|  |  |  |
| --- | --- | --- |
| **Form** | | |
| **No marketing / interruption of distribution** | | |
| **Identification number:** | ZL203\_00\_002 |
| **Version:** | 1.5 |
| **Valid from:** | 28.06.2023 |

# Basic information

|  |
| --- |
| **External reference (Company Reference):** **……** |
| **Authorisation no.: ……** |
| **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) | |

# Further information

|  |  |
| --- | --- |
| **Type of submission: No marketing / interruption of distribution** | |
|  | No marketing >1 year after first authorisation (Notification in accordance with Art. 11 para. 1 TPO): |
|  | Date of first authorisation: …… |
|  | Scheduled market launch: …… |
|  | Confirmation that the following condition for authorisation will continue to be met:  For KAS preparations whose product information is identical to that for the reference product (according to the criteria of the Guidance document *Authorisation of human medicinal product with known active pharmaceutical substance HMV4*) and for co-marketing medicinal products: Changes to the reference product/basic product will continue to be implemented. |
|  | |
|  | Marketing interruption >1 year (notification in accordance with Art. 11 para. 1 TPO): |
|  | Date of last delivery to wholesaler: …… |
|  | Resumption of distribution scheduled for: …… |
|  | Confirmation that the following condition for authorisation will continue to be met:  For KAS preparations whose product information is identical to that for the reference product (according to the criteria of the Guidance document *Authorisation of human medicinal product with known active pharmaceutical substance HMV4*) and for co-marketing medicinal products: Changes to the reference product/basic product will continue to be implemented. |
|  | |
| Swissmedic publishes the medicinal product in the list [Meldung Nicht-Inverkehrbringen/Vertriebsunterbruch](https://www.swissmedic.ch/dam/swissmedic/de/dokumente/listen/liste_der_meldungennicht-inverkehrbringenvertriebsunterbruch.xlsx.download.xlsx/liste_der_meldungennicht-inverkehrbringenvertriebsunterbruch.xlsx) or [Meldungen Nicht-Inverkehrbringen/Vertriebsunterbruch für Zulassungen im Meldeverfahren nach Art. 5, 17 und 19 ff der KPAV und Meldeverfahren HOMANT nach Artikel 5, 17, 19, 20ff der KPAV](https://www.swissmedic.ch/dam/swissmedic/de/dokumente/listen/liste_der_meldungennicht-inverkehrbringenvertriebsunterbruchfuerhomant.xlsx.download.xlsx/liste_der_meldungennicht-inverkehrbringenvertriebsunterbruchfuer.xlsx)*.* | |
| Veterinary medicines that are not available on the market will additionally be marked as „derzeit nicht erhältlich (Ausverkauft / Nicht lieferbar)!“ or « n'est pas disponible actuellement (en rupture de stock / n’est pas livrable) ! » in the electronic [Compendium of veterinary medicines](http://www.tierarzneimittel.ch). To this end, the authorisation holder must forward the notification to the editors of the electronic Compendium of veterinary medicines. | |

|  |  |
| --- | --- |
| **Commencement of distribution (marketing) or resumption of marketing (after interruption of distribution)** | |
|  | Marketing after first authorisation (Notification in accordance with Art. 11 para. 4 TPO): |
|  | Date of first authorisation: …… |
|  | Date of notification of no marketing for > 1 year after first authorisation: …… |
|  | Date of commencement of distribution (first delivery to wholesaler): …… |
|  | |
|  | Resumption of marketing after interruption of distribution (Notification in accordance with Art. 11 para. 4 TPO): |
|  | Date of last delivery to wholesaler: …… |
|  | Date of notification of interruption of distribution for > 1 year: …… |
|  | Date of resumption of distribution (first delivery to wholesaler): …… |
|  | |
| Swissmedic deletes the medicinal product from the list [Meldung Nicht-Inverkehrbringen/Vertriebsunterbruch](https://www.swissmedic.ch/dam/swissmedic/de/dokumente/listen/liste_der_meldungennicht-inverkehrbringenvertriebsunterbruch.xlsx.download.xlsx/liste_der_meldungennicht-inverkehrbringenvertriebsunterbruch.xlsx) or [Meldungen Nicht-Inverkehrbringen/Vertriebsunterbruch für Zulassungen im Meldeverfahren nach Art. 5, 17 und 19 ff der KPAV und Meldeverfahren HOMANT nach Artikel 5, 17, 19, 20ff der KPAV](https://www.swissmedic.ch/dam/swissmedic/de/dokumente/listen/liste_der_meldungennicht-inverkehrbringenvertriebsunterbruchfuerhomant.xlsx.download.xlsx/liste_der_meldungennicht-inverkehrbringenvertriebsunterbruchfuer.xlsx)*.* | |
| Regarding veterinary medicines, the indication „derzeit nicht erhältlich (Ausverkauft / Nicht lieferbar)!“ or « n'est pas disponible actuellement (en rupture de stock / n’est pas livrable) ! » must be deleted from the electronic [Compendium of veterinary medicines](http://www.tierarzneimittel.ch). To this end, the authorisation holder must forward the notification to the editors of the electronic Compendium of veterinary medicines. | |

# 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** |
| --- | --- | --- |
| 1.5 | New layout, no content adjustments to the previous version. | dei |
| 1.4 | Formal adjustments to the header and footer  No content adjustments to the previous version. | dei |
| 1.3 | 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 |
| 1.2 | Basic information: Deletion of the eCTD sequence no. | dts |
| 1.1 | Chapter 3 “Further information”. *To this end, the authorisation holder must forward the notification to the editors of the electronic Compendium of veterinary medicines.* | ze |
| 1.0 | Implementation of TPO4 | dts |
| XX | Text in case of change |  |