Joint industry statement
Concerns about the delay of EUDAMED implementation

The European Commission made the official announcement that the implementation of the European Database for Medical Devices (EUDAMED) is delayed by two years. As EUDAMED is considered to be at the heart (center) of the new Regulations, this delay has led to a number of questions and concerns within our membership relating to MDR Articles that require a functioning Eudamed. We understood during discussions at the MDCG UDI Working Group that the European Commission and member states are currently drafting a guidance on the detailed alternative arrangements for the transitional period until May 2022.

Unfortunately, the draft guidance is currently not being discussed in the EUDAMED or UDI Working Groups. We encourage stakeholder consultation and hope that all relevant experts, including industry, will soon be involved to ensure practicable solutions maintaining transparency. We would already like to share the following general concerns with you in view of the up-coming MDCG meeting:

Requirement applicability: industry requires a clear overview of the requirements that are applicable despite the fact that EUDAMED is delayed (e.g. assignment of UDI[i] and SRN, Vigilance reporting timelines, MDR specific documents such as SSCP) in the up-coming MDCG guidance document based on a thorough legal and practical review.

Clearly defined project plan: the change in timeline should also be taken as an opportunity to set out a clear project plan with early enough deadline to freeze specifications and to ensure that manufacturers have access to EUDAMED final specifications and to the test environment as soon as possible before the 'go-live' of the database. Testing is necessary for the validation of internal IT systems.

Database implementation: we are concerned that EU member states would alter their existing national databases or implement new databases in their countries in order to fulfil or exceed the last sentence of MDR Art. 123 3(d).

We strongly recommend to the European Commission and member states to align as much as possible at European level and avoid national fragmentation. Information to be provided in national databases should be limited to what is foreseen in the Medical Device Directives. The upcoming guidance document should not require operators to upload additional information from the MDR in these databases.

Industry will of course remain committed to contribute in the dedicated EUDAMED Working Groups and continue to provide our members' expertise to the development and testing of the database. Several associations have also submitted or are currently preparing detailed impact analysis and contributions.

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[i] *(*) As mentioned in MDCG 2019-4 "Timelines for registration of device data elements in EUDAMED"*