EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Medical Devices and Health Technology Assessment

Draft Minutes

MDCG - EUDAMED Subgroup
CAs only meeting

9 December 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 to the CAs only session and reminded the house keeping rules. The minutes from the previous meeting have been endorsed in writing and published.

The agenda was adopted.

2. Feedback of Plenary session

Participants had no comments on the Plenary session.

3. Change of CA responsible for EO – ACT module

COM went through a preparatory document shared in advance for which 2 MS provided comments, one in favour of CAs confirmation in all cases involving a change of responsible CA[1].

There are 4 scenarios triggering the change of CA:
1) **EU economic operators**: change of address within the same country in countries with multiple responsible CAs (e.g. Germany);
2) **non-EU manufacturer**s: change of AR or change of responsible CA for their AR;
3) **non-EU SPPPs**: change of market distribution for their products when no more products are placed on the market of the current responsible CA;
4) **de-activation of a CA** responsible for economic operators.

[1] the correct wording is confirmation, not validation as the validation is done at the registration, to issue the SRN

COM explained that, in all cases, the previous CA will be notified and the concerned EO will need to update their records manually. The change of CA for an AR is the more complex case. In case of change of AR, there is no action that will be done automatically, it will be up to the manufacturer to change the AR of its registered devices

COM stressed that in case a CA does not confirm the change we could end up in a blocking situation if no other option exists and pointed out that warning messages are not considered under MVP.

Participants agreed that it is suitable to have uniform rules and therefore a confirmation for all cases.

The COM will amend the document reflecting the CAs confirmation in all cases and the final document will be communicated to the WG.

4. **Feedback on ongoing work**

COM provided a state of play on the main ongoing topics:

Actor deactivation: the impact of actor deactivation has to be further analysed to consider the potential consequences depending on the module and it is not yet decided if this will be part of the MVP.

Change of VAT number in Actor module: MS apply different rules and there are cases when the VAT needs to be changed. Currently the VAT cannot be updated and for the time being the COM deals with this issue manually on case by case basis. COM suggestion is to have a similar rule as for the change of CA: VAT can change but with CA confirmation.

Country code: We have 2 errors concerning Serbia and Montenegro codes and 2 issued SRNs of Serbian manufacturers need correction. They will be corrected with the correct country code and all the concerned actors (MF, AR and CA) will be informed.

Art 59 derogation: COM brought up the issue if there is a need to flag in Eudamed the devices falling under Art. 59 derogation. Participants agreed that it is premature to decide on this topic and for the time being EUDAMED remains unchanged

Master UDI-DI for highly individualised devices (contact lenses): the solution is being developed together with issuing entities . The Master UDI DI will have an impact on the devices module and for the time being such devices cannot be registered.

AIMDD - Device/accessories used in combination with AIMDD are treated as AIMDD: currently EUDAMED has the constraint that for AIMDD the devices property is active implantable. Participants agreed to allow the possibility to

remove the active implantable property for AIMDD legacy devices. EUDAMED always identifies the applicable legislation for the registered device.

SSCP: The SSCP management is the biggest challenge for the system. As an SSCP can have several Basic UDI-DIs and can be attached to several certificates the complexity is significantly increased.

Vigilance: discussions on the final MIR form and on the PSUR are still ongoing but only about fine tuning for EUDAMED. The COM works in close collaboration with lead MS (BE, DE and FI)

CI/PS: A significant amount of requirements still needs to be defined and the highest complexity is brought by the coordinated assessment. The coordinated assessment process scope is under discussion and a survey is ongoing to decide the best approach to take.

For the Serious Adverse Events (SAE), discussions are ongoing mainly concerning the MDDs. The COM intends to go for a very basic solution, with an Excel file upload, as the info will be available in the national systems and the feature is only needed for a short time.

The interoperability with the EMA Clinical Trials DB has also to be addressed. The COM will discuss with EMA and with the CIE WG to find a very basic solution under MVP.

5. AOB /Q&A

COM will continue organising regular meetings in 2022 which will be an extremely challenging year with the target of having all development done by end 2022

The COM will circulate a draft 2022 working program to be first approved by the WG and second endorsed by MDCG in the mid-the March meeting.

The COM is working on a guidance document on alternative means in the absence of Eudamed for IVDR. The exercise will manly consist in matching the already published MDCG 2021-1 with IVDR provisions.

The next meeting, CAs only, is scheduled mid-February the dates of the Plenary meetings are still to be decided

COM closed the meeting thanking the participants.

Participation

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

Observers: TR, NO, IS

Commission: SANTE B6, SANTE A4