# Addresses

## Marketing authorisation holder

|  |  |
| --- | --- |
| Company name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| Postcode, town/city: | …… |
|  | |

# Basic information

*All specifications apply equally to PSUR and to PBRER.*

|  |  |
| --- | --- |
| **Name of medicinal product:** | …… |
| **Authorisation no.:** | …… |

|  |
| --- |
| **Reasons for submitting this PSUR** |
| …… |

|  |  |  |
| --- | --- | --- |
| **Supplementary documents submitted** | | |
|  | ICH E2E / RMP Update | |
|  | Previous version of ICH E2E / RMP approved by Swissmedic: …. | |
|  | * Application ID: …. | |
|  | * eCTD sequence (if applicable): …. | |
| **List relevant changes compared to previous version, i.e. the chapters or points where the changes are to be found:** | | |
| …… | | …… |
| …… | | …… |

|  |  |  |
| --- | --- | --- |
| Has this resulted in changes in the RMP Summary?  *If yes, please submit the current version of the RMP summary.* | yes | no |
| The submitted RMP update is the EU-RMP  *If no, please specify*  …… | yes | no |
| Comments: …… | | |

|  |  |
| --- | --- |
| **Dates of PSUR / PBRER** | |
| PSUR no. and period covered: | …… |
| International birth date *(dd.mm.yyyy)*: | …… |
| Active substance: | …… |
| ATC-Code: | …… |
| Pharmaceutical form: | …… |
| Dose per unit: | …… |
| First authorisation in Switzerland *(dd.mm.yyyy)*: | …… |

|  |  |
| --- | --- |
| **Exposure during period covered by PSUR** | |
| Switzerland: …… | Worldwide: …… |
| *(State the number of patients, in patient years/months/days or doses; use the same unit for Switzerland and worldwide.)* | |

|  |  |  |
| --- | --- | --- |
| **Safety-related changes, e.g. to the information for medical professionals** | | |
| Safety relevant variations submitted since last PSUR submission date: | yes  Please indicate the application ID: | no |
| Has an application for variation in the indication, recommended dosage or similar been submitted? | yes *(dd.mm.yyyy)* DATUM?  Please indicate the application ID: | no |
| During the period covered by the PSUR, were safety-related variations approved outside Switzerland (EU SPC, SPC of an EU Member State, US PI), or are any safety-related variations currently being reviewed? | yes (*please explain)* | no |
| Is there need for action in Switzerland based on the data contained in the PSUR? | yes (*please explain)* | no |
| Comments: …… | | |

# Signature

|  |
| --- |
| **All the entries made in this form are certified to be complete and accurate:** |

*Authorised signatory*

|  |  |
| --- | --- |
| Place, date / Signature: | …… |
| Last name / First name: | …… |
| Telephone: | …… |
| E-mail: | …… |

|  |  |
| --- | --- |
| **The PSUR / PBRER must be sent to** | **For enquiries contact** |
| Swissmedic  Swiss Agency for Therapeutic Products  Operational Support Services  Hallerstrasse 7  3012 Bern | Telephone +41 58 462 03 52  E-mail [Riskmanagement@swissmedic.ch](mailto:Riskmanagement@swissmedic.ch) |

**Mandatory elements of a Periodic Report IN accordance with the TPO**

* Format in line with the ICH Guideline E2C (R2) “ICH guideline E2C (R2) on periodic benefit-risk evaluation report (PBRER)“, January 2013 or ICH Guideline E2C “Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs“.
* PSUR and all documentation included must be submitted in an official language of Switzerland or in English.
* EU Summary of Product Characteristics (SPC), currently approved version with date *(if only national authorisations are available in the EU, include the SPC from the UK, France or Germany).*
* A **comparison must be made between the currently approved version of the Swiss information for healthcare professionals and the EU SPC** up to section 4.9. Key aspects are contraindications, warnings and precautions, adverse reactions. *(The comparison between the Swiss information for healthcare professionals and the EU SPC should be submitted in tabular form. The currently approved version of both documents should be used. Statements regarding safety for which the Swiss information for healthcare professionals has less or different information compared to the EU SPC should be clearly indicated. If such a comparison is not provided, a justification must be provided; e.g. the product is not authorised in any EU Member State).*

**Formal requirements**

The requirements can be found on Swissmedic’s website [www.swissmedic.ch](http://www.swissmedic.ch)

Change history

| Version | Valid and binding as of: | Description, comments (by author) | Author’s initials |
| --- | --- | --- | --- |
| **2.0** | **30.04.2020** | **Supplementary information requested in regard to previous submitted E2E / RMP and safety related information** | **dst** |
| **1.0** | **01.01.2019** | **Implementation of TPO4** | **dst** |