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

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**ANNEX III: General Information Related to the Presentation and Assessment of the Collected Data by the Manufacturer**

**1. How Data Should be presented**

* Each dataset specified in the PMS Plan should be presented and analysed individually. A summary providing the used datasets including the PMCF data should highlight the limitations related to the collected data.
* Datasets should be split by Basic UDI-DI or model of the device if the Basic UDI-DI does not exist.
* If the group of devices or the devices within a Basic UDI-DI(s) have changed then it is necessary to report separately the data with former and later combination of devices.
* The data should be split by region, when applicable. The used regions are EEA, TR, XI and worldwide. Worldwide data include data from EEA, TR and XI.
* Each PSUR should contain data from the data collection period of this PSUR compared with the same types of data from the previous PSUR periods (see tables 2 to 5 of Annex II of this guidance).
* The first PSUR data collection is not retrospective (does not go before the date of application of the MDR) except when no PSUR has been issued for the corresponding MDD compliant device: it is then recommended that the “historical data” collected before the MDR DoA be considered for the first PSUR of the MDR compliant device (see section 5.2.2.1).
* Data should be reported by year to year
	+ Class III and Class IIb: Reporting Day+ preceding 12 months (N); N – 12 months (N2); N2-12 months (N3); N3-12 months (N4)
	+ Class IIa: Reporting Day+ preceding 24 months (N); N – 24 months (N2)
* The manufacturer should present the data utilizing the International Medical Device Regulators Forum (IMDRF) Adverse Event Terminology when the content of the data facilitates it.
* The following IMDRF Adverse Event Terminologies, terms and codes should at least be utilized:
	+ - Annex A: Medical Device Problem
		- Annex C: Cause Investigation - Investigation Findings
		- Annex D: Cause Investigation - Investigation Conclusion
		- Annex F: Health Effects - Health Impact
	+ Level 2 terms are satisfactory to enable the grouping of cases.
	+ When the Level 2 terms are not available, manufacturers can use Level 1 terms/codes.

**2. How Data Should be assessed by the manufacturer**

* Findings from all datasets should be considered and evaluated by comparing data from the various sources and identifying possible conflicting results.
* The manufacturer should assess the results considering the different patient populations, sizes and models of the device, device combination or variants. When applicable, the manufacturer should evaluate the findings in relation to the state of the art.
* The manufacturer should assess the data in relation to the thresholds concerning known risks and side effects and benefits intended to be gained.
* The manufacturer should identify factors that support or refute previously identified safety and performance concerns as well as evidence relating to new safety signals or emerging risks.
* The manufacturer may also describe any new benefits that have been identified from the reporting period and benefits not achieved as intended.
* When applicable, the IMDRF Terminologies for Categorized Adverse Event Reporting should be used in the analysis.
* If the device is used in a combination of devices, the analysis should identify the role of each device in comparison to other devices or accessories used together.
* The performance and safety of the device should be compared to other devices with the same intended use.