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| --- | --- | --- |
| **Form** | | |
| **New authorisation variation antivenin** | | |
| **Identification number:** | ZL000\_00\_033 |
| **Version:** | 1.4 |
| **Valid from:** | 11.07.2023 |

# Basic information

|  |  |  |  |
| --- | --- | --- | --- |
| No. of venomous animal bites in Switzerland\* | …… Year …… | | |
| Name of medicinal product in Switzerland | …… | | |
| Name of medicinal product in country of origin | …… | | |
| Manufacturer\*  Address\*  Country\* | ……  ……  …… | | |
| Immunised species\* | …… | | |
| Antivenom type\* | Immunoglobulin  Monovalent  Polyvalent  Fab  F(ab)2 | | |
| Antivenom against\* | Snake  Spider  Scorpion  Other animal *(specify)* ……  Other venom *(specify)* …… | | |
| Venomous species used for manufacture\*  *(family, genus, species: Latin name)* | …… | | |
| Protected species\* | …… | | |
| Pharmaceutical form\* | Solution for injection *(ready to use)* | Lyophilisate | Other |
| Dosage strength | …… | | |
| Packaging / Volumes\* | …… | | |
| Shelf life\* | …… | | |
| Storage at oC\* | …… | | |
| Conditions for administration in short\*  *(dosage, pharmaceutical form, etc.; see packaging texts)* | …… | | |

\* These entries are compulsory

# 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

|  |  |  |
| --- | --- | --- |
| **Application type** | | **Code**  *(SMC internal)* |
|  | New authorisation of antivenom |  |
|  | Variation of antivenom (Type IB variation; A.108 according to guidance document *Variations and extensions HMV4*) |  |

# Additional documents 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 HMV4" form should be submitted for each proposed foreign manufacturer* 🡪 Guidance document *GMP compliance by foreign manufacturers HMV4* **Exception:** A *Manufacturer information TPO* form is not needed for teas in the notification procedure (Art. 12 KPTPO) or for cough and throat sweets and pastilles in the notification procedure (Art. 13 KPTPO). |

|  |  |
| --- | --- |
|  | Complete composition (form *Full declaration HMV4*)\* |
|  | Manufacturer's certificate(s) of analysis\* |
|  | Copy of foreign product information\* |
|  | Copy of foreign packaging texts\* |
|  | Additional label |
|  | Additional label including indication and dose |
|  | Other quality-related documents *(specify)*: …… |
|  | Preclinical / clinical documents *(specify)*: …… |
|  | Form *Manufacturer information HMV4* |
|  | Form *Status of authorisation applications abroad HMV4* |
|  | Basic company dossier on antivenoms\*  enclosed  the basic company dossier on antivenoms dated …… is valid |

\* These enclosures must be submitted

# 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 Berne | | Telephone +41 58 462 02 11  Fax +41 58 462 02 12  E-mail Anfragen@swissmedic.ch | |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 1.4 | New layout, no content adjustments to the previous version. | dei |
| 1.3 | Formal adjustments to the header and footer  No content adjustments to the previous version. | dei |
| 1.2 | Autor im System mit Autor in der Änderungshistorie synchronisiert. Freigabe durch Person im VM Team, da Dokument nicht in der VMS Suche angezeigt wird. | tsj |
| 1.1 | Chapter 4: Explanation regarding the list of forms to be submitted in addition. | ze |
| 1.0 | Implementation of TPO4 | dts |