EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Medical Devices and Health Technology Assessment

Minutes of the expert groups

MDCG EUDAMED Subgroup Plenary meeting
Brussels, 19 October 2020

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 housekeeping rules. This is the first meeting of the MDCG EUDAMED Stakeholders Subgroup, This Subgroup is co-chaired by the SANTE A4 (IT) and SANTE B6 (Policy) Heads of Unit.

COM has responded to a set of questions from MedTech, some of these questions will be also addressed today.

The agenda was adopted.

COM stressed the impact of the Covid-19 pandemic on the Medical Devices sector and thanked the participants for the significant work realised despite of the critical situation.

COM emphasised that the development of EUDAMED is a high priority for the COM. The input from CAs and Stakeholders is essential and all parties involved should have a realistic understanding about the EUDAMED expectations and focus on what is necessary to comply with the MDRs. The present challenge for the COM is having a comprehensive and fast fixing of the requirements. To respect the very tight and ambitions deadlines it is crucial to stick to the minimum viable product (MVP) approach as agreed in the March High Level MDCG meeting. The objective is to deliver a satisfying MVP fulfilling the legal requirements. Enhancements and nice-to-have functionalities will be developed at a further stage.

2. EUDAMED State of play – roadmap

COM presented the state of play and timeline of the first set of modules showing the different development steps and indicating that the planning for second set of modules is tentative as the requirements are not fixed yet. To respect the May 2022 deadline EUDAMED development must be finished by end 2021, the remaining time is necessary to perform the audit and present the audit results to the MDCG. This is very challenging.

COM stressed that the roadmap is a living document continuously updated reflecting progress in a transparent way.

COM explained that the Data Exchange (DTX) functionalities come together with the modules deployment and are available when a module Playground is open. Currently the Actor module DTX services are available and the DTX services for the UDI/Devices and Certificate modules are expected to be available Q1 2021.

COM conveyed a strong message: COM trust full support of participants, CAs and Stakeholders, to work together in a realistic and transparent way to have an MVP EUDAMED allowing relevant parties to comply with their legal obligations under the MDR. This mutual trust and high commitment is essential to deliver within the ambitious timeline.

3. .Preparation to use the Actor module

COM presented the Actor registration module situation: the Playground is open since end September. COM is interested in feedback on bugs, missing features and anything that can be improved. Feedback is possible until 31 October and the faster we get feedback the better. The EUDAMED Team is focusing on go live and will not reply and/or comment the feedback. After 31 October the Playground will remain open. The notifications are not part of the Playground and will be activated when the Actor registration module goes live.

When the modules will go live there will be another environment mirroring production. The Playground for the UDI/Devices and Certificates will be available some time before the deployment into production of these modules .

COM stressed not to enter real data in the Playground. All Playground data is dummy, including SRNs. Therefore, once the Actor registration module will be made available in production, the Actor registration requests must be done in EUDAMED production for having an SRN.

By December, when the Actor registration module will go live, all CAs responsible for economic operator validation and their first two Local Actor Administrators will be entered in EUDAMED and will directly have access to the system.

Stakeholders are concerned by the possible double registrations (at national level and in EUDAMED) and by the harmonisation of the validation process across Member States.

COM reminded that MDCG endorsed, with support by 26 of 27 MS, in August a MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States. According to this paper, the use of the actor module should be encouraged and double registration avoided. COM encouraged following this approach.

There is no harmonised process for the validation and the COM does not intervene for the validation. The decision to validate an economic operator belongs to Member States and could be specific depending on Member States requirements (i.e.: some will require the VAT).

If an economic operator has multiple roles, separated registration requests are required in order to obtain a different and specific SRN for each actor role. There is a unique SRN for each actor role.

One MS specified they will not require double registrations, a registration in EUDAMED will be enough. Other MS were asked to send information in writing.

The CA that has to validate an Actor registration request is the CA where the economic operator is located. When entering an Actor registration request, the name of the

manufacturer must match with the name put on the device label and in official documents like the certificates and the technical documentation.

The COM is working on an Actor registration module Q&A document that will be available once the Playground feedback is treated.

4. AOB

The COM has published new information on the Actor registration module in the Medical Devices Europa website.

5. Conclusions

COM closed the meeting thanking the participants for the useful discussions and underlining the COM commitment to deliver on time a MVP EUDAMED with the support of MS and Stakeholders and reminded that the Actor registration module will be made available in December 2020.

6. List of participants

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

Observers: CH, IS, NO, TR, Biomed Alliance, COCIR, EAAR, EIGA, EFPIA, EUCOPE, EUROM I, EUROM VI, EUROMCONTACT, GIRP, GS1, HOPE, MedTech, NB-MED, Team-NB

Commission: SANTE B6, SANTE A4