E.g. for systemic treatment of fleas in cats.* *The short form of the area of application will be published on receipt and completion of the application)* | | |
| **ATCvet code:** …… | | |
| **Dosage strength(s)** | **Primary container**  *(e.g. blister pack)* | **Secondary container**  *(e.g. cartons)* |
| …… | …… | …… |
| …… | …… | …… |
| …… | …… | …… |
| …… | …… | …… |
| …… | …… | …… |
|  | | |
| **Product category**  Select an option. | | |
| **Dispensing category**  Select an option. | | |

**To be completed additionally for medicinal products with known active substances**

|  |  |
| --- | --- |
| **Where applicable, information on the Swiss reference medicinal product** | |
| Name of the Swiss reference medicinal product: | …… |
| Swissmedic authorisation no.: | …… |

|  |  |  |  |
| --- | --- | --- | --- |
| **Where applicable, information on the foreign comparator medicinal product** | | | |
| Name of the foreign comparator medicinal product: | …… | | |
| Name and address of the authorisation holder abroad: | …… | | |
| Country of authorisation: | …… | | |
| Authorisation no.: | …… | | |
| LOT: | …… | | |
| EXP: | …… | | |
| Reference country / Reference source: | …… | | |
| Tabular compilation of the comparability of the foreign comparator medicinal product with the Swiss reference medicinal product | Available? | |  |
| Yes | No | If no, explain |
|  |  | …… |

# 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) | |

# Application type

## Medicinal product with indication

|  |  |  |
| --- | --- | --- |
| **Application type** | | **Code**  *(SMC internal)* |
|  | New active substance |  |
|  | Known active substance with innovation (incl. new combination according to Art. 6 TPLRO) |  |
|  | Known active substance without innovation |  |
|  | Known active substance herbal medicinal product (incl. new combination according to Art. 6 TPLRO) |  |
|  | Complementary medicine with indication |  |
|  | Known active substance for which simplified authorisation is not possible according to Art. 12 para. 5 TPLO |  |
|  | Co-marketing *(Art. 32 ff. TPLO) 🡪* Submit only the form *New authorisation for co-marketing of medicinal product HMV4*. |  |
|  | Parallel import *(Art. 14 para. 2 TPO) 🡪* Submit only the form *Import of a medicinal product according to Art. 14 para. 2 TPA HMV4.* |  |
|  | Authorisation in the notification procedure *(Art. 39 TPLO) 🡪* Submit only the form *New authorisation variation in notification procedure VMP HMV4*. |  |

## Complementary medicine without indication

|  |  |  |
| --- | --- | --- |
|  | Complementary medicinal product without indication according to Art. 25 para. 2 and Art. 30 KPTPO |  |
|  | Complementary medicinal product without indication with reduced dossier according to Art. 25 para. 1 KPTPO |  |
|  | Complementary medicinal product without indication in the notification procedure and submission of the corresponding documentation (e.g. basic company dossier, master dossier, sample quality documentation) 🡪 Submit only the form *New authorisation variation in notification procedure KPTPO HMV4*. |  |

# Special procedures / Status

|  |  |  |
| --- | --- | --- |
|  | Use of temporary authorisation1 | Approved on: …… |
|  | Herbal medicinal product with traditional use |  |
|  | Herbal medicinal product with Well Established Use |  |
|  | Application for use of procedure according to Art. 13 TPA  The form *Information for application Art.13 TPA HMV4* is enclosed (compulsory). |  |
|  | Application for use of procedure according to Art. 14 para. 1 letter abis TPA  EU/EFTA country with authorisation of the active substance for at least 10 years: …….  EU/EFTA country from which medicinal product information is taken over: …… | |
|  | Application for use of procedure according to Art. 14 para. 1 letter ater TPA  Countries with at least 30 years' experience of use in medical applications: ……  EU/EFTA countries with at least 15 years' experience of med. use: …… | |
|  | Application for use of procedure according to Art. 14 para. 1 letter aquater TPA  Swiss canton on which authorisation application is based: …… | |
|  | MUMS status | Granted on: …… |
| *1Prior approval / granting by Swissmedic required.* | | |

# Additional forms to be submitted

The list is not exhaustive. Please also consult the *directory Overview of documents to be submitted HMV4*.

|  |
| --- |
| The form *Manufacturer information HMV4* is enclosed (must be submitted)  *A "Declaration by the Responsible Person" form should be submitted for each proposed foreign manufacturer.* 🡪 Guidance document *GMP compliance by foreign manufacturers HMV4* |

|  |
| --- |
| The form *Full declaration HMV4* is enclosed (must be submitted) |

|  |
| --- |
| 1. Is any TSE risk material used for the manufacture of the medicinal product? 2. Are other materials of animal origin used for the manufacture of the medicinal product?   yes, TSE risk material and/or animal material is used; the form *Substances of animal and human origin* *HMV4* is enclosed  no |

|  |
| --- |
| Does the medicinal product contain active substances or excipients that contain, or may contain, substances derived from GMO?  yes, the form *Confirmation regarding substances from GMO HMV4* is enclosed  no |

|  |
| --- |
| Does a decision of a foreign authority exist for this application, or has the application been submitted to any foreign authority?  yes, *Status of authorisation applications abroad HMV4* form is enclosed  no  According to the Overview of documents to be submitted HMV4, the form need not be submitted for this application. |

|  |
| --- |
| Is a Drug Master File used?  yes, the form *DMF for first authorisations TPO* is enclosed  no |
|  |
| Is a QR code being added to the medicinal product information and/or the packaging?  yes, the completed *Mobile Technologies* form is enclosed  no |

# Further information

## Placing on the market

|  |  |
| --- | --- |
|  | Intended for placing on the Swiss market |
|  | Intended for export only |

## Company meetings

|  |  |  |
| --- | --- | --- |
| Was a company meeting conducted for this application? | | |
| Presubmission meeting | no | Yes, date: ……  Application ID: …… |
| Scientific Advice Meeting | no | Yes, date: ……  Application ID: …… |

## Advanced document protection

|  |  |  |  |
| --- | --- | --- | --- |
| Do you wish to apply for extended 10-year document protection for a new indication with significant clinical benefit over existing treatments (Art. 11b para. 2 TPA and Art. 30 para. 3 TPO)? | yes1 | no | n.a. |
| Do you wish to request 15-year document protection for important medicinal products for rare diseases (Art. 11b para. 4 TPA) as part of the new authorisation? | yes1 | no | n.a. |
| 1*Reasons in support of the application for extended document protection must be given in the cover letter.* | | | |

## Real world evidence

|  |  |  |
| --- | --- | --- |
| Does the application include real world evidence (RWE) in support of the proof of safety and efficacy? | yes | no |

If so:

Study design (please check all appropriate boxes):

|  |  |
| --- | --- |
|  | Randomised controlled study with pragmatic elements |
|  | Study designs that use real world data (RWD) to supplement the control arm |
|  | Single-arm study that uses RWD in an external control arm |
|  | Non-interventional (observational) study) |
|  | Other study design (please provide details): …… |

Other comments on the study design: ……

RWD sources (please check all appropriate boxes):

|  |  |
| --- | --- |
|  | Data from electronic patient records |
|  | Data from digital healthcare technologies |
|  | Data from production systems (incl. precision livestock farming) |
|  | Data from surveillance programmes (disease surveillance, lab data, etc.) |
|  | Other data sources (e.g. questionnaires) which could provide information on state of health (please provide details): …… |

Other comments on the RWD sources: ……

## Nanoparticles

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Does the medicinal product contain synthetic nanoparticles1? | | | yes | no |
| If yes, which component(s) of the medicinal product is/are involved? | | | | |
| Active substance(s): | …… | see Part(s): | …… | |
| Excipient(s): | …… | see Part(s): | …… | |
| Others: | …… | see Part(s): | …… | |

*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.*

## Narcotics

|  |  |  |
| --- | --- | --- |
| Does the medicinal product contain a narcotic substance? | yes | no |
| 🡪 If yes, the narcotic substance is classified as list | Select an option. | |

# Consents and confirmations

## Completeness of scientific documentation and compliance with formal requirements

|  |
| --- |
| The applicant confirms having submitted all available data that are relevant for assessing the quality, safety and efficacy of the medicinal product and that the application documentation conforms to the Guidance document Formal Requirements HMV4 and the Overview of documents to be submitted HMV4.  yes |

## eDok confirmation of identity (paper-based applications with eDok copy)

|  |
| --- |
| The applicant confirms that the electronic copy and the paper documentation are complete and identical. The applicant hereby consents to the review being conducted by Swissmedic exclusively on the basis of the electronic documents.  yes  n/a |

## Confirmation of identity for the bioavailability study

|  |
| --- |
| The applicant confirms that the test medicinal product used in the bioavailability study is identical to the medicinal product notified to Swissmedic.  yes*(no additional documents need to be submitted)*  no, a description and evaluation of the differences between the test medicinal product and the notified veterinary medicinal product is provided in the documentation (part, section):  n/a |

## Packaging material / laser colour prints

|  |
| --- |
| The applicant confirms that the enclosed laser colour prints for the above-mentioned product are completely identical to the original print of the packaging materials in terms of both text and graphic design.  yes  n/a |

## Sharing information with partner authorities

|  |
| --- |
| The applicant permits Swissmedic to share the assessment reports that it draws up on this medicinal product within the framework of the collaboration with partner authorities (Ireland: HPRA / Health Products Regulatory Authority; Canada: Health Canada; Austria: AGES / Agency for Health and Food Safety; Germany: BVL / Bundesamt für Verbraucherschutz und Lebensmittelsicherheit/Federal Office of Consumer Protection and Food Safety; Netherlands: CBG/MEB / College ter Beordeling van Geneesmiddelen/Medicines evaluation board; United Kingdom: VMD / Veterinary Medicines Directorate) based on [existing agreements](https://www.swissmedic.ch/swissmedic/en/home/about-us/collaboration/international-collaboration/bilateral-collaboration-with-partner-authorities/agreements-on-information-exchange.html) for the purpose of sharing information and as support for forming opinions. Swissmedic is thus authorised to provide its assessment reports to partner authorities on request1. The decision regarding an authorisation is made independently of any information sharing with Swissmedic. Swissmedic informs the applicant in writing if assessment reports are shared.  1 These assessment reports may contain confidential data, such as personal data, business secrets and both positive and negative evaluations with regard to the assessment of an authorisation.  yes  no |

## 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 TPO, a new application for authorisation of a medicinal product whose development is based on the utilisation 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 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. | | | |
| Is the new application for authorisation subject to the obligation to notify pursuant to Art. 4, 5 or 8 of the NagO? | yes | no | n/a |
| If yes, the registration number issued by the FOEN as evidence that the obligation to notify has been met is as follows: | …… | | |

## Dispatch of Assessment Report for Applicants

|  |  |  |
| --- | --- | --- |
| Will a request to view the Assessment Report for Applicants when the decision is opened be submitted simultaneously with this application? No Assessment Reports for Applicants are issued for medicinal products authorised in the notification procedure. | yes | no |

## Letter elements / texts in English

|  |  |  |
| --- | --- | --- |
| The applicant agrees that some parts of Swissmedic’s correspondence (e.g. in the List of Questions) may be written in English. If the response is “no”, all texts will be sent in the correspondence language. | yes | no |

# 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** |
| --- | --- | --- |
| 3.1 | New layout, no content adjustments to the previous version. | dei |
| 3.0 | New section 6.4 “Real world evidence”: Details on RWE must now be entered in application submissions | dts |
| 2.1 | Update due to the possibility of adding a QR code to the medicinal product information and/or packaging in section 5, addition of the VMD in section 7.5; previous term “evaluation report” replaced with “assessment report”. | ski, lac |
| 2.0 | Updates related to taking over immunologics; extended DP for a new indication added to section 6.3; section 7.4 added; section 7.5 updated. Minor formal and linguistic updates. | stb, ps, lac, fg |
| 1.7 | Section 4: Clarification of the text in the application for use of the procedure according to Art. 14 para. 1 abis TPA  New section 7.7: Declaration of consent that parts of the correspondence may be in English. | lac |
| 1.6 | Correction in wording from old: “public ER” to new: “Evaluation Report for Applicants” in chapter 7.6 | stb |
| 1.5 | Section 6.3: Addition regarding document protection | ze |
| 1.4 | Section „Application type“: Supplement new combination according to Art. 6 TPLRO | lac |
| 1.3 | Explanation regarding the Medical application. | fg, lac |
| 1.2 | Chapter 4: Explanation regarding the list of forms to be submitted in addition. | ze |
| 1.1 | Addition of medicinal product categories in the drop-down menu. | dts |
| 1.0 | Implementation of TPO4 | lac |