MedTech Europe
from diagnosis to cure

Smooth transition to the mandatory use of EUDAMED

Perspectives from manufacturers

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Table of Contents

This paper provides the industry perspectives for a smooth transition to the mandatory use of various EUDAMED modules by efficient use of resources, building on the points of the Joint open letter: In anticipation of EUDAMED availability for mandatory use.

The European central database for medical devices 'EUDAMED' is a critical infrastructure for the *In Vitro* Diagnostics (IVD) and Medical Devices (MD) Regulations. Its implementation represents an investment into a more efficient regulatory system providing oversight of devices, enhanced collaboration between Competent Authorities and users and more transparency for the public.

State of play

Today three out of six modules are made available in EUDAMED for voluntary use; in addition a comprehensive EUDAMED information centre, as well as UDI and EUDAMED helpdesks are set up to support users. All modules (except for one) are being finalised and most parts of the database are expected to become mandatory for use within the next 1.5-2 years[1]. At the time of writing, the ongoing audit of EUDAMED is assessing if the individual modules meet the criteria of being a 'minimum viable product' (MVP), i.e. providing those functionalities and usability which are strictly necessary for legal compliance.

Industry users are the main contributors of data to be present in the central database therefore its success depends on its technical useability for manufacturers and on the rules that are required to apply to transition to mandatory use. Industry anticipates that they and other actors such as Notified Bodies, Authorised Representatives and Importers will have to invest significantly to transition to EUDAMED. The benefits of the completed database with quality data are foreseen to come in the future, once the system is up and running and fully populated.

MedTech Europe welcomes the gradual implementation of EUDAMED. At the same time, system usability and efficiency issues mean that users need to expend excessive resources due to many manual processes, requests for repetitive data input and missing system optimisations. System usability and efficiency would be achieved by turning the current minimal viable product into an integrated, consistent, state-of-the-art, multi-modular system and by:

- prioritising the implementation of automated data submission and download methods;
- ensuring inter-module data consistency with autopopulation;
- avoiding the entry of the same data multiple times, across modules;
- reducing the number of non-updatable data fields;
- increasing the number of validation rules;
- providing pragmatic transition rules;
- harmonising member states' information needs channeled through EUDAMED.

[1] See EUDAMED Timeline published at DG SANTE website

We are concerned that many improvements will be necessary to ensure that users have a smooth transition to EUDAMED and for the database to deliver on its mission as being a central part of the IVDR and MDR infrastructure. A recent inquiry[2] among MedTech Europe members shows that they do not anticipate saving time or gaining efficiency by using the central database in its current state without further improvement vs. the fragmented national processes in place today.

Improve Accessibility, Efficiency and Consistency, Reduce Burden through technical and regulatory measures

MedTech Europe therefore proposes several areas of attention for the European Commission, which should be addressed:

- **Accessibility and workability**: The immediate goal should be to ensure that EUDAMED is **readily workable and easily accessible for users,** especially for small and medium-sized enterprises (SMEs). Accessibility to EUDAMED and its playground is crucial for manufacturers to familiarise with the system, prepare, align and comply on time. Access to the playground environment is currently difficult to find and navigate. Here we propose a step-by-step guidance on how to create actor and user account – both in playground and in production - and how to sequentially input information into individual modules that build on each other.

- **Adopt regulatory measures where no technical solution exists**: If a technical enhancement of the database to increase efficiency for users is not viable or may come only at the later stage, that situation should be balanced out by **regulatory measures** to ensure a pragmatic and smooth transition from voluntary to mandatory use of EUDAMED. In particular, MedTech Europe recommends starting to use EUDAMED for new (vigilance, clinical) reports and finalising ongoing reports via national routes.

- **Efficiencies need to be made in the data input method**: There is a concern that EUDAMED will place a significant burden on companies due to the increased number of data elements requested in device registration, vigilance reporting and clinical investigation/performance study reports, etc. The current necessity to manually complete EUDAMED templates is anticipated to require substantial resources. We suggest reprioritising some post-MVP functions and to launch them before the mandatory use of the respective modules.

- **Consistency by automation**: At present, EUDAMED is not structured as an **integrated system.** This considerably will impact the **consistency of data**. It is crucial to prevent any potential for inputting conflicting information in different modules. (i.e. the ability to enter inconsistent information). Enabling autopopulation of data fields which repeat information already registered in the source modules, is essential to establish a single source of truth and to ensure alignment among interconnected EUDAMED modules. We request to maximise data autopopulation between modules to avoid duplicative entry of data. We also request automated technical return messages to confirm electronic transactions have been successfully completed or not, in addition

[2] Based on experiences gained with playground environment.

to the planned notification emails. The manual tracking of email notifications is not sustainable provided the anticipated volume of activity within EUDAMED.

Measures needed to prepare users for transitioning to mandatory use of EUDAMED

1. Reliable and concrete implementation and transition timelines with technical documentation and transitional rules are provided

It is crucial that the European Commission provides users with:

- **reliable timelines and realistic transition period**[3] which enables users to build up resources, tools and infrastructures (set up a team of experts, establish a budget and a project plan) to execute a large-scale IT project to align internal systems and to enable technical interfaces with EUDAMED.
- **final technical documentation** for each module (data dictionaries, business rules, entity diagrams, XSDs etc.) at least 18 months before the mandatory use of any modules according to the published plans[4]. The documentation should be fully aligned with the modules.
- **regulatory information** to explain the process in addition to the IT technical documentation and user guides at least 18 months before the mandatory use of any modules. The goal should be for all users to have a clear understanding of the expected content of the various EUDAMED forms in all modules.
- **transitional guidance**[5] to facilitate a seamless transition from national administrative processes to the mandatory central submission. This will include
    - clarification on the implications of mandatory use for different modules,
    - the cessation of national registration,
    - details of the device registration transition period, and
    - the management of reports and studies ongoing at the end of the transition period.

Improvements including concise and meaningful post-MVP functionalities are expected to be released as part of the initial system launch as well as in incremental developments of the system in the future. MedTech Europe highlights that **each release of the mandatory system triggers significant development and re-validation efforts** of industry software applications. Therefore, such releases should be carefully planned, involving and informing users.

We appreciate the user **onboarding plan** presented by the European Commission, which includes training and access to the playground for both manual and automated [semi-automated bulk upload and fully

[3] EUDAMED roadmap published at the European Commission's website here in July 2024.

[4] This is based on Commission's planning to release full technical documentation for M2M communication in Q4 2024 before the planned mandatory use of ACT, UDID, CERT and MSU modules in January 2026

[5] The 'Q&A on practical aspects related to the implementation of the gradual roll-out of Eudamed pursuant to the MDR and IVDR, as amended by Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices' covers only some of these points – published here.

automated machine-to-machine - M2M] processes. We recommend that the European Commission organise free-of-charge, hands-on webinars or provide other means of training to **the widest possible range of users for accessing the playground and onboarding to EUDAMED**. The information and training provided should be simple and accessible, particularly for SMEs. MedTech Europe stands ready to support training.

2. The modules are fully developed, fit for purpose, tested, audited and ready for practical implementation

There are several needed activities to ensure modules are ready for their practical implementation:

- It is vital that **users are directly involved in the current last phases of testing through face-to-face workshops with the EUDAMED developers.** This approach ensures that the modules not only function 'as designed' but also 'as intended': they should be fit for purpose and enable practical use of the modules. During the 7-year period of EUDAMED development, manufacturers who are the primary contributors of data in the database were not provided the opportunity to engage with the developers directly to address technical challenges. The establishment of the EUDAMED Competent Authorities Oversight Board is welcomed to carry out joint end-to-end testing between stakeholders including Notified Bodies and industry users; however, it is not the proper platform for addressing technical issues collected by users.
- During the audit process, not only the functioning of the individual modules, but also the **interaction between all modules** should be thoroughly assessed. Any module released at a later date should be seamlessly integrated with the previously released modules and any impacts to already released modules communicated well in advance, to allow users to adapt their processes and IT systems in support. The same applies to as any post-MVP functionalities released after the initial system launch.
- It needs to be ensured that EUDAMED can support the high volume of activity anticipated across industry prior to the mandatory use dates becoming effective for all classes of devices at once. We emphasise the importance of carrying out **load testing** of the database to check its viability of a massive device data transfer along measurable parameters.
- We appreciate the possibility to **test the public website**. It enables users to verify that information is released from the Vigilance and later from the Clinical Investigation / Performance Studies modules, as intended by IVDR and MDR.

Measures needed in the post- minimum viable product phase for mitigating the burden of the transition to mandatory use of EUDAMED

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

MedTech Europe appreciates the decision that the **Vigilance module is planned to become mandatory only after the implementation period for the UDI/Device registration module**. This approach allows actors to establish their data first in EUDAMED, starting with the Actor and UDI/Device registration which enables the functioning of the interdependencies between these three modules.

Several measures are needed to enable efficient use of resources:

- It is essential that the future **addition of the Vigilance and Clinical Investigation / Performance Studies module does not necessitate incremental rework** of existing modules. The industry utilises validated systems along strict quality and regulatory standards which require considerable time for re-validation with major modifications.
- **To prevent the proliferation of unique device identifiers and supply chain disruption as well as to ensure data quality**, we advocate for **allowing editability of data fields**. During the transition, there should be a grace period where users can correct mistakes, meaning all fields can be edited for a specified period without triggering the registration of a new record. A high number of device registration elements are not updatable forcing the creation of a new UDI-DI and registration of a 'new' device should a data error be identified or a valid business event such as changing a Notified Body occur. This results in additional non-value-added activity within manufacturers and Notified Bodies organisations, multiplicate records in EUDAMED and in potentially jeopardized traceability in case of a vigilance event. Users need a transparent communication to understand what combination of legal requirements and database field editing rules will necessitate the creation of a new UDI-DI.
- **Develop rules to enable linking of devices across Actors / Single Registration Numbers (e.g. in case of mergers & acquisitions)** to maintain traceability and vigilance history of the devices and to enable data accessibility and retrieval by different Actors, where an accepted use case exists, throughout the product lifecycle.
- We emphasise the essential need of **ramping up helpdesk support**, particularly during transition periods and leading up to the EUDAMED compliance deadlines.
- We ask the European Commission to give priority to transferring the functionality to manufacturers for **uploading non-validated and translated Summaries of Safety and (Clinical) Performance (SS(C)Ps) to EUDAMED**. The supply of devices to patients should not be dependent on the upload of SS(C)P by Notified Bodies. Most SS(C)Ps are expected to be uploaded during the first registration wave of devices; therefore, this functionality is crucial when starting the UDID mandatory use. In alignment with the UDI/Device registration module mandatory usage timeline, that it is essential to prolong the measures of MDCG 2021-1 Rev. 1 and MDCG 2022-12 for the making available of the SS(C)P by manufacturers, to ensure manufacturers can continue to place product on the market compliantly.

4. Redundancy in national databases is eliminated

Once EUDAMED respective modules become mandatory for use, there will no longer be a legal requirement to register economic operators (except for distributors if required by national law) and devices in national databases and send new serious incident, post-market surveillance and serious adverse event reports, as well as clinical/performance study applications etc. via national processes.

Requiring device data at national level other than a list of distributed UDI-DIs can be regarded as a measure having equivalent effect. The implementation of UDI as a means to identify medical devices is expected to provide more accurate and reliable information compared to the current fragmented data found in national databases and other registries. To avoid creating double formalities, we urge Member States to leverage reliable and quality device data referencing or synchronizing data from the unique central source of truth, which is EUDAMED. **Existing distributor databases and other national registries should rely on device information contained in EUDAMED for a more effective use of available resources.**

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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REFERENCES:

- Joint open letter: In anticipation of EUDAMED availability for mandatory use (December 2023)
- MedTech Europe position papers for the Vigilance and the Clinical Investigation / Performance Studies modules being developed for more detailed suggestions on these individual modules

For EU legislation please see latest consolidated version.

The *In Vitro* Diagnostic Medical Devices Regulation / Medical Devices Regulation contains several provisions that are capable of being given more than one interpretation. In the preparation of this Position Paper, MedTech Europe has used its best efforts to ensure that the opinions and advice expressed are sound. However, the Association makes no assertion that those opinions and advice are correct and it accepts no legal responsibility for them. Specific legal advice should be sought before acting on any of the topics covered. MedTech Europe reserves the right to change or amend this document at any time without notice in order to keep the information up to date.

Members are reminded that, while competent authorities and notified bodies may be helpful in providing views as to the meaning of the *In Vitro* Diagnostic Medical Devices Regulation / Medical Devices Regulation, it is ultimately for the courts to interpret legislation.