EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Medical Devices and Health Technology Assessment

Draft Minutes

MDCG - EUDAMED Subgroup Plenary meeting

9 December 2021

MDCG EUDAMED Subgroup meetings are not public and are intended for MDCG EUDAMED Subgroup members and selected observers only. Due to the COVID-19 crisis the meeting is a virtual with video-audio connection.

1. Welcome & adoption of agenda

COM welcomed the participants and reminded the housekeeping rules. The agenda was adopted.

2. Planning & roadmap

COM presented the roadmap reminding that EUDAMED is a challenging project, integrating 6 modules and a public website.

The first set of modules is live, including data exchange; the Actor registration module since December 2020 and UDI/Devices and NBs & Certificates since September 2021 and no blocking issues have been reported. COM recapped all the functionalities that are so far delivered.

COM stressed that the timelines depend on the good progress of the clearance of the requirements and development itself. COM presented the state of play and current planning until EUDAMED is declared fully functional.

The target is to finalise the MVP system development by Q4 2022. Afterwards will follow the Audit, the MDCG consultation and the publication of the notice of full functionality in the OJEU. After the publication of the notice, the use of Eudamed will become mandatory as per the timelines set out in MDR and IVDR. The last three modules will be released only in Playground until that moment.

COM detailed the progress planned for both new Production (1st set of modules) and the Playground release (2nd set of modules) to be ready Q3 2022 (Q4 will mainly be for improvements and bug fixing). The first Playground release is

expected to include functionalities from all 2nd set of modules; Vigilance, CI/PS and Market Surveillance. In 2022, the COM expects to deliver releases in both Production and Playground every quarter.

COM clarified that when EUDAMED will be fully functional the playground will be open to everybody (from the publication of the notice of full functionality in the OJEU), but before that, the Playground will only have a limited access for the WG selected representatives to provide feedback. New features and improvements for the first set of modules are considered for Q3 2022 but need to remain within the MVP approach.

3. Eudamed Implementing act (IA)

COM informed about the adoption of the EUDAMED Implementing Act and stressed that it is an important achievement.

4. Use of ACT – DEV – CERT modules

The COM gave the floor to Team-NB and MedTech Europe to present their feedback on the 1st set of modules use.

Team NB presented NBs experience for the Playgrounds 1 and 2 and Production. NBs had some remaining questions about clarity on the actors' name, the CECP and could not widely test the IVDR as there are not enough IVDR devices in the Playground to test.

NBs also thought that there are class III and IIb devices requiring certificate registration for confirmation that should not be visible in the public site because no certificate were registered for them and that requirements of MDCG 2019-9 guidance for SSCP languages need to be clarified i.e. which languages are accepted by different Member States.

MedTech Europe presented their feedback, particularly about the number of access points per actor, managing mergers and acquisitions, the non-harmonised use of the Actor registration through the MSs (particularly about optional fields that could trigger new UDI-DIs), mandatory use of EUDAMED enforced by national law during voluntary period, MS that do not validate SPPP, change management (release process of playground and production environment updates including Release notes, Change log, Versioning of documents, websites), transfer of translated and non-validated SSCP upload functionality to manufacturers, Master UDI, EU UDI triggers list and UDID data fields' description (definitions) enhancements and Correction and Edit mechanism in EUDAMED. MedTech Europe also commented the IA, specifically the malfunction mode, the execution of data submission and the helpdesk.

COM replied to Team NB explaining that:

- To fully test the system in the Playground, there is a dependency between the manufacturer entering the devices and the NB entering those devices certificates. A possible solution would be giving NBs accounts to act as MF and enter the devices they need to test.

- For the SSCP the COM is analysing possibilities to enable flexibility on the SSCP management. On the Actor name there is no possibility to improve the actor registration, it depends on MS actor validation, for EUDAMED the name should be the one used in the label. The SRN identifies the EO in EUDAMED, not the name.
- Devices that are available in the public website are in Registered state, not in Submitted state: only class III, class IIb implantable (not suture, staples …) and class IIb devices requiring type examination are not visible if no certificate registered. The class III and class IIb visible are either Systems/procedure packs (not devices) or IIb devices for which the NB confirmation is not necessary because they require only QMS certificates or MDD (legacy) devices.
- SSCP translations' upload: two different actors cannot be given the possibility to enter data for a same record, so as MDRs do not involve MFs for the SSCP translations, for the time being it remains an obligation of NBs.

COM replied to MedTech Europe explaining that;

- 2 access points will be possible when the Vigilance module will be made available, one for the actor and another for a third party provider for a different module. More than two access points for one SRN for UDI + VIG modules are not possible.
- Mergers and acquisitions are not considered with MVP, COM will analyse the possibilities at a later stage, but logically UDIs will change if for another Actor.
- COM cannot force harmonised use among MS, and MS cannot legally mandate the use of EUDAMED during the voluntary period. The use of EUDAMED may only be mandatory after being fully functional via a notice in the OJEU from a time determined in MDR Art 123 (3d).
- For the change management of EUDAMED version releases there will be a difference between Playground and Production, the IA explains the change management (timeline indicated in (EU) 2021/2078 Article 9(3): changes in M2M first to be introduced for testing and training) and depending on how significant the change is the timing could change, with MDCG agreement.
- IA rules will only apply when EUDAMED is fully functional, including malfunction rules.
- COM clarified that manufacturers' legal obligations on devices registration are fulfilled upon submission of the devices data into EUDAMED (i.e. in "submitted" state). It does not depend on the Notified Body confirmation (for certain classes of devices the data only becomes "registered" once the Notified Body links the device data to a certificate). The registration obligations depend on the compliance with the rules to place a device on the market, therefore the next step is for the NB (placing on the market of the devices may only be done after NB confirmation when required).

- The helpdesk is being settled, it is still in a learning curve and is constantly being improved. No escalation mechanism is considered, stakeholders can always contact the B6 unit at DG SANTE.
- About non-editable fields in the actor module, role and country will never be editable as they are fundamental characteristics that if changed will mean inevitably another Actor and that determine the SRN, the other optional but non-updatable fields data fields (VAT information, EORI Number, National Trade Register) are under discussion and for the moment they are considered case by case.

5. AOB / Q&A

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, Biomed Alliance, COCIR, AESGP, EAAR, EIGA, EFPIA, EUCOPE, EUROM I, EUROM VI, EUROMCONTACT, GIRP, GS1, HOPE, MedTech Europe, NB-MED, Team-NB

Commission: SANTE B6, SANTE A4