**MDCG 2022-21 – Periodic Safety Update Reports (PSUR)**

(Provided by Casus in word format. This is an exact transposition from the PDF version of MDCG 2022-21)

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**ANNEX II: Templates for the Presentation of Data in the PSUR**

These tables are intended to provide guidance to manufacturer and are only examples.

It is up to the manufacturer to present the data in the most appropriate manner depending on the nature of the data and of the device.

Please read this Annex II in conjunction with Annex I when forming tables.

**Table 1. Volume of sales\* by region over time**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Basic UDI-DI/ Legacy device name or model | | | | | |
|  | Total Number of devices | Reporting Day+ preceding 12 months (N) | N – 12 months (N2) | N2-12 months (N3) | N3-12 months (N4) |
| EEA+TR + XI\*\* |  |  |  |  |  |
| Worldwide |  |  |  |  |  |

\*Indicate according to which criteria the number of devices on the market is provided (Annex II, 4.1)

\*\*EEA: European Economic Area, TR: Turkey, XI: Northern Ireland.

**Table 2. Estimated size of the population using the device\* over time**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Estimated size of population using the device Reporting Day+ preceding 12 months (N) | Estimated size of population using the device N – 12 months (N2) | Estimated size of population using the device N2-12 months (N3) | Estimated size of population using the device N3-12 months (N4) |
| EEA+TR + XI |  |  |  |  |
| Worldwide |  |  |  |  |

\*When clinically relevant and known by the manufacturer

**Table 3. Characteristics of the population using the device\* over time**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Characteristic X of population using the device Reporting Day+ preceding 12 months (N) | Characteristic X of population using the device N – 12 months (N2) | Characteristic X of population using the device N2-12 months (N3) | Characteristic X of population using the device N3-12 months (N4) |
| EEA+TR + XI |  |  |  |  |
| Worldwide |  |  |  |  |

\*Characteristics of the population using the device is defined by the manufacture based on the usage of device

**Table 4. Total number (N) and rate (%)\*of the serious incidents by IMDRF Adverse Event Terminology (AET) Annex A – Medical Device Problem by time and region over time**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Basic UDI-DI/Legacy Device name or model | | | | | | | | | |
| IMDRF Adverse Event Medical Device Problem code (Annex A) and term by region | | Reporting Day+ preceding 12 months (N) | | N – 12 months (N2) | | N2-12 (N3) months | | N3-12 (N4) months | |
| N | % | N | % | N | % | N | % |
| EEA+TR + XI |  |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |  |
| EEA+TR + XI |  |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |  |

\*The denominator is compatible to the number of devices in table 1 or based on manufacturer’s reasoning e.g. reusable instruments

**Table 5. Total number (N) and rate (%)\* and of the serious incidents by IMDRF AET Annex C - Cause Investigation-Investigation Findings by time and region over time**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Basic UDI-DI/Legacy Device name or model | | | | | | | | | |
| IMDRF Adverse Event Investigation Findings (Annex C) code and term by region | | Reporting Day+ preceding 12 months (N) | | N – 12 months (N2) | | N2-12 months (N3) | | N3-12 months (N4) | |
| N | % | N | % | N | % | N | % |
| EEA+TR +XI |  |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |  |
| EEA+TR + XI |  |  |  |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |  |  |  |

\* The denominator is compatible to the number of devices in table 1

**Table 6. IMDRF AET Annex F - Health Effects-Health Impact code of the serious incidents by IMDRF Adverse Event Terminology Annex D - Investigation Conclusion in last 4 years**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| BASIC UDI-DI/Legacy Device name or model | | | | | | |
| IMDRF Adverse Event Health Impact (Annex F) code and term by region | | Number of serious incidents | Investigation conclusion code+ term1 % | Investigation conclusion code+ term2 % | Investigation conclusion code + term3 % | Investigation conclusion code + term4 % |
| EEA+TR +XI |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |
| EEA+TR + XI |  |  |  |  |  |  |
| Worldwide |  |  |  |  |  |  |

**Table 7. FSCA initiated in current reporting period and open FSCAs\***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| BASIC UDI-DI/Legacy Device name or model | | | | | | |
| Type of action | Issuing date | Scope of the FSCA | Status of the FSCA\*\* | Manufacturer Reference number | Rationale and description of action taken | Impacted regions |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

\*Will be further developed when the new FSCA form is in use

\*\*Follow-up, final at the time the data collection time ended

**Table 8. CAPA initiated in current reporting period and open CAPA**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| BASIC UDI-DI/Legacy Device name or model | | | | | | | |
| Type of action | Initiation Date | Scope of the CAPA | Status of the CAPA | Manufacturer Reference number | CAPA description | Root cause\* | Effectiveness of the CAPA if closed\*\* |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

\*Internal codes with the explanation, IMDRF codes or free text

\*\*If CAPA is still open then this is not applicable, if CAPA is closed comment on whether it is resolved, not resolved or comment if additional CAPA has been opened.