EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Medical Devices and Health Technology Assessment

Minutes of the expert groups

2nd MDCG EUDAMED Subgroup CAs only 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.
COM highlighted that EUDAMED is a high priority for the COM and the CAs input is essential to cope with the very tight and ambitions deadlines as well as with the complexity of the system.

The additional difficulties to implement the MDR arising because of EUDAMED unavailability are also a good reason to speed up the process of making EUDAMED functional.

COM is aware of the Member States expertise on medical devices and would be in favour of having a few people in the Member States clarifying the requirements and validating the solutions on behalf of all. Having a quick and straightforward communication to gather the MVP requirements is essential to make possible the EUDAMED delivery by May 2022.

COM addressed a strong message to the participants: the present Subgroup has a key function to help the COM in the development process by coordinating the MS feedback between different modules, helping to reduce expectations and taking strategical and difficult decisions with a realistic view and respecting the political commitment on the minimum viable product (MVP) approach and the gradual roll up of the modules as agreed in the March High Level MDCG meeting and to streamline and simplify to the extent possible interactions with Member States/actors.

The agenda was adopted.

2. Endorsement of previous MoM

The COM has not received any comment to the last meeting draft minutes previously circulated. The last meeting minutes are endorsed.

3. 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. 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 regularly updated reflecting progress in a transparent way.

COM explained that for the first set of modules; Actor registration, UDI/Devices and Certificates requirements are defined, only remain some fine tuning currently in progress and the COM does not expect input from MS. On the other hand, the COM needs still much input from Member States for the second set of modules.

Currently there are some data exchange (DTX) issues within the Actor module Playground. These issues will be most probably solved in the coming days and the Actor registration module will have machine-to-machine (M2M) data exchange functions to download actors' data (on registration requests and registered actors).

A Member States expressed concerns on an excessive ambitious EUDAMED and suggested to minimise the information that must be in EUDAMED, abandoning past ideas and focus on realistic solutions otherwise there is danger of not having achieved what Member States need.

COM answered that there will be no revisions on already determined requirements and we must stick with the MVP approach allowing to fulfil legal obligations. To do so, the COM needs the Member States support to build a system as basic as possible, more advanced functionality can be developed further after MVP delivery.

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. The COM also informed about its intention to work closely together with a few "lead MS" per module to ensure quick and agile feedback. A few MS indicated their support and commitment in this respect.

4. 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. 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.

COM reminded not to enter real data in the Playground. All Playground data is dummy, including SRNs.

By December, when the Actor registration module will go live all CAs responsible for economic operator validation and their first two Local Actor Administrators (LAA) will be entered in EUDAMED by the COM and will directly have access to EUDAMED and be able to accept more users for their CAs.

A Member States had problems to understand the legal value of the EUDAMED CA designation and the role and responsibilities of the LAA. COM will clarify the question.

As a general EUDAMED principle, the EUDAMED users access management will be delegated to the Actor LAA and will be established in the EUDAMED Implementing Act.

If the Ministry of Health is the main authority, which was already known, COM would have liked to have more detailed information on the CA department responsibility for each module (responsibility is equivalent to competent for a EUDAMED module). A Member States can have several CAs and change responsibilities if needed. The CA responsible for economic operator validation is needed for the Actor registration module in December. The main CA is the only "legal one" and all CAs will have access in general to all data in EUDAMED whatever are its responsibilities.

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 and asked Member States to report how they intend to use the system.

5. Guidance on EUDAMED alternative administrative practices and technical solutions

The COM is aware that the absence of EUDAMED will require additional efforts to comply with the legislation. All parties concerned will be affected, the COM has tried to take on as much as possible, for example by using CIRCA BC. Again, this is also a good reason to speed up the process of making EUDAMED functional.

The last comments received from stakeholders highlight one outstanding issue, which is the making public of SSCP. Manufacturers consider it is not their responsibility to publish the SSCP and the general remark is that stakeholders do not want to invest in any new temporary solution but concentrate on being compatible with EUDAMED hoping that EUDAMED will be the unique tool to use.

The COM will shortly send an updated document for written MDCG endorsement.

6. Eudamed2

One MS asked what will happened will all the registered data in Eudamed2. COM explained that it will not invest anymore in Eudamed2. As communicated from the beginning of the EUDAMED project, there will be no data transfer from Eudamed2 to EUDAMED. The data is not the same and the legal basis is different. Whilst in Eudamed2 the data is entered by the CAs, in EUDAMED different actors are responsible to provide the data following the MDRs provisions, CAs cannot enter data~~e~~ in EUDAMED on behalf of the economic operators. In addition as Eudamed2 is not used in a harmonised way by Member States the Eudamed2 data are not reliable enough. As a general principle, the still active actors registered in Eudamed2 will need to register themselves in EUDAMED, they will have the obligation to submit an actor registration request in EUDAMED in order to get the SRN.

The idea to use Eudamed2 as alternative solution in the scope of the Guidance on EUDAMED alternative administrative practices and technical solutions is abandoned as mixing data from MDD and MDRs would be inappropriate. However, anything ongoing

under MDDs, as NCARs for legacy devices should continue to be entered in Eudamed2. The NCARs for MDR devices will need to go through the MDR alternatives.

Eudamed2 data will not be considered for signal detection. Signal detection will start from EUDAMED data but at a further stage as is not part of the MVP.

Eudamed2 will exist still for a while and CAs can still update their data, probably at least until 2024. Afterwards Eudamed2 will switch to read only mode with no more possibility to enter data. Eudamed2 will become an archive for Directive data for a duration to determine.

7. Rules on retrospective registrations

COM reminded the main rules for retrospective registrations: on the first set of modules - actors, devices and certificates - all data required to be entered in EUDAMED for placing a device on the EU market, will have to be provided retrospectively if not already done (at least if still active and current); on the second set of modules - CI/PS, vigilance and market surveillance - the general rule should be to have retrospective registrations only for all still current events/reports/applications (not final yet) for which updates are expected but the initial registration was done in the past outside EUDAMED. Closed/final ones should not be registered retrospectively; if data shall be entered retrospectively, it shall always be done by the actor that has the obligation to do it from MDR. For example, device data and vigilance data of a manufacturer can only be entered in EUDAMED by this manufacturer never by a CA. There will be no transfer from Eudamed2 or national systems to EUDAMED.

If an economic operator registers in EUDAMED production and gets an SRN before EUDAMED is fully functional it will be considered as already registered when MDR legal obligation will apply after full functionality. COM refers to the position paper; the SRN will have a legal value when EUDAMED is fully functional and will not change. The data entered in the modules gradually made available is to be seen as the same data as for the fully functional EUDAMED. (All MS endorsed the position paper except one).

A Member States pointed out that the COM has no legal basis to require registration in EUDAMED before being officially considered as fully functional as MDRs have no such requirement and unless EUDAMED is fully functional national systems and related Directives obligations apply.

COM explained that the Vigilance and CI/PS modules will be available not before May 2022, so as from that moment the start clock for the legal obligation will exist. In particular for Vigilance, having the concerned device (regulation device or legacy devices) registered in EUDAMED will be a prerequisite to register a vigilance report. The Vigilance module will also consider "other devices" which include devices custom made or older than MDD. These "other devices" will have data only registered in the Vigilance module, which will be considered as vigilance data and not device data available in the UDI/device database.

Some Member States recalled their support to the Position paper insisting on the Member States need for being able to download the information from EUDAMED via M2M DTX. If Member States can get the info via DTX they will encourage the economic operator to register in EUDAMED. COM explained that the objective is to have M2M DTX available in December.

8. Conclusions

COM stressed that achieving EUDAMED on time is a difficult and ambitious goal requiring a collaborative and interactive way to get the feedback from CAs quickly and with no later changes.

The preparation of the Actor registration module is progressing very well, most of the CAs to be registered in EUDAMED have been identified together with their first two LAAs,

COM closed the meeting thanking the participants for all their efforts and commitments to the project.

9. List of participants

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

Observers: CH, IS, NO, TR

Commission: SANTE B6, SANTE A4