



Draft Minutes

MDCG - EUDAMED Subgroup Plenary meeting

28 April 2021

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 last plenary meeting took place the 9 December and since then two new releases have been deployed: Production 2.7 with new functionalities for Designating Authorities and the Commission and Playground 3.0 with the first functionalities of the Vigilance and Market Surveillance modules. In today's plenary session, both CAs and stakeholders can share their comments and questions on the new releases.

The COM is also working on the guidance on alternative means in the absence of EUDAMED for IVDR. The COM is currently processing the comments received.

Two additional AOB points were added the agenda: a Notified Bodies (NB) presentation about the NBs concerns and a MedTech Europe presentation to address industry readiness.

The previous meeting minutes have been endorsed by written procedure and are published in the RegExp.

The agenda was adopted.

2. Planning & roadmap

COM presented the state of play. COM is focusing on delivering audit ready functionalities under the Minimum Viable Product (MVP) approach. Anything that does not clearly fit the MVP context is to be considered out of scope.

The coming Production releases will mainly focus on bug fixes, but will also contain essential changes and enhancements agreed during the evaluation of feedback. If required, more frequent Production bug fix releases can be considered.

The coming Playground releases will also include all the Production enhancements. A Playground release is planned minimum once a quarter. Each release scope and content will be timely communicated.

The COM is gradually improving the EUDAMED customer service. The [SANTE EUDAMED SUPPORT](#) can be contacted for any problem.

COM invited the participants to provide Playground 3.0 feedback by 10 May and underlined the value of the participants support and collaboration during the next releases to help the COM to deliver a stable and performing MVP. .

3. New releases

COM reminded that for each deployment (both, in Production and Playground) the release notes are available in EUDAMED under the help menu and also in the landing page “user guide” link and recommended users testing the Playground to read the release notes, particularly the pre-requisites and the known issues.

For the current Playground 3.0, COM specified that a user can only be associated to one single actor to test vigilance. COM expects to have this bug fixed in the next release.

If some users have difficulties to access the Playground, [SANTE EUDAMED SUPPORT](#) can help them.

The COM will analyse any piece of feedback brought on by test users and current users, solve the bugs and prioritise the improvements.

4. AOB / Q&A

MedTech Europe presented the Industry readiness to use EUDAMED under voluntary basis and listed the challenges to early use the UDI/Device module. The main benefit is obtaining the SRN but using the system extensively has a value only once it reaches a stable and validated state. CAs uniform use of the system would be welcome to avoid duplicate registrations in national databases. Non-harmonised use of EUDAMED may prevent some actors (SPPPs) from accessing EUDAMED during the voluntarily period.

MedTech Europe commented the new releases and stressed that over 30 bugs are reported for the Vigilance Playground, some issues are not indicated in the release notes and the Vigilance module is quite unstable and not complete. MedTech Europe also said that it is important to ensure stability and, as far as possible, completeness of the functionalities in the releases to maximise the

usefulness of the feedback and to avoid testing multiple times the same functionality. M2M specifications are particularly expected.

MedTech Europe stressed the importance of first testing in Playground for new features/improvements to detect issues prior to deployments in Production and mentioned some M2M functionalities that are broken since the new Production release.

MedTech Europe suggested a categorisation to assign a severity level to the issues reported to the support, an harmonised application of the UDI-DI data elements definitions and welcomed the alignment of the releases version numbers with the related documentation, as well as with the release notes and change logs.

MedTech Europe highlighted once more the urgent need to clarify the UDI-DI triggers (the list of device registration data elements which if changing will trigger a new registration thus the assignment, labelling and registration of a new UDI-DI – i.e. if the field is updatable or not) that will be imposed by EUDAMED.

NBs presented their main concerns:

- That DTX M2M for NBs and the discard function are considered out of the MVP scope,
- open questions remain about the CECF, the SSCP and the PSUR,
- the use of CIRCABC for the management of (PECF) Class D with no Common Specifications,
- the Management of refusals and withdrawals (because the SRN and the Basic UDI-DI are required)
- no trainings for NBs are planned so far

NBs stressed that when the system will be fully functional existing certificates will need to be registered, so registering certificates only with issued and re-issued status is too restrictive. NBs also voiced that the NBs need access to the CI/PS module, particularly regarding PMCF /PMPF and, finally, spotted the enormous amount of documentation relevant for NBs (as MDCG Guidance and EUDAMED documentation) and underlined that it takes time to acknowledge all these documentation and changes.

COM thanked MedTech Europe and Team NB. COM is aware of the voluntary uses challenges that has both advantages and disadvantages, COM is very much in favour of an harmonised approach among all the MS but as long as EUDAMED use is voluntary this cannot be forced.

About the amount of documentation the COM is trying to find the right balance and takes note of the training needs and the testing challenges.

A new Playgrounds release is scheduled by mid-May with the first functionalities of the Clinical Investigation and Performance Studies module,

The date of next Eudamed WG Plenary is not yet fixed, possibly after summer.

The COM closed the meeting thanking the participants.

Participants

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

Observers: TR, NO, IS, AESGP, Biomed Alliance, COCIR, EAAR, EFPIA, EUCOPE, EUROM I, EUROM VI, EUROMCONTACT, GS1, HOPE, MedTech Europe, NBCG-MED, Team-NB

Commission: SANTE B6, SANTE A4