|  |
| --- |
| **Form** |
| **Signal Notification Form VMP** |
| **Identification number:** | ZL404\_00\_002 |
| **Version:** | 1.1 |
| **Valid from:** | 20.09.2023 |

**Signal Notification Form VMP / 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 (VEDDRA term)*

*[*……*] \_ [*……*] \_ [*……*]*

**General guidance**

*This form should be used to* ***notify signals and FU information on signals*** *according to* [*ZL404\_00\_004d \_WL Arzneimittelsignale*](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)*\_TAM. This template should be used by marketing authorisation holders to notify signals detected in a database (incl. MAH database) or any other source, for which they conclude that further regulatory actions are needed.*

*It can also be used for signals for which a thorough assessment has been performed and the conclusion is to refute the signal or to propose close monitoring.*

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

*Once completed please send the form to Swissmedic, Abteilung Tierarzneimittel by post 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. MA Nr.)* |
| **Trade name(s)** | **MA Nr.** |
| …… | …… |
| …… | …… |
| …… | …… |
| …… | …… |

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

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

# Signal Description

## Administrative information, summary

|  |
| --- |
|  |

|  |
| --- |
| **Safety issue (VEDDRA 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 or equivalent evaluation** *(If Yes, please specify the authority)* | [ ]  Yes [ ]  No |
| …… |

 |
| **Clinical relevance of the signal** |
| …… |
| **Relevant statistical measures** |
| …… |

|  |
| --- |
| **Incidence:** …… |

|  |
| --- |
| **Previous awareness** |
| …… |

Additional sources used:

[ ]  Literature [ ]  EudraVigilance Veterinary (EVvet)

[ ]  Clinical or post-marketing studies [ ]  Other: ……

## Background

……

## Signal assessment

### Evidence from database query

Database[[1]](#footnote-1): ……

Date of query: ……

Description of evidence: ……

### Evidence from other sources[[2]](#footnote-2)

……

# Conclusion and proposal for action

……

|  |
| --- |
| **Risk minimisation measures planned by evaluating foreign 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)*  |
| **……** |

 |
|  |

|  |
| --- |
| **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 toSwissmedicSwiss Agency for Therapeutic ProductsOperational Support ServicesHallerstrasse 73012 Bern | E-mail vetvigilance@swissmedic.ch |

 |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 1.1 | New layout, no content adjustments to the previous version. | hem |
| 1.0 | Initial version | muc/zai |

1. zB. EVvet, company database, other database (please define), etc. [↑](#footnote-ref-1)
2. zB. Publications, communications (please define), expert reports, etc. [↑](#footnote-ref-2)