EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Medical Devices and Health Technology Assessment

Draft Minutes

MDCG - EUDAMED Subgroup
CAs only meeting

27 April 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 with the Chair's clarification on the preparation of new CIRCABC spaces/folders following the endorsement of MDCG 2021-1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional. The COM is currently organising the CIRCABC structure and methodology and will shortly send a communication asking MS to nominate members for the use of the new CIRCABC spaces.

The previous meeting minutes have been endorsed by written procedure.

2. Planning & roadmap

COM presented the roadmap stressing that EUDAMED is a challenging project, integrating 6 systems in one for which the involvement of MS is essential. COM counts on MS continuous support and cooperation to make progress and achieve this highly complex and very important project.

The roadmap is an ongoing process constantly reviewed and adapted by iterations following the evolution of the discussion and additional requirements and provides an estimation based on the knowledge of the requirements known today.

The revised roadmap foresees a production release in September for the UDI/Devices and NBs & Certificates module. The intention is to continue making the modules available on a gradual basis and today estimation for the delivery of

the complete Eudamed modules is Q4 2022. The COM will keep MS closely involved and regularly informed on the project progress to allow MS to align IT planning more swiftly.

The roadmap focus on the development and does not consider the final audit. COM is considering how to best organise the audit and the auditing period should be added to the estimated development finalisation date to have EUDAMED fully functional.

A MS asked if the COM is considering the need to change the legislation to enable the Eudamed implementation step by step, as if the legislation is not changed it is not possible to foresee how and if the system will be used at national level on a gradual and voluntary basis. The step by step approach brings no benefit if not everybody uses it and the roll out approach has not been deeply assessed.

COM explained that from the outcome of the March 2020 High Level MDCG the progressive roll out was welcomed and encouraged by MS. However, it is clear that following the deployment of the Actors module in December 2020 COM can see that MS have different approaches that result in non-harmonised practices..

A few participants referred to the need of a legal basisto ensure coherence during the gradual roll-out before full functionality.

3. WG role

The COM reminded the communication channels for EUDAMED issues which are the MDCG meetings, the CIRCABC related spaces, the Europa EUDAMED website, the EUDAMED restricted website, and the functional mailboxes (FMBs).

The COM consults the relevant technical MDCG WGs and works closely together with a few lead MS experts per module to ensure quick and agile feedback in collecting the requirements and providing clarifications for the development of EUDAMED.

The present WG has endorsed the 2021 work program (WP). The WP reinforces the WG horizontal role to advice the COM on policy, legal and technical matters, to help, at the COM request, to solve MVP scope-related issues, determine priorities and to help making decisions on complex issues not solved in technical (module specific) groups.

To improve the communication, the COM suggested to organise, as of June 2021, monthly meetings with a standing agenda with the roadmap and issues to be solved, to provide more regular planning updates, to organise short regular meetings for updates and to discuss relevant issues and “one topic targeted” meetings when needed.

MS welcomed these suggestions and asked for the possibility to allow MS to also set issues in the agenda, such as complex issues requiring a consensus solution. COM stressed that it is open to listen to MS concerns and MS are welcome to add agenda points; keeping in mind that the objective is to make progress, not to reopen issues that are closed and solved.

4. Roll out approach – Vigilance

The COM reminded that the gradual roll out was welcomed and agreed in the March 2020 High Level MDCG meeting to allow all parties to gradually adjust their systems and practices to the new modules and, at the same time, leverage the benefits of each module already prior to EUDAMED full functionality mitigating the Big Bang risk. After the deployment of the Actor module in December 2020 it is clear that the MS use the module in divergent ways.

If the voluntary use is not consistent across all MS the gradual roll out will lead to unworkable issues for some of the modules. The problems will appear already in the NBs & Certificates module when about CECP/Mechanism for scrutiny, Nominated expert for JAT, Applications withdrawal/refusal, Requests for certificate suspension/withdrawal.

For the last three modules, particularly for vigilance and post market surveillance, a coherent approach it is even more necessary to avoid double registration of data in national system and Eudamed which would lead to fragmentation of such data.

A MS stressed that such difficulties cannot be solved without changing the MDRs and suggested the COM to also envisage other solutions as changing the EUDAMED FS. The COM reminded the discussion with MS about whether it would be useful to go for a gradual roll out started in 2019 when the COM announced the first delay. At that moment most of MS agreed and committed to strongly encourage the use of the modules progressively. A change in the MDR would require co-decision by the European Parliament and the Council.

Some MS stressed that they agreed to strongly encourage the use of the actor registration module, but the situation for a voluntary use of Vigilance and CI/PS is much more complex.

COM underlined that if it is not possible to agree on and apply a common approach for using the 3 last modules and alternative could be not to roll out the modules and have them deployed only in the Playground until EUDAMED is fully functional.

COM has started to work on a guidance for the common approach, even if solving this situation through guidances seems challenging.

5. Ongoing work

COM updated the participants on the ongoing work state of play.

Implementing Act

The COM has taken into account most of the comments, generally positive, received from the present WG.

The COM is now proceeding with the internal consultation process and will keep the WG informed. The Implementing Act is expected to be adopted by Q3 2021.

Guidances

MDCG 2021-1

The COM has circulated to MDCG a revised version of the guidance document including a correction in the introductory text.

Guidance on transition periods as regards Eudamed

As per Eudamed WG work program Priority 3/1, the COM is studying the different provisions in the MDR and IVDR to clarify the date of application of certain obligations.

The guidance will address the period in which Eudamed is not yet fully functional until its use becomes mandatory and will contain sections corresponding to each EUDAMED module clarifying the transitional provisions that apply to each of them, under both MDR and IVDR.

The COM will launch the draft guidance consultation within the present WG in the coming weeks.

Q&A on Actor registration in EUDAMED

The COM is drafting a Q&A document that will address questions concerning the registration in EUDAMED of actors other than those mentioned in Article 31 MDR and Article 28 IVDR, the issue of the SRN and EUDAMED identifier and the validation of non-EU SPPP.

The draft Q&A will be sent to MDCG for consultation and Eudamed WG for information.

Eudamed 2 – Annex to MDCG 2021-1 with technical instructions

The COM is preparing technical instructions on the Eudamed2 use and will send soon the document for information.

6. Report from sector/module specific discussions and outstanding issues

Contact lenses

The UDI WG is working on solutions for registering contact lenses avoiding high number of entries, with no impact in the UDI/Device module and allowing the issuing entities to implement the solution..

Should the participants have specific questions on that issue, they can liaise with their UDI WG group colleagues. This issue will be in the agenda of the 4 May UDI WG meeting.

EMDN European Medical Devices Nomenclature

The EMDN will be delivered before UDI/Devices module is made available and is expected to be endorsed for publication on 30 April in the Nomenclature WG.

COM clarified that the mapping between EMDN and GMDN is not an obligation and there is currently no tool in EUDAMED for such purpose under the MVP approach but this could be considered for the future. There is no intention to have a synchronisation with the GMDN codes, the mapping will only be for searching purposes of the EMDN codes.

For further info MS can revert to their Nomenclature WG colleagues.

Enumeration clinical sizes

The COM has ongoing consultations within the UDI WG and has received some suggestions from stakeholders. A draft list for both CST and MoU will be presented for agreement at the 4 May UDI WG meeting.

7. AOB / Q&A

The COM thanked the participants and recapped the conclusions arising from the meeting:

- COM will send the revised roadmap timelines to the MDCG and the Stakeholders

- COM takes note of the positive messages about the proposal to improve communication and the work with the WG and as from June there will be more meetings.

- The Roll out approach needs to be re-assessed to identify the most optimal way forward. The COM will try to get a better picture of the situation in Member States.

- Several Guidance documents are in the pipe-line, the first that will be sent for consultation is the Q&A on actor registration. MS can liaise with their MDCG representatives.

- About the preparation of the structure to manage the alternative administrative practices and technical solutions until EUDAMED is fully functional the COM will soon send to the MDCG the request to nominate representatives for the new CICABC spaces.

8. List of participants

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

Observers: TR, NO

Commission: SANTE B6, SANTE A4