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### **Joint open letter: In anticipation of EUDAMED availability for mandatory use**

Dear Ms Giorgio, Mr Gevaert,

Several Ministers of Health called for early mandatory availability of the European medical devices database (EUDAMED) at the Employment, Social Policy, Health and Consumer Affairs Council meeting held on 30 November 2023. The undersigning industry associations highlight important preconditions that are needed before any modules of EUDAMED would be made mandatory:

1. The modules are fully developed, tested, audited and ready for practical implementation.
2. EUDAMED enables the most efficient use of Notified Body and Manufacturer resources.
3. Realistic and reliable implementation and transition timelines are provided.
4. Redundancy in National Databases is eliminated.

#### **The modules are fully developed, tested, audited and ready for practical implementation.**

Any modules of EUDAMED whose use shall become mandatory must be fully tested by users, including the Post-market Surveillance & Vigilance module and the public website. The firm expectation is that any elements or modules (such as Clinical Investigation & Performance Studies) which would become mandatory at a later date, must be smoothly integrated and usable with the existing modules including already-populated data and should not cause an incremental rework of the modules that have already been in use.

#### **EUDAMED enables the most efficient use of Notified Body and Manufacturer resources.**

The first mandatory version of EUDAMED must include a Machine-to-Machine communication functionality for the Notified Bodies & Certificates module. At the same time, the functionality to upload (non-validated and translated versions of) Summary of Safety and (Clinical) Performance reports must be transferred from Notified Bodies to Manufacturers. This is important because it directly affects the manufacturers' ability to supply devices to patients in the EU. To maintain data accuracy and prevent issues with device traceability and in the supply chain, it is essential to allow editing of data fields. This prevents the unnecessary proliferation of unique device identifiers (UDI-DIs).

**Realistic and reliable implementation and transition timelines are provided.**

Reasonable implementation timeline should be communicated and provided for companies and compliance partners such as the Notified Bodies to align their procedures and build up their resources, tools and infrastructure for EUDAMED readiness including connectivity for automated submission. All EUDAMED users should have the final documentation and a lead time of at least 24 months communicated to them prior to starting mandatory use of any modules. A reliable and well-resourced implementation plan is particularly important for industry, given that the timelines have shifted in the past, with significant implications for budget and IT resources dedicated to EUDAMED.

**Redundancy in National Databases is eliminated.**

Today companies' administrative resources are being stretched to comply with multiple national database requirements to register economic operators and device data. During their transition period after EUDAMED is released, actors and devices should no longer be obliged to register in national databases once they register in EUDAMED. National databases for distributor reporting, if maintained, should align with EUDAMED and leverage data attributes on devices from this central and single source of truth. Once the EUDAMED transition plan for mandatory use is established, any duplication of the same information in national databases for distributors must be phased out by Member States. National distributor databases if needed should only ask for a minimum data (e.g. the Unique Device Identifier UDI-DI or Basic UDI-DI) that allows the identification of the particular device in the EUDAMED database for data download.

**Our associations fully support the availability of EUDAMED as an integral part of the Medical Devices Regulation and IVD Regulation. The integrity of the database and its practical implementation are essential for ensuring the success of a mandatory EUDAMED.**

