|  |  |  |
| --- | --- | --- |
| **Form** | | |
| **Mobile technologies** | | |
| **Identification number:** | ZL000\_00\_040 |
| **Version:** | 1.1 |
| **Valid from:** | 01.10.2023 |

# Application type:

## Addition of a QR code as part of a new authorisation procedure

## Addition of a QR code after a new authorisation procedure

## Modification of additional information accessible via a QR code

## Removal of a QR code

# Basic information

|  |
| --- |
| **External (company) reference:** …… |
| **Name of medicinal product:** …… |
| **Active substance(s):** …… |
| **Pharmaceutical form:** …… |

# Addresses

## Marketing Authorisation Holder

|  |  |
| --- | --- |
| Company name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| Postcode, town / city: | …… |
| Canton: | …… |
| Tel.: | …… |
| E-mail: | …… |

## Address for correspondence (if not the same as 3.1)

|  |  |
| --- | --- |
| Company name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| P.O. Box: | …… |
| Postcode, town / city: | …… |
| Tel.: | …… |
| E-mail: | …… |

## Legal representative (if not the same as 3.1)

|  |  |
| --- | --- |
| Name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| P.O. Box: | …… |
| Postcode, town / city: | …… |
| Tel.: | …… |
| **Swissmedic has received power of attorney**   Yes  No\*  *\*If no: Power of attorney is enclosed with this application (incl. original signature)* | |

# Details of the platform hosting the information

|  |  |
| --- | --- |
| Where will the information be hosted? | |
| Website Web page  Other, please describe: …… | |
| Direct URL on hosting platform: ……  Short URL (if applicable): …… | |
| The applicant is aware of the current data protection provisions and information safety requirements applicable to the use of mobile technologies. | ☐ Yes |
| The applicant confirms the guaranteed accessibility and integrity of the information provided via mobile technologies and that the information can be viewed on all browsers widely used in Switzerland. | ☐ Yes |
| The applicant confirms the guaranteed availability of the data accessible via mobile technologies throughout the authorisation period. | ☐ Yes |

# Information linked by QR code

## Information required by therapeutic products legislation:

|  |  |  |
| --- | --- | --- |
| Information required by therapeutic products legislation:  Yes  No  If you answered yes, what information will be displayed? | | |
| Information for healthcare professionals  Patient information or package leaflet (veterinary medicinal product)  Packaging  Training material according to RMP | | |
| The applicant confirms that the electronic version is consistent with the most recently approved texts (Information for healthcare professionals/Patient information, package leaflet/packaging or training material according to RMP). | Yes |
| The applicant confirms that the information does not violate legal provisions governing therapeutic products advertising. | Yes |
| The applicant confirms that the mobile technologies will permit unimpeded access to the information in the languages required by therapeutic products legislation. | Yes |

## Additional information:

|  |  |  |
| --- | --- | --- |
| Additional information:  Yes  No  If you answered yes, please describe the information: ……  Material that should be linked is attached.  *(E.g. video/script of an instructional video on using the medicinal product).* | | |
| What efficacy and safety benefits do users obtain from this additional information?  …… | | |
| Demonstrate the connection between the intended additional information and medicinal product information requirements (Information for healthcare professionals, if available):   |  |  | | --- | --- | | **Intended use of additional information** | **Compliance with medicinal product information (Information for healthcare professionals, if available)** [*Indicate relevant sections*] | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | | | |
| The applicant confirms that the information on handling the medicinal product (e.g. videos) is based on the most recently approved texts (Information for healthcare professionals/Patient information or package leaflet/packaging/risk management plan). | ☐ Yes |
| The applicant confirms that this additional information does not violate legal provisions governing therapeutic products advertising. | ☐ Yes |
| The applicant confirms that the mobile technologies will permit easy access to the information in the languages required by therapeutic products legislation. | ☐ Yes |

# Location of QR code and URL

## QR code with URL

|  |  |
| --- | --- |
| The QR code with URL will be printed on the following medicinal product information and/or packaging:  On Patient information or package leaflet for veterinary medicinal products – manuscript attached.  On Information for healthcare professionals – manuscript attached.  On packaging – mock-ups attached. | |
| The applicant confirms that the QR code is legible. | ☐ Yes |

# Signature

**Signature of applicant**

|  |  |  |  |
| --- | --- | --- | --- |
| **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: | …… |

|  |  |
| --- | --- |
| **The application must be sent to** | **For enquiries contact** |
| Swissmedic  Swiss Agency for Therapeutic Products  Operational Support Services  Hallerstrasse 7  CH-3012 Bern | Telephone +41 58 462 02 11  E-mail anfragen@swissmedic.ch |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 1.1 | Section 5.1.: New: Training material according to RMP is information required by therapeutic products legislation. | ski, sab, lac, iom, jua, zsa, ber, er |
| 1.0 | New form | ski, sab, lac, iom, jua, zsa, ber, er |