EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Medical Devices and Health Technology Assessment

Minutes of the expert groups

3rd MDCG EUDAMED Subgroup CAs only meeting
23 February 2021

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.

The agenda was adopted with the Chair's suggestion to deal with a request from one MS on how to deal with System and Procedure pack Producers (SPPP) validation under agenda point 6 and in case of time discuss priorities suggested by another MS under AOB.

2. Endorsement of previous MoM

The COM has received one comment to the last meeting draft minutes previously circulated. The last meeting minutes are endorsed.

3. EUDAMED State of play – roadmap

COM presented the roadmap. The task is challenging but lot of progress has been achieved since last meeting.

The roadmap is an ongoing process constantly reviewed and adapted by iterations following the evolution of the discussion and additional requirements.

The Actors module is in production since 1st December 2020. The module is widely used with no major issues.

The next target is to finalise the UDI/Devices and the Certificate modules by the end of the year. The next key milestones are a First Playground in March and a second Playground in July with increased functionalities and the deployment in production of the UDI/Devices and the Certificate modules in September instead of May as initially planned. COM expects to deliver an additional release some time after September to have the 1st set of modules fully functional.

For the 2nd set of modules the roadmap is an approximation as the detailed requirements and MVP are not yet fixed and a minimum set of functionalities needs to be fixed to start development.

Some MS stressed that they have problems with Machine to Machine Data Exchange (M2M DTX) as the system to register and the activation before sending transactions are very complex. Additional guidance, phone support and workshops would be very welcome. COM will consider additional support and invited MS to contact the EUDAMED SUPPORT for any DTX technical problem.

COM reminded that the roadmap is an evolving document and will regularly report on the development and underlined that it is essential to stick to the agreed requirements and not reopen already agreed issues as this will result in delays.

4. Eudamed Actor module use

The Actor registration module is in production since 1st December 2020. The members of the MDCG (*except one*) agreed that double registration requirements for actors should be avoided as much as possible as set out in an MDCG Position Paper (MDCG 2020-15) published in August 2020.

COM launched a survey on the use of the Actor module to have a real picture on its use and the results are that: 9 countries acknowledge EUDAMED registrations; 11 countries request double registration; one country has suspended the validations and the remaining countries either did not replied or have not decided.

The COM will follow this situation regularly to see how much EUDAMED is used at national level.

5. Implementing Act (IA) on Eudamed

COM presented the draft Eudamed IA and next procedural steps. The IA lay down the detailed arrangements for the setting up and maintenance of Eudamed. The document is currently subject to internal discussions in the Commission.

The COM agreed to circulate the draft to the MS for consultation shortly after the meeting.

6. Outstanding issues

COM underlined that significant progress has been done on several items subject to written consultation and there is now a common understanding on several points.

Custom Made Devices (CMD)

The CMD note circulated and after some amendments a final consensus was reached: CMD manufacturers would need to register in some specific cases when, according to the MDR, they have an obligation to enter data in EUDAMED. They will need to register only when this data has to be entered.

A few MS asked questions about the issuance of a single registration number (SRN) and validation.

It was concluded and agreed that some actors not mentioned in Art. 31 have the obligation to enter data in EUDAMED according to other MDR articles; these actors need access to EUDAMED to enter this data; in order to grant access a certain control is needed; therefore these actors need to be registered and verified.

The COM explained that the system generates an identification for any actor registered (a EUDAMED Actor ID) and the pragmatic MVP solution would be to always call this identifier a SRN. Otherwise, it could be clarified in a guidance in which case the EUDAMED Actor ID can be considered also as a SRN. This solutions will also avoid multiple registrations for the same actor.

The COM received requests to add some Q&A and guidance for CMD manufacturers' validation rules.

COM concluded that there is a general understanding on the CMD document whilst further discussions are needed on the CA validation and SRN.

TDA certificates in case of self-testing, near patient testing and companion diagnostics

A common understanding on the issuance of the EU technical documentation assessment certificates has been reached. As an outcome of the multiple procedures mentioned in IVDR Article 48, the notified body should issue a single EU technical documentation assessment certificate.

Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional

The document went through a written MDCG endorsement procedure and will be published on the MD web site.

Two MS asked questions on the document including one raising objections on the way the guidance deals with SSCP.

COM referred to the endorsement procedure being closed and the need to publish the document and move forward.

The COM will publish the guidance and should a MS object, COM ask to explicitly inform them and it will be quoted in the meeting minutes[1].

Eudamed2

Eudamed2 remains untouched and is the tool for the MDD but will be used to get the CIV ID for the MDRs clinical investigations. COM has provided some basic recommendations on how to use Eudamed2 for getting the CIV ID as putting "MDR" at the beginning of the CIV title to easily identify MDR CIVs. Eudamed2 Support will remain as well.

It will be possible to continue updating devices and certificates, anything that is possible now will continue at least until the end of the transitional period. All certificates on MDD devices must be in Eudamed2 until the MDD are repealed. COM reminded that the info on

[1] A single MS, Germany, objects and does not endorse the guidance

the certificate in Eudamed2 is very limited, the link to a device is optional and only MDD certificates can be entered.

CAs need guidance and transparency on the interpretations of the transition period, the idea is to avoid unnecessary burdens when the modules will be available

COM understands that some rules on how to act during the transition period would be welcome. Such guidance has to be separated from the guidance on alternatives in the absence of EUDAMED and should be linked to the use of the new EUDAMED.

Brexit

As a Brexit consequence, MHRA has lost access to the Eudamed2 CI module. However, they continue having access to actor, devices, certificates and NCARs (only if UK is impacted in case of NCARs). MHRA should from 2021 enter in Eudamed only records related to Northern Ireland (XI). MHRA will have obligations and need access to fulfil their obligations, any incident in XI has to be reported by MHRA, and vice versa, they need to see incidents of devices placed in XI or for which the manufacturer is established in XI.

In the future EUDAMED references will be to GB (UK excluding Northern Ireland) and XI (UK only Northern Ireland). MHRA access should be limited to XI issues when the info is not publicly available. In the existing Eudamed2, UK will remain because of all the data already entered for which we cannot know if GB or XI, but normally, for data entered from 2021, UK should mean Northern Ireland.

Gibraltar has a special agreement on free movement and there are no particular provisions to consider regarding EUDAMED. There are special rules for Authorised Representatives and importers in XI as they have only the right to place devices from non-EU manufacturers only in XI, not in the other parts of the EU territory.

SPPP validation rules

SPPP are not mentioned in MDR article 31 but have to be registered as they have obligations to enter data in Eudamed coming from other MDR provisions.

One MS asked about how to deal with non-EU SPPP: which CA should they approach for their validation as they do not have an AR and some are not able to produce the data required for EUDAMED validation

The SPPP issue joins the question on CMD manufacturers and actors not mentioned in MDR Art. 31. COM considers that the knowledge of CMD manufacturer and SPPP is at national level.

Whilst there is agreement on this approach, some MS asked for further clarity via common rules and guidance based on the CMD note referred previously.

Eudamed priorities & major challenges

A MS sent a document challenging requirements of the Actor module and SRN, the UDI/Devices and the Clinical investigation.

The COM voiced that is in favour of pragmatism but always in compliance with MDR,

COM concluded stressing that the COM will stick to the agreed requirements and to what has been fixed in different WGs and guidance concerning Eudamed. Looking at the challenges ahead of us and the complexity of the system, any change on already developed functionality will mean significant delay and re-opening agreed issues at the request of a single MS is not suitable.

7. AOB Conclusions

COM is doing the outmost to speed up the process.

COM, will continue to keep the WG informed and will look into how communication regarding EUDAMED can be further improved.

The WG will soon receive the draft IA, The guidance document is considered endorsed. COM will follow up on how to further clarify validation rules and other aspects of the actors not listed in MDR Art. 31. COM closed the meeting thanking the participants for the productive and good discussions.

8. List of participants

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

Observers: CH, IS, NO, TR

Commission: SANTE B6, SANTE A4