EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Medical Devices and Health Technology Assessment

Minutes

MDCG - EUDAMED Subgroup
CAs only meeting

28 June 2021

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

1. Welcome & adoption of agenda

COM welcomed the participants and reminded the housekeeping rules.

The main discussion of the meeting will be the gradual roll out. After the summer the COM has the intention to organise MDCG EUDAMED WG monthly meetings to provide update on development and discuss and solve potential issues very quickly.

The previous meeting minutes have been endorsed by written procedure.

A Member State (MS) suggested exchanging about the MS experience with of the Actor module and the possibility of improvements. This topic will be in the September meeting agenda.

The agenda was adopted.

2. Planning & roadmap

COM presented the state of play and described the new features that will be available with the July Playground. The roadmap has not changed since the last meeting in April. COM reminded that the roadmap is an ongoing process constantly reviewed and adapted by iterations following the evolution of the discussion and additional requirements, and provides an estimation based on the knowledge of the requirements known today.

The target remains a production release in September for the UDI/Devices and NBs & Certificates module, and Q4 2022 for the delivery of the complete

Eudamed. During 2022 there will be additional Playground releases for the coming modules. The Audit will take place afterwards and is expected to last between 3 and 6 months.

3. Roll out approach

The discussions about the gradual roll-out started in early 2020, after the first delay announcement. MS welcomed and agreed to this approach in the March 2020 High Level MDCG. The general thought was that gradual roll out and a voluntary use of the module deployed could work and reduce duplications.

While the release of the Actor module in December 2020 in general has been welcome and works well, it has not been possible to ensure a fully coherent approach due to the voluntary nature of the system at this point in time (before full functionality). This has resulted in discussions and further reflections about the feasibility of releasing, on a gradual basis, the remaining modules in production.

COM has circulated a short survey to MS and based on the input received assessed the situation. A document was circulated ahead of the meeting presenting the potential issues in case of a non-harmonised approach to the gradual roll-out of the various modules, illustrating the workability or the impossibility of certain functionalities.

COM summarised the situation:

Actor module: current voluntary use works well

UDI/Devices module: voluntary use would be possible, but certain information related to Vigilance and Certificates will not be available yet.

NBs and Certificates module: Certificates registration would be possible, however two new features from MDR, the mechanism for scrutiny (MfS) and the Clinical Evaluation Consultation Procedure (CECP) registrations, cannot be enforced in EUDAMED without enforcing the certificates registration as well. Therefore, voluntary use will not work for MfS and CECP and it was suggested to keep those functionalities out of the September production release.

CI/PS module: cannot work under voluntary use as a fully coherent approach cannot be ensured.

Vigilance module: cannot work under voluntary use as a fully coherent approach cannot be ensured.

MSU module: voluntary use could work for all functionalities except for the procedure dealing with devices presenting unacceptable risk to health and safety.

A few MS took the floor in the discussion, mainly supporting the roll-out of the 1st set of modules (Actors, UDI/Devices and partially NB & Certificates), even if double registration in some MS could to be ruled out. Information relating to economic operators, devices and certificates will need to be in EUDAMED and

the use of these modules may facilitate the transition to EUDAMED once it becomes mandatory.

Since the guidance on alternative solutions in the absence of a fully functional EUDAMED (MDCG 2021-1 Rev.1) enforces the use of CIRCABC, COM with support from some MS, suggested that CIRCABC could be replaced by using EUDAMED when the concerned functionality is available. COM stressed that the idea is not to enforce EUDAMED via national provisions, but simply using EUDAMED functionality when available on voluntary use or instead of CIRCABC.

On the other hand, it was generally understood that the MfS and CECP functions were more problematic as directly attached to certificates registration. This should be in only one place and have the same location for all MS (national level, EUDAMED or CIRCABC).

For the 2nd set of modules (Vigilance, CI/PS and Market Surveillance), it was generally agreed that, except for market surveillance, release before EUDAMED full functionality is not possible because a fully coherent approach cannot be ensured.

One MS raised an issue about the design of EUDAMED that links the certificate registration to the MfS. COM replied that the design of EUDAMED was done to be optimal at the end of the transitional period. It was also explained that the links between the different modules will work when fully functional and will avoid entering several times the same information by different actors with a better guarantee on the data quality and no discrepancies on data between modules wherever possible.

It was concluded that MSs agree in general with the document circulated by the COM.

4. Ongoing work

COM informed that the MDCG 2021-13 Q&A actors registration has been recently endorsed and presented the progress in the technical WGs.

Vigilance: COM informed about the final discussions about the MIR PDF form v.7.3. EUDAMED will be compatible with the xml generated by the PDF form. The next EUDAMED Vigilance WG is scheduled 8 July and will include discussions on the 6 Vigilance items (MIR, FSCA/FSN, NCAR, PSUR, PSR and Trend reports) The requirements setting is very advanced, except for the PSR and Trend Report for which the COM will present a MVP proposal.

Market surveillance: the relevant MSWG TFs have provided all the requirements for the 6 MS items. A few clarifications on the procedure for dealing with device presenting an unacceptable risk to health and safety will still (most probably) be needed.

CI/PS: a CI/PS WG meeting took place on 17 June. The application and notification forms and their updates are defined. The main points to clarify are substantial modifications (two issues under MVP: no possibility of requesting additional info and clock stop), coordinated assessment (having all steps managed in EUDAMED is complex and it is extremely challenging to make it workable, a new work package about coordinated assessment has been established within the CIE WG) and end report (metadata to be defined depending on template still to be elaborated by CIE).

COM underlined that the highest risks of delay for having EUDAMED fully functional come from the PSR and the CI/PS coordinated assessment, which is paradoxical as both are optional to use but required according to MDR.

5. AOB / Q&A

COM closed the meeting thanking the participants for their input on the roll out approach.

The next meeting is scheduled 23 September and there will be an agenda point on the MS experience on using the Actor module and actor use as well as the usual agenda point on the roadmap.

COM will send the working documents in advance to a maximum extent but the roadmap can only be sent one or two days in advance as it is done just before the meeting.

6. List of participants

MDCG EUDAMED members: AT, BE, DK, DE, ES, FR, FI, EL, HU, IE, IT, MT, NL, PT, PL, RO, SE

Observers: TR, NO, IS

Commission: SANTE B6, SANTE A4

Brussels 12 August 2021