EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Medical Devices and Health Technology Assessment

Draft Minutes

MDCG - EUDAMED Subgroup
CAs only meeting

28 April 2022

MDCG EUDAMED Subgroup meetings are not public and they are intended only for MDCG EUDAMED Subgroup members and selected observers. The meeting was held as a virtual meeting with video-audio connection.

1. Welcome & adoption of agenda

COM welcomed the participants and reminded the house keeping rules. The previous meeting took place 17 February and the minutes have been endorsed in writing and published.

The agenda was adopted.

2. Feedback on plenary session

Some Member States (MS) understand the Notified Bodies (NB) concerns and advice the COM to investigate how to make NBs obligations regarding EUDAMED easy, decrease complexity and consider the Data Exchange (DTX) machine to machine (M2M) upload possibility for NBs.

Some MS stressed the importance of having a system stable enough in the Playground as they have noticed Stakeholders reluctance to test when the modules are not stable enough and constantly improved. As a consequence if the Economic Operators (EO) are late in the testing process the CAs testing may be challenging and delayed.

3. Eudamed functional specifications

The COM explained that as regards the interoperability with the CTIS, it had followed up with European Medicines Agency (EMA) as agreed last meeting and confirmed that EMA agrees with the COM approach to start working together to implement interoperability after Minimum Viable Project (MVP).

The COM had circulated an updated functional specifications (FS) document focusing on the first 3 modules (Actor registration, UDI/Devices and NBs &

Certificates) FS. The main updates concern the prioritisation of functionalities after MVP (priority scale “High, Medium and Low now only refers to those) and the adjustment of some FS to reflect changes needed and agreed at technical level.

The changes to the document do not constitute a revision of the FS or the MVP but a necessary adjustment to reflect more accurately the situation in view of the independent audit. The document has been shared to keep the MS involved in the finalisation of it, since the FS document will serve as the basis for the audit itself. CAs have still time for comments until 15 May.

MS underlined that a detailed planning would be welcome, including for the FS after the MVP. MS also voiced that a too restrictive MVP approach is not ideal for CAs and may be cumbersome to use and result in extra costs and in practice lead to a partial audit.

4. **Requirements finalisation**

COM provided a detailed state of play on the requirements to be closed for all modules and presented the COM proposal for DTX for the second set of modules (Vigilance, CI/PS and Market Surveillance).

Most of the DTX requirements are still to be defined for the 2nd set of modules services as well as the technology for the UDI/Device bulk download from public website.

A DTX WG is scheduled 12 May and the COM hopes to make significant progress on the requirements definition.

COM clarified that User Interface (UI) is developed first and the development of DTX M2M comes after because the UI has to be first stable enough and agreed to start DTX M2M development for avoiding as much as possible changes in DTX that are costly for everyone implementing it. COM said that if certain DTX functionalities are developed quickly enough after MVP they could still be ready before the end of the MDRs transitional period.

COM explained that DTX is a significant investment for EC, CAs and Stakeholders and the download is much easier than the upload. Functionalities, although facilitating the use of Eudamed, but not strictly required by the regulations (non-MVP) should be implemented after the MVP delivery. This will avoid to further delay the delivery of an MVP EUDAMED. If more functionalities than those presented in the COM proposal have to be delivered together with the MVP functionalities, this will have an impact on the planning.

Some MS were in favour of adding to the MVP the NBs upload and download M2M.

COM stressed that the general objective is to find a right balance to get a fully functional EUDAMED mandatory to use within the best delay. If the M2M functionalities out of the MVP can come quickly after MVP it would be a good compromise. COM added that when a new system is released it evolves and can

be gradually improved. The MVP is to be understood as the absolute minimum with what the system can work and, afterward, make the system evolving.

5. AOB /Q&A

COM closed the meeting thanking the participants for the very productive discussions and reminded that CAs have time to comment the FS document until 15 May.

The next meeting is provisionally scheduled 7 July and will be CAs only. The next Plenary meeting will be after the summer.

Participation

MDCG EUDAMED members: AT, BE, CZ, DK, DE, ET, GR, IE, ES, FI, FR, HR, HU, IT, MT, NL, PT, RO, SI, SE,

Observers: TR, NO, IS

Commission: SANTE B6, SANTE A4