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| **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 [ ]  NoIf 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 [ ]  NoIf 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*] |
|  |  |
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| 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** |
| SwissmedicSwiss Agency for Therapeutic ProductsOperational Support ServicesHallerstrasse 7CH-3012 Bern | Telephone +41 58 462 02 11E-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 |