|  |  |  |
| --- | --- | --- |
| **Form** | | |
| **Adverse Reaction Report CT ATMP** | | |
| **Identification number:** | BW315\_00\_960 |
| **Version:** | 8.0 |
| **Valid from:** | 15.02.2024 |
| *Form for reporting the following adverse reactions during a clinical trial with ATMPs and other products (bacteriophages, etc.) and procedures:*   * *SUSAR (Suspected Unexpected Serious Adverse Reaction), SADR (Serious Adverse Drug Reaction), cases of death* * *Quality defects* * *Exceptional Release of an OOS (Out of Specification) batch* * *Release into the environment, transmission to other persons or animals of a medicinal product consisting of genetically modified organisms (GMO) or contain GMO.* | |

# Sender

|  |  |
| --- | --- |
| **Sponsor name / Swiss Representative, Sponsor located in Switzerland / CRO:** | …… |
| **Street / no:** | …… |
| **Postcode, town/city:** | …… |
| **Person responsible / contact / e-mail:** | …… |
| **All the entries made in this form are certified to be complete and accurate (based on information currently available):** |  |

# Basic information

*(Date format: dd.mm.yyyy)*

|  |  |  |
| --- | --- | --- |
| **Date when report submitted:** | …… | |
| **Date of receipt of the notification by reporting person:** | …… | |
| **Study Code:** | …… | |
| **Study Title:** | …… | |
| **Swissmedic Case-ID:** | …… | |
| **Name of the ATMP (IMP):** | …… | |
| **Product category:** | Somatic cell therapy | |
|  | Tissue Engineering | |
|  | Ex vivo Gene therapy | |
|  | In vivo Gene therapy | |
|  | Medicinal product consiting of GMO or containing GMO | |
|  | Other therapies: …… | |
| **Country (where event occured):** | …… | |
| **Patient no. / centre no.** | …… / …… | |
| **Intitial report:** |  |
| **Follow-up:** | No.: ……, linked tot he initial report from: …… |
| **Relevant additional information expected within the next 14 days** | Yes  No |

# SUSAR, SADR, cases of death

|  |  |  |
| --- | --- | --- |
| **SUSAR** |  | |
| **SADR** |  | |
| **Criteria:** | Fatal case | |
| Life-thratening | |
| Hospital stay / extended hospital stay | |
| Permanent or serious disability or incapacity | |
| Congenital anomaly | |
| **Use of ATMP during pregnancy:** | Yes  No |
| **Harvesting/donor problem:** |  |
| **Problem with application:** |  |
| **Suspected viral, bacterial or other contamination from the ATMP:** |  |

|  |  |  |
| --- | --- | --- |
| **ADR Terms** (Adverse Drug Reaction Term) *(coded according to* ***MedDRA / CTCAE)*** | | **Labelled in the IB / IP CH \*** |
| 1 | …… | Yes  No |
| 2 | …… | Yes  No |
| 3 | …… | Yes  No |
| 4 | …… | Yes  No |
| 5 | …… | Yes  No |
| 6 | …… | Yes  No |

\* *Investigator’s Brochure / Information for porfessionals, last text approved by Swissmedic*

|  |  |
| --- | --- |
| **Short text extract of related adverse reactions from the product information\*, if the currently reported reactions are not listed yet:** | …… |
| Q**uote what is already documented in the corresponding organ class in the IB\* and comment on the "relatedness" between the medication and the reaction:** | …… |
| **Have risk mitigation measures been implemented:** | Yes  No  Comment: …… |
| **Additional comments regarding the submitted case:** | *(Case discussion – what does the Sponsor know about the problem – missing data – stance on labelling.)*  …… |

**If you are not submitting an accompanying CIOMS form, please complete the following patient details:**

|  |  |  |
| --- | --- | --- |
| **Patient data** | | |
| **Age of patient:** | …… | |
| **Sex:** | Female  Male  …… | |
| **Relevante Krankengeschichte:** | …… |
| **Co-medication incl. start/end dates:** | …… | |
| **Start date of the event:** | …… | |
| **Description of event incl. medical history:** | …… | |
| **Presumed link with the following product/s:** | …… | |
| **Dosage:** | …… | |
| **Administration route:** | …… | |
| **Start / End of treatment:** | …… / …… |
| **Date of the last administration of the ATMP bevor the event:** | …… |
| **Improvement after discontinuation of the product?** | Yes  No  Not applicable | |
| **Worsening after discontinuation of the product?** | Yes  No  Not applicable | |
| **Recovered?** | Yes  No | |
| **In case of death: date** | …… | |

# Quality defect

|  |  |
| --- | --- |
| **Description of the quality defect/problem (e.g. manufacture, transport, storage)** | …… |
| **Name and address of manufacturer (end product)** | …… |
| **Affected batches/patient(s) (batch numbers / date of manufacture / strength / expiry date / batch size / type of packaging / number of packs)** | *If necessary please attach separate list.*  …… |
| **Auslieferung der betroffenen Chargen (Länder, Ärzte [Chargennummer / Anzahl Packungen / Auslieferungsdatum])** | *If necessary please attach separate list.*  …… |
| **Is the defect connected with an SUSAR/SADR?** | Yes  No  *If so, please describe:*  …… |
| **Is there any evidence or suspicion of a risk to public health (adverse reaction or lack of efficacy)?** | Yes  No |
| **Classification of defect (I, II oder III)\***  *\*Swissmedic Journal 3/2006 and Dokumente PI 010-2 "Procedure for handling rapid alerts and recalls arising from quality defects" des Pharmaceutical Inspection Co-operation Scheme (PIC/S) bzw. Annex 4 to SOP/EMEA/008 "Classification of Batch Recalls for Quality Defects" der European Medicines Agency (EMEA)* | I  II  III  Rationale: …… |
| **Names and addresses of authorities already informed:** | …… |
| **Measures taken to date:** | …… |
| **Is a batch recall or withdrawal of the product planned?** | Yes  No  *If so, please attach draft information letters to the participating trial centres.* |
| **What happens to the packs affected by the withdrawal?** | …… |
| **Further planned or proposed measures:** | …… |
| **Other relevant information:** | …… |
| **List of attached documents:** | …… |

# Exceptional Release of an OOS batch\*

*\* Guideline on Good Manufacturing Practice for Advanced Therapy Medicinal Products as a new Part IV of EudraLex Volume 4*

|  |  |
| --- | --- |
| **Affected batch / patient (batch number / patient number / indication) / date of manufacture / expiry date / clinic / hospital / trial centre / treating doctor** | …… |
| **Description of the OOS result:** | …… |
| **Cause of the OOS result evaluated?** | Yes  No  Description: …… |
| **Has the RP decided on the OOS and the trial centre / treating doctor been informed?** | Yes  No  …… |
| **Benefit-risk assessment (by Sponsor):** | Yes  No  …… |
| **Administration of the OOS batch (decision of the treating doctor)?** | Yes  No  Rationale: …… |

# Release into the environment/transmission to other persons/animals (GMO)

|  |  |
| --- | --- |
| **Release into the environment:** |  |
| **Transmission to another person:** |  |
| **Transmission to an animal / animal species:** | …… |
| **Description:** | …… |
| **Risk evaluation:** | …… |

# Notification address

|  |  |
| --- | --- |
| **The notification must be sent to:** | Via email using the **Filetransfer Service (FTS)**. To be able to use this service, please contact [biovigilance@swissmedic.ch](mailto:biovigilance@swissmedic.ch) |
| **For further questions:** | [biovigilance@swissmedic.ch](mailto:biovigilance@swissmedic.ch) |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 8.0 | Adjustment of form name, structure, layout, notification address. | pad |
| 7.0 | Transfer ATM processes in the area of authorisations  New ID number assigned  Formal adjustments, new layout | dei |