**Signal Notification / Follow up (FU) information on signals**

**Date of notification:** DATE

**Initial notification** [ ]

**Follow-Up notification** [ ]

**If Follow-Up notification, Notification date of previous information on the current signal:** DATE

**FU number :** ……

*Active substance \_ brand name (therapeutic class) \_ adverse reaction (MedDRA term)*

*[*……*] \_ [*……*] \_ [*……*]*

**General guidance**

*This form should be used to* ***notify signals and FU information on signals*** *according to* [*MU101\_20\_001e\_WL Drug\_Safety\_Signals HMP*](https://www.swissmedic.ch/dam/swissmedic/en/dokumente/marktueberwachung/mu/MU_HMV4/mu101_20_001d_wlarzneimittelsignalehmv4.pdf.download.pdf/MU101_20_001e_WL_Guidance_document_Drug_Safty_Signals_HMV4.pdf)*.*

*Please consider that the form is not applicable for submission of any documentation related to signals with already assigned Swissmedic signal ID.*

*Once completed please address the form to the Swissmedic, Risk Management Unit and send it by post (CD) or via the Swissmedic Portal. A cover letter is not needed.*

*All applicable sections should be completed with the information requested or a justification should be provided. Sections should not be left blank.*

# Address

## Marketing authorisation holder

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

# Basic information

|  |
| --- |
| **Trade name(s) of concerned products***(incl. ZL Nr.)* |
| **Trade name(s)** | **ZL Nr.** |
| …… | …… |
| …… | …… |
| …… | …… |
| …… | …… |

|  |
| --- |
| **Active Substance(s)** |
| …… | …… |
| …… | …… |
| …… | …… |

|  |
| --- |
| **ATC Code(s)** |
| …… | …… |
| …… | …… |

# Signal Description

|  |
| --- |
| **Please indicate the “Day 0”:** DATE*Definition of day 0:**Signals/procedures of foreign authorities (EMA, FDA, MHRA):**Day 0 = MAH informed of the procedure status of the foreign authority's signal evaluation/referral procedure (information provided by the evaluating authority to the MAH or, if this does not apply, publication of the information by the respective authority)**Risk minimisation measures ordered by foreign authorities in connection with PSUR/PBRER/PSUSA procedures:* *Day 0 = day on which the MAH was informed about the necessary measures by the evaluating authority.* |

|  |
| --- |
| **Safety issue (Meddra term)** |
| …… |

|  |  |
| --- | --- |
| **Emerging safety issue** | [ ]  Yes [ ]  No |

|  |  |
| --- | --- |
| **Signal or referral procedure of foreign authority***(If Yes, please specify the authority)* | [ ]  Yes [ ]  No |
| …… |

|  |  |
| --- | --- |
| **Risk minimisation measures imposed by foreign authorities following PSUR / PRBER evaluation (incl. PSUSA procedures)***(If Yes, please specify the authority)* | [ ]  Yes [ ]  No |
| …… |

|  |
| --- |
| **Short description of the signal***(Concise summary of available evidence and information on the signal)* |
| …… |

|  |
| --- |
| **Planned risk minimisation measures by evaluating authority***(incl. timetable)* |
|   |
| **If the evaluation is ongoing, please indicate the anticipated timetable for the next FU information submission to Swissmedic:** DATE |

 ……

|  |
| --- |
| **Planned risk minimisation measures for Switzerland incl. timetable** |
| …… |

|  |  |  |
| --- | --- | --- |
|

|  |
| --- |
| **If applicable:****Wording of the variation** *(Please provide the text proposal in German or French language)*  |
| **……** |

**Rationale***(if discrepancies between planned risk minimisation measures in other countries and Switzerland)* |
| …… |

|  |
| --- |
| **Annexes***(e.g. assessment reports, study reports, list of literature references )* |
| …… | …… |
| …… | …… |
| …… | …… |
| …… | …… |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Signature

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

*Authorised signatory*

|  |  |
| --- | --- |
| Place, date / Signature: | …… |
| Last name / First name: | …… |
| Position: | …… |
| Telephone (contact person): | …… |
| E-mail (contact person): | …… |

|  |  |
| --- | --- |
| **The signal notification form must be sent** | **For enquiries contact** |
| via Swissmedic Portalor by post (CD) toSwissmedicSwiss Agency for Therapeutic ProductsOperational Support ServicesHallerstrasse 73012 Bern | E-mail Riskmanagement@swissmedic.ch |

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**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 |
| --- | --- | --- | --- |
| 2.1 | 03.04.2023 | Revidiert im Jahr 2023. Keine Anpassungen. | dts |
| 2.0 | 20.03.2021 | Neues Feld eingefügt “Wording of the variation”Redaktionelle Ergänzungen | dst |
| 1.0 | 15.11.2019 | Erstversion erstellt | dst |