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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
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Minutes of the expert groups

Meeting of the MDCG Subgroup EUDAMED

Brussels, 25 June 2020

1. Approval of the agenda and of the minutes of previous meeting

COM welcomed the participants and reminded the housekeeping rules. This is the first meeting of the MDCG EUDAMED Subgroup. Only competent authorities (CAs) participate, stakeholders will participate as from next meeting. The selection process for stakeholders will start soon. This Subgroup is co-chaired by the SANTE A4 (IT) and SANTE B6 (Policy) Heads of Unit.

The file was transferred on 1 January from GROW to SANTE with the new Commission. The EUDAMED project is extremely challenging and requires efforts from all parts involved and is a high priority for the Commission, explicitly mentioned in the SANTE Commissioner's letter of mission.

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.

COM added two points to AOB: UDI issues and Transparency. SE asked for information about the format of future meeting, physical presence or teleconferences.

The agenda was adopted.

2. Introduction from the COM co-chairs

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.

As a crisis consequence, the MDR date of application has been postponed to 26 May 2021 following the proposal from the Commission. The postponement affects to some extent the technical roll-out of the different EUDAMED modules. However, the COM underlined that the work on EUDAMED has continued progressing during the crisis and

the project remains of high priority for the Commission, as pledged at the MDCG meeting in March.

The COM confirmed its readiness to make the modules available to Member States on a gradual basis starting from the Actor Registration module. The Actor Registration module release was postponed from May 2020 to March 2021. The final ultimate deadline for deploying a fully functional EUDAMED remains May 2022. The gradual delivery of the modules will be further discussed in this meeting.

COM conveyed two messages: the need to work closely together with MS in a pragmatic and transparent manner and having realistic views on building a basic system (Minimum Viable Product (MVP)) which allows relevant parties to comply with their legal obligations under the MDR.

3. Objective of Subgroup on EUDAMED

COM explained the objective of the present Subgroup, operating under the MDCG, chaired by the COM and composed of MS and having Stakeholders as observers. COM stressed the importance of feedback from Member States in the development process and the role that the Subgroup will play, especially for the three more complex modules (market surveillance, vigilance and clinical investigation).

The Subgroup will provide help to coordinate the input of the different EUDAMED Module Task Forces avoiding parallel discussions in different MDCG Subgroups; advice on critical issues and help to find appropriate and feasible solutions within a MVP scope; monitor EUDAMED implementation activities and report progress and potential issues to the MDCG. The Subgroup will also act as advising organ, elevating concerns to the MDCG, when agreement cannot be reached or would carry major implications.

4. EUDAMED development

a. General governance structure

COM presented the Governance structure. The purpose is, from one side, to optimise and streamline the consultations reducing the number of different fora to discuss EUDAMED issues and from the other side to optimise and reduce the time required for the IT development. In case of complex issues, related to the MDR implementation, the best support will come from the appropriate MDCG subgroup dealing with legislation. For technical issues the best expertise could be in the appropriate ad hoc EUDAMED WGs. COM also presented the different levels of requirements from the most general, the functional specifications to the most granular, the user stories.

b. State of play and timeline of different modules

COM presented the state of play and timeline of the different modules showing the different development steps, the moment when the module will be ready for playground and the possible gradual releases dates. COM explained that the objective is to deliver an MVP fulfilling the legal requirements. Enhancements and nice-to-have functionalities will be developed at a further stage. 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.

COM requested the participants' opinion on the possibility of advancing the Actors module deployment. The COM is currently working on the preparation of the production environment and the Actor registration module could be made available to Member States as early as Q4 2020.

A MS asked: why should there be a second testing although the first two modules have been already tested? COM explained that as the project has been transferred to SANTE, two phases of tests are necessary to ensure that the modules delivered are working properly and COM confirmed that the functionalities of those modules have not been changed.

A MS asked the confirmation of the availability of Machine to Machine (M2M) data exchange functionality. COM responded that to be ready for deployment each module will include the restricted site, the public site and the data exchange functionalities. However, to use such M2M possibilities MS have to adapt their own systems. COM is currently managing the MS on-boarding process to use the required Commission access point technology (EU send) for M2M data exchange. Previous to the date of release the COM will make available the XSD for each module.

A MS mentioned the need of a Guidance on a CAs common position to validate the Actors registration requests. COM explained that this question is out of the present Subgroup scope as do not relates to the EUDAMED development. The MDCG Subgroup on Market Surveillance is the place to discuss about this possibility.

A MS pointed out that some analysis on why the original plan/project failed is missing and suggested to set a short analysis of the functional specifications (FS) on the agenda of the next MDCG EUDAMED Subgroup to verify that they are in line with the needs of the different parties. COM responded that the SANTE IT Unit audited the development methods and adapted them. So far the results are that the development team delivers, but looking forward, the hardest modules are still to be tackled but SANTE counts on the MS as well to keep the planning as much as possible The COM do not consider a FS review necessary. The FS are stable, have been previously agreed on by the MDCG and the system is progressing on that basis. Any change to the FS at this stage would seriously derail the EUDAMED development process.

No participants are against an early deployment of the Actor Registration Module, possibly even by the end of Q4 2020. However, the COM stress that the effectiveness of this gradual approach also required MS commitment to ensure the use of the module on their territories. This point is also related to the position paper on the use of the actor registration module.

c. Upcoming ad-hoc working groups with Member States and stakeholders

COM presented the situation and the planning of the working groups concerned by EUDAMED.

The ad-hoc EUDAMED Actor registration WG is considered closed. COM clarified that the Actor Registration module is ready to register economic operators only. The registration of the notified bodies will come through Nando with the certificates module

and the registration of sponsors will come with the clinical investigation/performance study module.

The ad hoc EUDAMED UDI/Devices registration WG is also considered closed. The module still needs fine tuning and some clarifications for which the MDCG UDI Subgroup is consulted.

The ad hoc EUDAMED NBs & certificates WG will meet Q3 or Q4 2020 to finalise the module requirements. The most challenging issues for the NBs & certificates module is the CECP and the management of the experts panels and it is still under discussion to which extend these features will be included in the first release.

The UDI/Devices and the NBs & certificates modules should be made available together as they are closely linked, particularly for high risk devices.

The ad hoc EUDAMED Vigilance and Clinical investigations WGs will remain active and the next meetings will be organised Q4 2020.

The ad hoc EUDAMED Market Surveillance WG stopped its activities and COM works now directly with the MDCG MS Subgroup. The COM needs to have MS requirements fixed by Q1 2021.

The COM purpose is to speed up the process, limit the number of modules progressing in parallel and consult the most appropriate experts. COM stressed that WGs and Task forces involved with EUDAMED should always go for the simplest solutions.

Due to the Covid-19 crisis the COM do not know when physical meetings will be possible again. As UK was member of EUDAMED Vigilance and Clinical Investigation WGs there is place for a new MS wishing to join these WGs.

5. Guidance documents

COM presented two guidances:

The **Alternative administrative and technical solutions until EUDAMED is fully functional**, which is part of the Joint Implementation Plan (JIP) endorsed in March by the high level MDCG.

The purpose of such guidance is providing interim alternative solutions during the absence of EUDAMED where the obligations under the MDR cannot be met using the corresponding provisions under the Directives. These solutions have been proposed in a way that ensure added value, especially from an enforcement point of view, while seeking to limit any additional burden on relevant parties. COM stressed that the COM itself is undertaking many tasks in relation to the proposed solutions in order to ensure fair share of tasks between COM, MS and other concerned parties.

A first draft of the document was sent to MS with deadline for comments today and COM has received comments from only a few MS.

The Subgroup then discussed a few questions from participants. Questions referred to data management and data protection, legal status of the gradual roll-out and the scope of the guidance document. Concerning data management, the COM confirmed that there

was no intention to transfer data from the interim alternative solutions to EUDAMED once fully functional. On data protection, the COM replied that questions on data controller and data processing had to be analysed in the context of the respecting technical solution, including whether the personal data were hosted in Commission systems, in national systems or third party systems (e.g. websites). The COM suggested that a follow-up discussion on this topic takes place once agreement on the final text of the guidance document and the respective solutions has been reached.

The **position paper on the use of actor registration module and SRN** has been submitted to the MDCG for endorsement at the next meeting on 2 July**.** COM reminded the discussions held during the MDCG meeting of March about the gradual deployment of EUDAMED and confirmed that is ready to make available to MS the actor registration module by March 2021 or earlier.

However, as the COM has no legal basis to require economic operators (EO) to use this module, the final decision lies with the MS. COM declared that using the actor registration module, allowing the issuance of the SRN before EUDAMED is fully functional, will have an added value only if there is common agreement among all MS to use it. It was also important to avoid the need for double registration at national and EU level once the Actor Registration module is used in the MS.

MS confirmed the general willingness to use the Actor Registration module. However, certain legal questions remain and the current position among MS to make the Actor Registration module mandatory appears diverse.

Participants asked for the possibility of a training for MS about Actor validation and about the possibility to download the registered actors to the national systems. COM replied that training sessions can be organised and download to national systems will be possible, however for data exchange issues, the national systems need to adapt.

6. AOB

COM explained that is currently working with the MDCG UDI Subgroup for the module fine tuning and the Subgroup is consulted about the possibility of registering multiple Basic UDI-DIs for systems in the Summary of Safety and Clinical Performance (SSCP) as well as in the product certificates. The COM needs a quick answer to maintain the delivery deadlines.

COM stressed the importance of the decisions of the Transparency Task Force as EUDAMED will be a tool for transparency. COM needs quick decisions about what can be public in the Vigilance and Clinical Investigation module, otherwise those modules will not have data available to the public.

7. Next meeting

Next MDCG EUDAMED Subgroup meeting is tentatively scheduled on 19 October 2020. It is too early to know if it will be a teleconference or a physical meeting. There is also the possibility to have a mix of face-to-face and remote connexions meeting if not all participants are able to travel to Brussels. In the next meeting stakeholders will participate as observers.

8. Conclusions

The feedback on the gradual release of the first modules was positive; COM noted general agreement to advance the release of the Actor registration module to Q4 2020. The modules UDI/Devices and NBs & certificates will follow and there will be a progressive roll-out of the modules.

COM will look into the written comments from MS on the **Alternative administrative and technical solutions** guidance document and will update it before submission to the MDCG for endorsement.

The position paper on **the use of actor registration module and SRN** will be presented to the 2 July MDCG with the intention of endorsement, but potential follow-up discussions remained possible.

COM closed the meeting thanking the participants for the useful discussions and underlining the COM commitment to work closely with MS within a coordinated approach, to develop EUDAMED as a MVP delivered on time.

9. List of participants

MDCG members: AT, BE, DK, DE, EE, EI, ES, FR, HR, IT, LT, MT, NL, PT, PL, SE, FI

Observers: CH, IS, NO

Commission:

- SANTE B6
- SANTE A4