**Manufacturer’s Trend Report**

**(TrendR)**

**Reporting Template Version 1.1**

**Medical Devices Vigilance System**

**For initial application all the fields should be completed except 4.2 analysis update.**

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| Section 1: Administrative information | |
| **1.1** | **Corresponding competent authority** |
| **a** | To which NCA(s) is this report being sent? |
| **b** | Reference number assigned by NCA for this TrendR |
| **1.2** | **Date, type, and classification of Trend Report** |
| **a** | Date of submission  YYYY.MM.DD |
| **b** | Date the trend was identified  YYYY.MM.DD |
| **c** | Time period of trend analysis  YYYY.MM.DD to YYYY.MM.DD |
| **d** | Type of report  Initial  Follow up  Combined Initial and final  Final |
| **e** | In case of initial and follow-up reports, please indicate the expected date of the next report  YYYY.MM.DD |
| **f** | What is the trend based on?  Increase in the frequency of not serious incidents  Increase in the severity of not serious incidents  Increase in the frequency of expected undesirable side-effects  Increase in the severity of expected undesirable side-effects  Increase of expected erroneous results  Other, please specify: |

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| **1.3** | **Submitter information** | | |
| **1.3.1** | **Submitter of the report** | | |
| **a** | ManufacturerAuthorised representativeOther, please specify | | |
| **b** | Manufacturer's reference number for this Trend Report | | |
| **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** | Single registration number (SRN) | | |
| **c** | Contact’s first name | **d** | Contact’s last name |
| **e** | Email | **f** | Phone |
| **g** | Country | | |
| **h** | Street | **i** | Street number |
| **j** | Address complement | **k** | PO Box |
| **l** | City name | **m** | Postal code |

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| **1.3.4** | **Swiss authorised representative information** | | |
| **a** | Authorised representative Organisation name | | |
| **b** | Swiss single registration number (CHRN) | | |
| **c** | Contact’s first name | **d** | Contact’s last name |
| **e** | Email | **f** | Phone |
| **g** | Country | | |
| **h** | Street | **i** | Street number |
| **j** | Address complement | **k** | PO Box |
| **l** | City name | **m** | Postal code |

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| Section 2: Medical device information | | | | | | | | | |
| **2.1** | **Unique Device Identification (UDI)** | | | | | | | | |
| **a** | UDI-DI | | Issuing entity: | **b** | | | UDI-PI | | |
| **c** | Basic UDI-DI | | Issuing entity: | **d** | | | Unit of use UDI-DI | | Issuing entity: |
| **2.2** | **Categorisation of device** | | | | | | | | |
| **a** | Medical device terminology  EMDN  GMDN  UMDNS(ECRI)  GIVD/EDMS | | | | | | | | |
| **b** | Medical device nomenclature code | | | | | | | | |
| **2.3** | **Description of device and commercial information** | | | | | | | | |
| **a** | Medical device name(s) (brand / trade / proprietary or common name) | | | | | | | | |
| **b** | Nomenclature text(s)/Description of the device(s) and its/their intended use | | | | | | | | |
| **c** | Model  List all applicable | | | | **d** | | Catalogue/reference number  List all applicable | | |
| **e** | Serial number  List all applicable | | | | **f** | | Lot/batch number  List all applicable | | |
| **g** | Software version  List all applicable | | | | **h** | | Firmware version  List all applicable | | |
| **i** | Device manufacturing date  YYYY.MM.DD to YYYY.MM.DD | | | | **j** | | Device expiry date  YYYY.MM.DD to YYYY.MM.DD | | |
| **k** | Notified body (NB) ID number(s) (if applicable) | | | | | | | | |
| **l** | Notified body (NB) certificate number(s) of device (if applicable) | | | | | | | | |
| **m** | Please indicate the date of one of the following:  First declaration of conformity  The device first CE marked  First placed on the market  First put into service  If software, date first made available  YYYY/MM | | | | | | | | |
| **2.4** | **Risk class of device when placed on market** | | | | | | | | |
| **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 | |
| **2.5** | **Market distribution (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 | | | | | | | | |
| **2.6** | **Use of accessories, associated devices or other devices** | | | | | | | | |
| **a** | Relevant accessories used with the device(s) under this trend (please list with corresponding Manufacturer if different from device being reported on) | | | | | | | | |
| **b** | Relevant associated devices used with the device(s) under this trend (please list with corresponding Manufacturer if different from device being reported on) | | | | | | | | |

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| Section 3: Description of Trend | |
| **a** | Background information on the trend, including probability of problem arising and the predicted risk to patient of other users. |
| **b** | Please describe established trigger level: |
| **3.1** | **Coded information on trend** |
| **3.1.1** | Medical device problem information |
| **a** | IMDRF Medical device problem codes (Annex A)  Coding with IMDRF terms is a mandatory requirement.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  | Choice 1  (most relevant) | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 | | IMDRF 'Medical device problem codes' | Code | Code | Code | Code | Code | Code |   If you think the incident is unique and a suitable IMDRF term is missing, briefly explain: |
| **3.1.2** | Possible risks to the health or safety |
| **a** | IMDRF 'Health Effect' terms and codes (Annex E, F)  Coding with IMDRF terms is a mandatory requirement.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  | Choice 1  *(most relevant)* | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 | | IMDRF 'Clinical signs, symptoms, and conditions codes' (Annex E) | Code | Code | Code | Code | Code | Code | | IMDRF 'Health impact' codes (Annex F) | Code | Code | Code | Code | Code | Code |   If you think the trend is unique and a suitable IMDRF term is missing, briefly explain: |
| **3.1.3** | If trend is based on a root cause: |
| **a** | IMDRF ‘Cause Investigation' terms and codes (Annex B, C, D)   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Coding with IMDRF terms is a mandatory requirement. | Choice 1  *(most relevant)* | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 | Choice 7 | Choice 8 | | IMDRF Cause investigation : Type of investigation  (Annex B) | Code | Code | Code | Code | Code | Code | Code | Code | |  |  |  |  |  |  |  |  |  | | IMDRF Cause investigation : Investigation findings (Annex C) | Code | Code | Code | Code | Code | Code |  |  | |  |  |  |  |  |  |  |  |  | | IMDRF Cause investigation : Investigation conclusion (Annex D) | Code | Code | Code | Code | Code | Code |  |  |   If you think the trend is unique and a suitable IMDRF term is missing, briefly explain: |
| **b** | IMDRF Component codes (Annex G)  Coding with IMDRF terms is a mandatory requirement.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  | Choice 1  *(most relevant)* | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 | | IMDRF 'Component' codes (Annex G) | Code | Code | Code | Code | Code | Code |   If you think the trend is unique and a suitable IMDRF term is missing, briefly explain: |
| **3.2** | **Use of IMDRF terms and codes for identifying the trend** |
| **a** | Identification of trend using IMDRF Adverse Event Reporting terms and codes  Tick-mark which code or combination of codes were used for identifying the trend.   |  |  | | --- | --- | |  | 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’) |  | | IMDRF code relating to most relevant  'Clinical signs, symptoms, and conditions codes' (Annex E) |  | | IMDRF code relating to most relevant  'Health impact' codes (Annex F) |  | | IMDRF code relating to most relevant  'Componet' codes (Annex G) |  |   Other – enter description of what the trend is based on and the rationale why the above IMDRF codes were not used: |
| **3.3** | **Use of in-house terms/codes for identifying the trend** |
| **a** | If trend was 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 trend is based on and the rationale why the above codes were not used: |
| **3.4** | **Number of devices on the market** |
| **a** | Indicate on which basis the trend was identified regarding the device or device variant:  Model  Software  Lot/Batch  Product platform  Other variant  Details of the selection made above |
| **b** | Indicate to 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 please describe: |
| **c** | Enter the number of similar events (that are non-reportable incidents (not serious incidents or expected undesirable side- effects or expected erroneous results) or reportable incidents and devices on the market for the indicated time periods  Please use time periods that best highlight the trend and describe why:     |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | Time period (N) | | Time period (N-1) | | Time period (N-2) | | Time period (N-3) | | | 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 | | Switzerland |  |  |  |  |  |  |  |  | | EEA + CH + TR |  |  |  |  |  |  |  |  | | World (incl. EEA + CH + TR) |  |  |  |  |  |  |  |  | |
| **d** | Have any of the trended events been submitted individually as reportable events under vigilance?  Yes  No  If yes, please list reference numbers and the country where the event occurred: |

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| Section 4: Manufacturer analysis | |
| **4.1** | **Manufacturer’s preliminary comments** |
| **a** | For **initial** and **follow-up** reports: preliminary results and conclusions of manufacturer’s investigation |
| **b** | Initial actions (corrective and/or preventive) implemented by the manufacturer |
| **c** | What further investigations do you intend in view of reaching final conclusions? |
| **4.2** | **Results of manufacturer’s final investigation into trend** |
| **a** | **For Final:** Description of the manufacturer’s evaluation concerning (possible) root causes/causative factors and conclusion |
| **b** | Is root cause confirmed?  Yes  No |
| **c** | Has the risk assessment been reviewed?  Yes  No If 'No', rationale for no review required:  If the risk assessment has been reviewed, is it still adequate?  Yes  No Results of the assessment: |
| **d** | Description of remedial action / corrective action / preventive action / field safety corrective action (FSCA) |
| **e** | Time schedule for the implementation of the identified actions |
| **f** | Final comments from the manufacturer on cause of investigation and conclusion |
| **g** | Further investigation |

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|  | **Section 5: General comments** |
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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)