EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Medical Devices and Health Technology Assessment

Minutes

MDCG - EUDAMED Subgroup meeting CAs only

6 October 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

The Commission welcomed the participants and reminded the housekeeping rules.

The Commission announced that following DG SANTE reorganisation, since 1 October, the new name of the Units are D3 – Medical Devices and R3 - IT Unit.

The Commission reminded the progress made since last meeting; the Q2 releases were deployed mid-July. For the Playground with the first functionalities of the Clinical investigation/Performance Study (CI/PS) module and for Production bringing improvements, bug fixing and the launch of the EUDAMED information centre.

The EUDAMED information centre is available in the Production environment. It will gather all the documentation of EUDAMED in one place and will be significantly improved with Q3 release.

In the AOB, the Commission will also inform about the interoperability with the Clinical Trials Information System (CTIS) database and a participant asked to add a point on how to manage the withdrawal/deactivation of economic operators (EO).

The minutes of the previous meeting have been endorsed in writing and are published in the RegExp.

The agenda was adopted.

2. EUDAMED **planning**

The Commission presented the project status and statistics, the customer service, the next releases scope (Playground and Production), a video demo and the roadmap.

The next releases dates are scheduled end October for Production and mid-October for Playground with a deadline for feedback until mid-December.

The Commission detailed the delivery plan for Q3 2022 and its impact on the roadmap. The development is progressing well and only the CI/PS module is behind schedule.

The Commission presented a demo of the Market Surveillance module mainly presenting the new features that will be delivered with the Q3 release.

The Roadmap presented the number of Use Cases to implement per module and per quarter.

The Commission explained that the priority of the change requests is generally a result of the users' feedback analysis and they are added to the existing development plan.

3. Priorities for Functionalities after Minimum Viable Product (MVP)

A document to prioritise the non-MVP functional specifications (FS) was shared in July with the participants and the Commission received comments from 3 Member States (MS) by the deadline for feedback in mid-September.

After the publication of the notice on EUDAMED full functionality[1] which will follow the independent audit of the full MVP, there is a transition period of 6 months before the fully functional minimum viable system goes live in production and becomes mandatory to use. The Commission expects achieving the development of a number of non-MVP features already within these 6 months. There are 15 high priorities that are selected for after MVP.

Following a request for clarification from a MS, the Commission reminded that, there are currently two different environments available for use: the Production : is the real environment, to be used to enter the real data for the purpose of complying with the MDR/IVDR obligations and the Playground: the testing/training environment to be used to test the system and provide feedback and to learn how it works and for which all the data entered are considered as dummy.

[1] Fully functional minimum viable system includes all the functionalities indicated as MVP for their legal priority in the Functional specifications document, either because strictly required by the MDR/IVDR or because absolutely necessary for the workability and usability of the system

In Production, the first three modules (Actors registration, UDI/Devices and NBs & Certificates) have been made available to be used on a voluntary basis. In Playground, the first three modules with some additional functionalities (including CECP and mechanism for scrutiny), and part of the last three (Post-market surveillance and Vigilance, CI/PS and Market surveillance) are currently available only for testing/training purposes.

According to the planning, the forthcoming releases containing the remaining functionalities of the last three modules will continue to be deployed only in the Playground environment.

The last three modules, together with some functionalities of the first three modules (e.g. the mechanism for scrutiny and CECP), will not be deployed in Production before they are mandatory to use and will remain in the Playground environment until the end of the 6 months period after publication of the notice in the Official Journal of the European Union (OJEU). This is following the decision taken in 2021 by the EUDAMED WG, due to the impossibility of ensuring an harmonised use of the system before its use becomes mandatory from MDR/IVDR. Making available such functionalities to be used on a voluntary basis would cause uncertainty and high risk of non-compliance and therefore, resulting in possible public health issues.

The audit will be performed after finalisation of the MVP development and after the positive outcome of quality checks on the MVP scope. The audit will be performed in a dedicated environment restricted to the Auditors to avoid disrupting the use of the Production and Playground environments. This 'frozen' Audit environment will include only MVP functionalities. During the audit time, the Commission will continue developing the Playground environment in parallel adding non-MVP functionalities. Therefore the Commission could deploy some releases in the Playground with a wider scope (with additional functionalities only, not changes to the existing ones), which will not be audited. This will be possible as the post-MVP functionalities do not require audit.

In this context, The Commission has to fix the scope of the audit by closing the FS document specifying the FS with the MVP timing priority, which will serve as a general basis for the functionalities to be audited (all the ones with MVP timing priority).

The Commission went through the non-MVP FS for which it has received comments:

Importer link with devices (comment for having it in high priorities): currently Importers can only link to manufacturers (MFR), about the linking to devices, as there is a transitional period, The Commission considers that increasing the priority is not so important. Priority remains (except possibly if some are out).

Authorised Representative (AR) to indicate disagreement with the devices (comment for having it with a higher priority): as this is not a legal requirement is considered medium priority. Anyway the MDRs establish that the AR will need to

inform the CAs outside EUDAMED if there is an issue with the devices they represent. Priority remains (could be increased a bit if others are decreased).

View & Search European Medical Devices Nomenclature (EMDN) code: this possibility already exists in the public site. Priority remains.

Notified Bodies (NB) Upload/download of certificates (comment for having it with a higher priority): because of the 2 years transitional period for certificate registration after the notice publication in the OJEU for the fully functional MVP, this functionality is not really necessary within MVP. The Commission has received opposite comments (higher and lower) for download. Priority remains.

Request for additional info to the Sponsor: this will be part of the MVP.

Added FS notifying the Sponsor about CA measures (comment for having it in high priorities): in EUDAMED the exchange of info between CAs is only for CAs eyes. What would be possible is just a notification to the Sponsor about the CA decision on a measure. The addition of these new FS is under analysis.

Machine to Machine (M2M) Data Exchange (DTX) upload CA measures on CI/PS: according to the comments received, it seems not to be a priority. To remove from the 15 high priorities after MVP

M2M DTX MFR upload of Periodic Safety Update Report (PSUR) (comment for having it with a higher priority): Higher priority agreed.

MFR upload of the trend report (comment for having it with a higher priority): Priority remains.

M2M DTX Periodic Summary Report (PSR): as this is optional, requires a validation process and it is not about PSR periodic analysis updates that will have that possibility. Priority remains (not a priority for after MVP).

M2M DTX NB upload of PSUR evaluation (comment for having it with a lower priority): Lower priority agreed (switch priority with PSUR upload by MFR).

CAs upload of comments to a draft Field Safety Notice (FSN) (comment for having it with a lower priority)**:** Lower priority agreed but to check with PMSV.

Monitor data for vigilance (comment for having it with a higher priority)**:** this is probably the most challenging functionality to have after MVP. Moreover, before being able to monitor data, first the data has to be entered in the system and it is only after the end of the transitional period that all data will be registered in EUDAMED. Priority remains.

CAs upload of Final Inspection Report (FIR) (comment for having it with a lower priority even outside the high priorities): Lower priority agreed.

The Commission stressed that the needs for M2M DTX upload are to be considered in relation with the number of records to upload considering the significant investments to make for having M2M DTX. It is important to avoid

prioritising DTX features that are not going to be used, or only for few data and/or only by very few Actors.

Once the development of MVP has been finalised (EUDAMED ready for audit), the Commission will continue reassessing the planning, taking into account that, once a system goes live, there is a peak of interventions (fixes/changes/improvements). The Commission expects to be able to continue deploying new releases quarterly in the Playground after MVP development finalisation and before the 6 month after the notice publication.

4. Functional specifications

The Commission objective is to finalise the FS in view of the audit. The Commission has now a better view, particular for the Vigilance and CI/PS modules where some gaps have been filled.

The Commission will send to the participants the FS version 7 for final review, with the The Commission suggested updates for accuracy. These updates will be in track changes. The Commission kindly requests the participants to send their comments, if any, only on the track changes.

This document with the high level FS will be the pillar for the Audit. However, more documentation, as Use Cases and/or test scenarios should be provided to the auditor to perform its task.

The Commission summarised the main updates in FS v7 document:

Actor module: the Designating Authority (DA) is considered separately from the CA.

Horizontal update on data exchange signification: the system will have both possibilities: DTX M2M and manual bulk XML upload. Under the MVP the Commission will consider only XML as file format for data exchange (M2M and bulk).

Devices: DAs considered separately from the CA but with same access rights.

Certificates: DA considered separately from the CA.

CI/PS: addition of new FS considering requirements necessary for the coordinated assessment and the acknowledgment of the post-market performance follow-up / post-market clinical follow-up (PMPF/PMCF) and Serious Adverse Events / Device deficiencies (SAE/DD) because of the particularities of the sponsor registration (Sponsors are not considered fully valid for public information until a CA has acknowledged or validated once CI/PS data entered)

Vigilance: addition of new FS considering requirements related to the PSR (the most challenging feature to implement in Vigilance module because including an

advanced workflow involving different reports), with a distinction between CA and coordinating CA

Market Surveillance: addition of the discard functionalities (in case of mistakes), merge of the FSs (FS-MSU-003 and FS-MSU-004) on the manage and communicate the full and summary reports of 4 years of results of the reviews and assessments of the market surveillance activities and change in the FS requiring an adjustment of the conditions on when the NB can access market surveillance information.

Public part: clarified that for serious incidents, only public part of final reportable Manufacturer Incident Reports (MIR).

The Commission will send shortly the FS v7 document for comments (only for mistakes and strong objections) within at least two weeks. The Commission specified that the non-MVP priorities information discussed in point 3 is included in the FS v7 document (Timing priorities). The FS v7 document should be considered as a final consolidated document containing everything (all MVP functionalities and a prioritisation of additional functionalities for after MVP).

The auditor will get the final FS document as it is defining the audit scope (only FS with timing priority 'MVP' are the to be considered for the audit to confirm that EUDAMED has reached full functionality in the context of Art 34 MDR).

5. AOB

The Commission reminded that the initial idea was to progressively make available the six modules of EUDAMED in production, but last year the EUDAMED WG decided that the CI/PS, Vigilance and Market surveillance modules should remain in Playground until full functionality (because voluntary use is not a possible option for CAs).

The Commission would like to follow up on use of the first three modules on a voluntary basis and asked the participants whether the use of EUDAMED is encouraged in their country and, if any of the MS has, via national legislation, actually requested the use of EUDAMED.

Three MS said that they ask the registration in their national system, but encourage the use of EUDAMED on voluntary basis

A MS obliges the EO to register in EUDAMED and the devices in the national system.

A MS has an act requiring EO and devices to be registered in EUDAMED to avoid double registration and because their national register was not adapted for the MDRs

The Commission reminded that EUDAMED MVP is expected, from current planning, to be officially fully functional Q2 2024 and could be mandatory to use at the earliest Q4 2024. The end of the development is planned end Q4 2023, in the

following 6 months the audit should be performed successfully and the notice to be published. Six months after the publication of the notice in the OJEU EUDAMED can be mandatory to use as established in the MDRs (Art. 123 (3) (d) MDR / Art 113 (3) (f) IVDR).

The Commission gave an update on EUDAMED interoperability with CTIS requirements (post-MVP). The Commission has already had meetings with EMA and reached an agreement on most of what this interoperability could achieve for a first version. The interoperability will go only in one direction: EUDAMED getting info from CTIS (no legal basis in CT legislation for the opposite direction and EMA has already too many things to handle to improve the CTIS). EMA does not want to disclose any confidential/sensitive info even to MDR CAs. EUDAMED will be able to check if the CT ID entered by the sponsor in EUDAMED exists in the CTIS and on the CA side, additionally they will see the status, title (full or short, not determined yet) and some of the sponsor details of the related CT. All CAs registered in EUDAMED will have the same access to that information.

About the withdrawal/deactivation of EOs, the Commission explained that the functionality of setting an EO actor as deactivated by its Local Actor Administrator is expected to be part of Q4 22 release (that should be deployed in Production beginning of Q1 2023).

About how to deal with the Person Responsible for Regulatory Compliance (PRRC) data, that should not be visible to the public anymore after an Actor deactivation, the Commission will consider it as well.

The Commission recapped the meeting outcoming actions:

The FS v7 document will be sent shortly[2] (including adjustments of non-MVP high timing priorities) for at least a 2 weeks period for comments that should be only on the track changes.

The next meeting agenda could have a point on how to deal with the PRRC that wish to be deleted.

The next MDCG EUDAMED WG is scheduled 15 December and it will be with stakeholders.

The Commission closed the meeting thanking the participants for the common efforts to achieve the MVP within best delay.

Participants

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

Commission: SANTE D3, SANTE R4

[2] The FS v.7 document was sent on 12 October with 4 November deadline for comments