**Form to be submitted with every individual case safety report**

**Sender: send to:**

°°°°° Swissmedic

°°°°° Division Safety of Medicines

°°°°° Section Pharmavigilance

°°°°° Hallerstrasse 7

°°°°° PO Box

°°°°° 3012 Berne

|  |  |  |  |
| --- | --- | --- | --- |
| **Date sent:** | | °°°°° | |
| **Responsible Person / contact / e-Mail:** | | °°°°° | |
| **Drug / Trade name:** | | °°°°° | |
| **Substance(s):** | | °°°°° | |
| **Type of Report** (in case of a notified clinical trial[[1]](#footnote-1)) | | Spontaneous  Literature[[2]](#footnote-2)  other | |
| **Sender’s Reference-ADR-number:** | | °°°°° | |
| **If not a domestic report** | | Reason for submission: °°°°° | |
| **This is a:** | | Initial report  Follow-up Nr ……….  Swissmedic Number of the corresponding  initial report: ………. | |
| **Relevant additional information expected within 15 days** | | yes  no | |
| **Seriousness**  **(If not indicated specifically in sections 8-12 of CIOMS form)** | | serious  non-serious | |
| **Drug Exposure During Pregnancy** | | yes | |
| **Adverse Event Following Immunization** | | yes | |
| **ADR Terms** | | | Labelled in CH PI\* |
| \* yes / no |
| 1 | °°°°° | | °°°°° |
| 2 | °°°°° | | °°°°° |
| 3 | °°°°° | | °°°°° |
| 4 | °°°°° | | °°°°° |
| 5 | °°°°° | | °°°°° |
| 6 | °°°°° | | °°°°° |

|  |  |
| --- | --- |
| **Short extract from the current Swiss Product Information for all ADR terms is not literally mentioned there. If no similar ADR(s) are mentioned, please quote text(s) for respective system organ class.** | |
| °°°°° | |
| **Risk minimizing measures taken:** | yes |
| Comment:  °°°°° | |
| **Further comments to report:** If not mentioned in CIOMS form, such as discussion of the case, relevant information available to the company on the topic, comment on labeling etc. | |
| °°°°° | |

\* PI: Product information (local labeling), last text approved by Swissmedic

Change history

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Valid and binding as of: | Description, comments (by author) | Author’s initials |
|  | 19.09.2014 | Telephone and fax number in the footer, new change history inserted in the document, document name modified in the header | sel |

1. SUSARs from Clinical Trials notified by Swissmedic are to be reported solely to the Clinical Trials division (susar@swissmedic.ch) [↑](#footnote-ref-1)
2. Original article attached with highlighted reference [↑](#footnote-ref-2)