EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Medical Devices and Health Technology Assessment

Draft Minutes

MDCG - EUDAMED Subgroup
CAs only meeting

17 February 2022

MDCG EUDAMED Subgroup meetings are not public and they are intended only for MDCG EUDAMED Subgroup members and selected observers. Due to the COVID-19 crisis the meeting is 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 9 December 2021 and the minutes have been endorsed in writing and published.

Significant progress has been made since the last meeting, both for gathering requirements and for the system development. COM encouraged the participants support the EUDAMED project helping to close the remaining requirements and providing feedback in the coming Playgrounds.

A MS asked for an AOB point concerning the “promotion” of the Playground to gather feedback and having enough testing data for the different use cases. COM always promotes the use of the Playground and about the testing data COM relies on the active participation of all testers to create all the data needed to simulate all scenarios.

A MS brought an issue about NBs & certificates module new functionalities and how those new features match with the CAs administrative tasks. To be discussed under AOB.

The agenda was adopted.

2. AWP – NWIP

The Annual Work Program (AWP) and a New Work Item Proposal (NWIP) for a Guidance on alternative technical solutions for IVDR have been sent for consultation on 31 January with deadline for comments 15 February.

A MS sent comments requesting the addition of a new work item in the AWP to assist stakeholders in the use of EUDAMED (this include extensive

documentation, guidance, trainings etc) and said that from their experience they know that Industry is hesitant to engage with EUDAMED for the devices registration.

COM will provide as much documentation and support as possible but advised not to add a specific work item in the AWP as the AWP lists activities of the EUDAMED subgroup (not of the COM). COM reminded that 2022 is fully dedicated to the delivery of the EUDAMED MVP on time, therefore all additional items not strictly related with the development would need to be deprioritised and/or postponed.

COM reminded that the use of EUDAMED is for the time being under voluntary use and suggested to put the topic of industry preparedness and engagement on the agenda of the next MDCG EUDAMED Plenary meeting with Stakeholders.

A MS would like to discuss about the interoperability with CTIS. This topic will be addressed in agenda point 4 and COM will come back to the AWP at the end of the meeting.

Following the discussion on CTIS, participants endorsed the AWP and the NWIP. They will be sent to the MDCG for final endorsement.

3. State of Play - Roadmap

COM presented the roadmap reminding that EUDAMED is a challenging project, integrating 6 modules and a public website, the first 3 modules are in production and the other 3 coming modules will be only in Playground until EUDAMED is fully functional and mandatory to use.

COM presented the state of play, some figures, the target for the next release in production of the first 3 modules, the target for the Q1 Playground with features of the last 3 modules and the delivery roadmap.

COM underlined the importance of next steps: closing the requirements Q1 2022 and the Playground feedback all over 2022. COM called on participants to liaise with experts active in the technical working groups to ensure that the timelines could be kept. COM said that the timelines will be assessed regularly and after Q3 2022 there is a 3 months time period to finalise the development to be ready for the audit.

COM also presented general information on the EUDAMED customer service underlining that more than 70% of the support requests are related to the fact that CAs do not provide any feedback on the economic operators Actor Registration requests.

A MS asked for more details on the COM decision of releasing new versions of a module, how this is communicated and the timing.

COM fixes the requirements with the support of the different concerned WGs and task forces. Sometimes it is agreed to apply some improvements in the first 3 modules and the COM widely informs in advance on the timing and the scope of the new releases and the new functionalities that will be deployed. Afterwards the Playground is available to provide feedback.

The timing depends on when features will be implemented. The rule is that when something is developed it is released as fast as possible in the Playground in order to get the related feedback as soon as possible.

COM explained that voluntary use for the Vigilance and Clinical Investigation/Performance Studies (CI/PS) modules is not possible and that for Market Surveillance module it is not foreseen yet. This was decided in a former WG[1]. These modules will only be available when EUDAMED is fully functional and mandatory to use.

COM insisted on the need of the participants help and support to close all requirements asap.

4. **Requirements finalisation**

COM provided a detailed state of play on the requirements to be closed and encouraged the participants to liaise with their CAs representatives in the other WGs to finish the requirements.

For the 1st set of modules, Actors, UDI/Devices and Certificates, as well as for the Market Surveillance module all requirements are defined and COM will deliver the remaining functionalities during 2022.

For Vigilance and Post market surveillance, COM expects to close the requirements during the next EUDAMED Vigilance WG meeting scheduled 3rd March.

For CI/PS the coordinated assessment process is expected to be approved during the next CIE WG meeting scheduled 7-8 March. The Substantial modification in the context of coordinated assessment and the transparency are still pending of final requirements. For the other topics only fine tuning remains.

A background document on the COM position about the interoperability with the CTIS has been sent. The COM proposal is to postpone the implementation of the interoperability between CTIS and EUDAMED for after the EUDAMED MVP as it is practicably not possible to close this requirement at this point in time because the CTIS has just been put in production and is still in a transitional period.

Thus, the COM suggests, in order not to significantly delay the whole system, to remove the functionality from the audit scope, to work on this in the period between declaration of full functionality and mandatory use. Following some discussion, during which a few MS asked questions and expressed concerns about the proposal. Following further explanations by the COM the EUDAMED WG agreed to the approach suggested by the COM but called upon the COM to come back with a specific timetable for this interoperability requirement. It was also agreed to inform the MDCG about this approach.

[1] See MDCG EUDAMED WG 28 June 2021 minutes

For Data Exchange (DTX) many of the requirements for the 2nd set of modules (Vigilance, CI/PS and Market Surveillance) are to be defined/agreed as well as the technology for the implementation of UDI/Device bulk download from public website. COM will organise a DTX WG meeting Q2 2022.

The Q1 Playground will include the NCAR feature to tackle the exchange of info between CAs. CAs will be able to communicate between them corrective actions they required, but for MVP, the NCAR feature will only allow exchanging minimum essential information, not to provide all details about a corrective action. In the context of DTX for sure download by CA will be possible, however the upload is a pending question except for MIR, PSR and FSCA/FSN by manufacturer/AR.

5. Eudamed Demo

COM presented some Q1 Playground functionalities.

The demo is a sneak peek of the Vigilance and CI/PS modules. COM will provide similar videos for each of the forms that will be released in the Playground.

The demo was well received.

6. AOB /Q&A

A MS expressed concerns on the NBs & Certificates module: currently any DA can enter a withdrawal or suspension request of a certificate of any NB. One MS sent feedback to the EUDAMED team asking to add business rules to prevent misuse. A DA should only be able to register request concerning its own country NBs.

COM is aware of this issue, ideally EUDAMED should prevent such possibility but in the context of the MVP approach COM considered that DAs should know their rights and that since only for exchange of information between DAs/CAs, such rule is not really essential and was not implemented under MVP simply to save time (there is also a discard possibility in case of mistake). However, since it is considered important, the change for having this constraint will be implemented.

The next meeting, is scheduled 28 April and most probably there will be a Plenary session with the stakeholders.

COM recapped the meeting conclusions:

- All remaining requirements should be closed by end of March 2022, participants are encouraged to help and support the COM.

- COM will promote the use of the Playground

- The MDCG EUDAMED WG agrees to postpone the interoperability with CTIS and exclude it from the Audit scope
- The EUDAMED AWP was endorsed and will be sent to MDCG
- COM will circulate the demos and the meeting presentations
- COM closed the meeting thanking the participants.

Participation

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

Observers: TR, NO, IS

Commission: SANTE B6, SANTE A4