Open letter from the CAMD Executive Group to the medical devices community concerning Eudamed

Executive Summary

A key component of the Regulations (EU) 2017/745 and (EU) 2017/746 is Eudamed, which is essential to all major activities of both of these Regulations and the coordination of Competent Authorities and transparency of the new regulatory systems.

With the two years postponement of the whole Eudamed all economic operators (EO) and competent authorities (CA) are facing an enormous challenge, since the alternative is a set of heavily burdensome administrative transitional solutions. Such solutions are not only resource intensive, costly and will take time, but also increase the challenge in providing certainty and ensure consistency in application from the outset.

The core of the new Regulations is patient safety, and this is only be ensured with realistic and executable requirements which are applied consistently across Europe.

Eudamed is necessary for the proper and effective functioning of the regulatory system. Therefore, the CAMD network urgently calls for constructive discussion with the authorities and the EU Commission to find practical solutions, which are executable for the EO and CA as long as Eudamed is not put into application. Those discussions will be used to take stock on the overall readiness for implementation and to discuss potential short, medium- and long-term solutions to identified challenges. In this context partial releases of Eudamed shall be discussed.

The CAMD offers its support to the Commission and MDCG to find solutions, which are executable for all MS.

Background

The European database on medical devices is intended to improve the transparency and coordination of information of medical devices on the European market. It will contain different modules on actors, UDI and devices, notified bodies and certificates, vigilance, clinical investigations, performance studies and market surveillance.

At the end of 2015. the Commission has constructed a comprehensive set of working groups to support its development. These are groups are currently: Steering, Registration, NBs & Certificates, UDI, Data Exchange Clinical Investigation, Vigilance, Market Surveillance, and the Nomenclature system.

After almost four years of preparation and development, the European Commission is announcing the delay of the launch of Eudamed as a whole until May 2022 for legal reasons. The new launch date for Eudamed coincides with the implementation date for the *In Vitro* Diagnostic Regulation, set to take effect May 26, 2022.

Eudamed is a database composed of different systems. Until October 2019 three systems were announced as being able to be functional at least partially in March 2020.

The delay will not extend the effective date of the Medical Device Regulation, which remains applicable from May 26, 2020.

The Eudamed is at the heart of the new Regulations. However, the postponement of Eudamed as a whole and the simultaneous retention of the validity of the MDR raises many operational and enforcement questions and also raises challenges to transparency, confidence in regulatory framework and security of operation.

Observation

The Commission has clearly recognised the importance of Eudamed and is making serious efforts to develop a system that meets the requirements of the Regulations.

Although the Regulations foresee the potential for a Eudamed delay, many practical issues remain unresolved.

Concerns

The solutions proposed by the Commission, which are now being worked out, are very strongly oriented towards the most precise legal interpretation possible rather than operational effectiveness of implementation. The technical possibilities, the available resources and the necessary timeframe which were necessary for a successful operational execution are not sufficiently considered.

Some systems were supposed to be ready at the date of application and competent authorities have been preparing on that basis and have not anticipated a delay of those systems such as the actor, UDI/DM and certificates modules.

A proposed way forward

The CAMD offers its support to the Commission and MDCG to find legal, effective and operational solutions, which are executable for all MS. The most relevant forum for this discussion is most likely at the Medical Device Coordination Group (MDCG) and specific focus should be placed on establishing regular discussion at this forum to identify solution and monitor progress on implementation of the Regulations in close partnership between the Commission and the Member States.

Together with the Commission the Member State authorities need to urgently define a joint plan for implementation with clear and consistent approaches to provide for effective implementation and operation of the regulatory system to address identified challenges across the implementation programme with short, medium and long term operational and strategic solutions.

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CAMD Executive Group