EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Medical Devices and Health Technology Assessment

Draft Minutes

MDCG - EUDAMED Subgroup meeting

4 July 2022

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

1. Welcome & adoption of agenda

COM welcomed the participants and reminded the housekeeping rules.
The COM pointed out the importance of having feedback as soon as possible on releases deployed in Playground.

The agenda was adopted as it was proposed by the COM.

2. Eudamed planning

COM presented the EUDAMED state of play slideshow starting with status (3 modules in Production and 2 additional modules in Playground with technical support treating around 200 tickets/week) and statistics (numbers of actors and devices registered in EUDAMED are increasing regularly).

Q2 releases (Production 2.8.1 and Playground 3.1.0) are targeted for mid-July with deadline for feedback by mid-September. Release in Production and Playground releases include improvements on functionalities and for Playground additionally first features for clinical investigation/performance study, as well as new features for market surveillance and certificate modules. Therefore Q2 release in Playground will be the first release that will include functional specifications from all 6 modules of EUDAMED.
A video demo was shown on new features of clinical investigation/performance study and market surveillance modules.

Information on the EUDAMED customer service was provided indicating that the number of tickets to deal with is increasing slowly with time, this is consistent with the increased number of users and new functionalities made available with a peak after Q1 releases deployment.

The machine-to-machine data exchange support will improve and will be closer to the CAs technical staff using such functionalities to facilitate usage and integration.

A publicly available information centre website on EUDAMED is being set up and will be made available around mid-July for Production and end of September for Playground.

The roadmap/planning has been revised with now end of 2023 as expected target for completion of EUDAMED MVP (Minimum Viable Product) development. New releases are foreseen every quarter. The audit will be carried out in 2024.

COM explained some of the issues encountered on previous releases which contributed to the revised planning. These include: quality assurance checks and detected instability of the system, implement numerous change requests to respond to feedback and to additional clarifications received throughout the process, complexity of the use cases, including interdependencies between modules. The support of both production and playground in parallel, human resources issues due to the Covid situation and a few key people that left the team early 2022 also contributed to the revised timeline. There is still significant work to be done on all 6 modules, especially on vigilance and clinical investigation/performance study modules.

Some Member States noted with concern the revised timelines. The attention to the machine-to-machine data exchange was welcomed and several Member States reiterated the importance of the data exchange features, in order to facilitate especially the work of notified bodies.

The setting up of an Information centre was appreciated so to allow a better accessibility of Eudamed documentation and so to have a repository of such information.

Some were wondering how the complexity of the system could not have been reduced in the context of the MVP. COM explained that the complexity is mainly coming from the requirements of the MDR/IVDR that cannot be reduced by the MVP. In addition, the complexity of the transition period rules, requiring a lot of flexibility from the system in a strict framework, defined also by numerous guidance documents, pose additional challenges to the development of the EUDAMED, which remains a very ambitious project.

Member States recognised the complexity and the ambition of the EUDAMED, especially considering data exchange needs, but noted with concerns that more delay means more cost for Member States, therefore underline the importance to limit as much as possible delay. COM is well aware and is trying to put in place all possible measures to face the challenging situation.

The COM will share with the audience the planning with the additional supporting material that will give a good view on what remains to be delivered per quarter. This delivery plan shall allow all following up progress more closely.

3. Functionalities after MVP

COM presented a proposal of prioritisation of the functional specifications (FS) to be implemented after MVP with an introduction to clarify once more what MVP means, and that only the MVP scope will be audited.

A first set of 15 non-MVP top priorities ranked from 1 to 15 were proposed knowing that all of them could be implemented within the 2 years transition period starting from EUDAMED full functionality. It was also pointed out that most of them could be even implemented within the 6 months after MVP, therefore, that they could be available as soon as EUDAMED will be mandatory to use.

Other functional specifications were presented with a lower priority (like FS on CECP workflow management) or as alternatives of some of the first 15.

The full list of non-MVP functional specifications was already shared with the members of the WG for them to provide feedback to the COM by mid-September on changes they would like to have in the non-MVP priorities.

It was agreed that EC will send the consolidated current list of functional specifications, for enabling Member States to indicate whether there are functional specifications not included in MVP, but that should be considered as a non-MVP high priority.
COM clarified that the current list of functional specifications could be still subject to adjustment in the future, members of the WG will be kept informed on any developments through the process.

COM will continue open communication on regular basis, took note of concerns on impact on national planning, and needs feedback on non-MVP priorities by mid-September at the latest.
These regular meetings will resume after mid-September.

Participants

MDCG EUDAMED members: AT, BE, CZ, DK, DE, ET, FI, ES, IE, IS, FR, FI, GR, HU, IT, MT, NL, NO, PL, PT, RO, SE, TR

Commission: SANTE B6, SANTE A4