**Manufacturer Periodic Summary Report (PSR)**

**for Serious Incidents (MDR/IVDR)**

**Reporting Template Version 1.0**

**Medical Devices Vigilance System**

**For initial application all the fields should be completed except 4.3 analysis update.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 1: Administrative information** | | | |
| **1.1** | **Competent authority coordinating this PSR application** | | |
| **a** | Name of competent authority coordinating this PSR application | | |
| **1.2** | **Date and type of Manufacturer PSR** | | |
| **a** | Date of submission  YYYY.MM.DD | | |
| **b** | Type of PSR  Application for PSR  Periodic analysis update  Closure PSR | | |
| **1.3** | **Submitter information** | | |
| **1.3.1** | **Submitter of the report** | | |
| **a** | ManufacturerAuthorised representativeOther, please specify | | |
| **b** | Manufacturer's reference number for this PSR: | | |
| **1.3.2** | **Manufacturer information** | | |
| **a** | Manufacturer organisation name | | |
| **b** | Swiss single registration number (CHRN) | **c** | Single registration number (SRN) |
| **d** | Contact’s first name | **e** | Contact’s last name |
| **f** | Email | **g** | Phone |
| **h** | Country | | |
| **i** | Street | **j** | Street number |
| **k** | Address complement | **l** | PO Box |
| **m** | City name | **n** | Postal code |
| **1.3.3** | **European authorised representative information** | | |
| **a** | Authorised representative Organisation name | | |
| **b** | Swiss single registration number (CHRN) | **c** | Single registration number (SRN) |
| **d** | Contact’s first name | **e** | Contact’s last name |
| **f** | Email | **g** | Phone |
| **h** | Country | | |
| **i** | Street | **j** | Street number |
| **k** | Address complement | **l** | PO Box |
| **m** | City name | **n** | Postal code |
| **1.3.4** | **Swiss authorised representative information** | | |
| **a** | Registered commercial name of company | | |
| **b** | Swiss single registration number (CHRN) | **c** | Single registration number (SRN) |
| **d** | Contact’s first name | **e** | Contact’s last name |
| **f** | Email | **g** | Phone |
| **h** | Country | | |
| **i** | Street | **j** | Street number |
| **k** | Address complement | **l** | PO Box |
| **m** | City name | **n** | Postal code |

|  |  |  |
| --- | --- | --- |
| **Section 2: PSR information, rationale** | | |
| **a** | PSR Type:  Incidents described in a Field Safety Corrective Action (FSCA)  If the incidents are covered under an FSCA, please provide the relevant number(s):   * Swiss FSCA reference number(s): Vk\_ * Manufacturer’s FSCA reference number:   Root cause | Common and Well documented incidents  Root cause |
| **2.1** | **PSR related IMDRF code(s)** | |
| **a** | Please provide the IMDRF code(s) on which this specific PSR is based    If you think the incident is unique and a suitable IMDRF term is missing, briefly explain: | |
| **2.3** | **PSR investigation update report frequency** | |
| **a** | Requested frequency of reporting:  1 month  3 months  6 months  9 months  12 months | |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Section 3: Medical device information** | | | | | | | | | |
| **3.1** | **Unique Device Identification (UDI)** | | | | | | | | |
| **a** | UDI-DI / Eudamed ID | | Issuing entity: | **b** | | UDI-PI | | | |
| **c** | Basic-UDI-DI / Eudamed-DI | | Issuing entity: | **d** | | Unit of use UDI-DI | | | Issuing entity: |
| **3.2** | **Categorisation of device** | | | | | | | | |
| **a** | Medical device terminology  EMDN  GMDN  UMDNS(ECRI)  GIVD/EDMS | | | | | | | | |
| **b** | Medical device nomenclature code | | | | | | | | |
| **3.3** | **Description of device and commercial information (Single device)** | | | | | | | | |
| **a** | Medical device name (brand / trade / proprietary or common name) | | | | | | | | |
| **b** | Nomenclature text **/** Description of the deviceand its/their intended use | | | | | | | | |
| **c** | Model  List all applicable | | | | **d** | Catalogue/reference number  List all applicable | | | |
| **e** | Notified body (NB) ID number(s) (if applicable) | | | | | | | | |
| **f** | Notified body (NB) certificate number(s) of device (if applicable) | | | | | | | | |
| **3.4** | **Risk class of device when placed on market** | | | | | | | | |
|  | This device has been placed on the market before the implementation of the MDD/AIMDD/IVDD | | | | | | | | |
| **a** | **MDD/AIMDD**  active implant  class III  class IIb  class IIa  class I  class Is  class Im  class Ism  custom-made | | | | | | **IVDD**  IVD Annex II List A  IVD Annex II List B  IVD devices for self-testing  IVD general | | |
| **b** | **MDR**  class III  class IIb  class IIa  class I | Type (Multiple choice)  implantable  active device  intended to administer and/or remove a medicinal product  sterile conditions  measuring function  reusable surgical instruments  software  systems  procedure packs  custom-made  non-medical purpose | | | | | **IVDR**  class D  class C  class B  class A | Type (Multiple choice)  self-testing  near-patient testing  professional testing  companion diagnostic  reagent  software  instrument  sterile conditions | |
| **3.5** | **Market distribution of device (region / country)  (according to the best knowledge of the manufacturer)** | | | | | | | | |
| **a** | All EEA, Great Britain, Switzerland, and Turkey  AT  BE  BG  CH  CY  CZ  DE  DK  EE  ES  FI  FR  GB  GR  HR  HU  IE  IS  IT  LI  LT  LU  LV  MT  NL  NO  PL  PT  RO  SE  SI  SK  TR | | | | | | | | |

|  |  |
| --- | --- |
| **Section 4: Manufacturer PSR analysis** | |
| **4.1** | **Problem statement and background** |
| **a** | Preliminary results and conclusions of manufacturer’s investigation |
| **b** | What further investigations do you intend in view of reaching final conclusions? |
| **4.2** | **Initial cause investigation and conclusion /outcome** |
| **a** | Description of the manufacturer’s evaluation concerning possible root causes/causative factors and conclusion/outcome |
| **b** | Is root cause confirmed?  Yes  No |
| **c** | Has the risk assessment been reviewed?  Yes  No If ‘No’, rationale for no review completed:  If the risk assessment has been reviewed, is it still adequate?  Yes  No If 'No', rationale: |
| **4.3** | **Periodic PSR analysis update**  **Only to complete after PSR approval** |
| **a** | Any important change which could affect or modify the manufacturer’s initial risk assessment  Yes If 'Yes', Please provide updated risk analysis  No If 'No', rationale: |
| **b** | Please highlight the changes in the manufacturer analysis since the last PSR e.g. threshold, trends, investigation update, corrective/preventive action (CAPA) |
| **c** | Relevant documentation attached to this PSR-form e.g. FSCA, Risk assessment, HHE, PSUR |
| **4.3.1** | **PSR related incidents** |
| **a** | During the periodic analysis update PSR related incidents should be submitted separately. |

|  |  |
| --- | --- |
| **4.4** | **Similar incidents** |
| **4.4.1** | **Use of IMDRF terms and codes for identifying similar incidents** |
| **a** | Identification of similar incidents using IMDRF Adverse Event Reporting terms and codes  Tick-mark which code or combination of codes were used for identifying similar incidents.   |  |  | | --- | --- | |  | Choice 1 | | IMDRF code relating to most relevant 'Medical device problem' (Annex A) |  | | IMDRF code relating to most relevant'Investigation finding' (Annex C, 'Cause investigation') |  |   Other – enter description of what similar incidents are based on and the rationale why the above IMDRF codes were not used |
| **4.4.2** | **Use of in-house terms/codes for identifying similar incidents (only for transition period)** |
| **a** | If similar incident were not identified by IMDRF codes but by in-house codes, please provide the codes and terms below.   |  |  | | --- | --- | |  | Choice 1 | | Code/term for most relevant medical device problem | Code  Term | | Code/term for most relevant root cause evaluation | Code  Term |   Other – enter description of what similar incidents are based on and the rationale why the above codes were not used |
| **4.4.3** | **Number of similar incidents and devices on the market** |
| **a** | Indicate on which basis similar incidents were identified regarding the device or device variant:  Model  Software  Lot/Batch  Product platform  Other variant  Details of the selection made above |
| **b** | Indicate what criteria the number of devices on the market (also known as denominator data) is based on.  (Tick the most appropriate):  Devices placed on the market or put into service  Units distributed within each time period  Number of tests performed  Number of episodes of use (for reusable devices)  Active installed base  Units distributed from the date of declaration of conformity/CE mark approval to the end date of each time period  Number of devices implanted  Other – describe: |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **c** | Enter the number of similar incidents and devices on the market for the indicated time periods  You must use yearly time periods unless:  A: a different time period has been specified by the European vigilance Working Group  B: the device has not been on the European market for more than three years   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | Time period (N)  Year to date = PSR year | | Time period (N-1)  calendar year one year before PSR | | Time period (N-2)  calendar year two years before PSR | | Time period (N-3)  calendar year three years before PSR | | | Start date |  |  |  |  |  |  |  |  | | End date |  |  |  |  |  |  |  |  | |  | Number of similar  incidents | Number of devices on market | Number of similar  incidents | Number of devices on market | Number of similar incidents | Number of devices on market | Number of similar  incidents | Number of devices on market | | Country of incident |  |  |  |  |  |  |  |  | | EEA + CH + TR |  |  |  |  |  |  |  |  | | World |  |  |  |  |  |  |  |  | |
| **d** | Comments on how similar incidents and associated number of devices on the market were determined |

|  |
| --- |
| **Section 5: General comments** |
|  |

Submission of this report does not represent a conclusion by the manufacturer and / or authorised representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Please send the completed report as Word or PDF file to [materiovigilance@swissmedic.ch](mailto:materiovigilance@swissmedic.ch)