EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Medical Devices and Health Technology Assessment

Draft minutes

MDCG - EUDAMED Subgroup
CAs only meeting

23 September 2021

MDCG EUDAMED Subgroup meetings are not public and are intended for MDCG EUDAMED Subgroup members and selected observers only. The present meeting was a virtual with video-audio connection.

1. Welcome & adoption of agenda

COM welcomed the participants and reminded the housekeeping rules.

The Main agenda point will be the state of play and roadmap.

The COM underlined the progress made since June meeting and thanked the participants for their collaboration and feedback both for the system delevopment and policy documents.

The previous meeting minutes have been endorsed by written procedure.

The agenda was adopted.

2. Planning & roadmap

COM presented the state of play highlighting that an important milestone will be soon achieved with the release in production (end of September) of the 2nd and the 3rd EUDAMED modules: UDI/Devices and NBs & Certifictes. This is according to the planning.

The COM will deliver a workable system and, after the September release, the COM will focus on bug fixing until end of the year and there will be regular production releases. COM presented figures and some examples of the bugs to be fixed, for a significant number of them solutions existand will be documented for the users

Afterwards, the COM will continue working on the 3 modules in production implementing critical improvements and making progress on the next 3 modules in the Playground.

MS expressed the importance of downloading data and having a delta for downloads. COM explained that EUDAMED users will be able to download data via the user interface and a delta is being implemented, it will be included in the coming service definition document and is part of the next release.

The COM will provide training via interactive information sessions in addition to the user guides and the technical documentation. Users can always contact the support via the SANTE-EUDAMED-SUPPORT@ec.europa.eu FMB.

3. Information on access to NB first Local Actor Administrator (LAA)

The Commission will register the DAs and their first LAAs in EUDAMED and the NBs designated under the regulations will be automatically registered in EUDAMED from the data in NANDO. Then, the authorities responsible for NBs (Designating Authorities - DA); will validate the first LAA of their country NBs.

To do so each NB has to designate the person that will act as the first LAA and inform its DA. This done, the NB first LAA will submit a user access request in EUDAMED and the DA of the NB will receive a notification prompting to validate the NB first LAA.

Once the first LAA has access, all the other users of this NB can request access and start operating in EUDAMED. There is no limitation on the number of users.

The COM will provide detailed technical information to DAs and NBs during the first half of October.

This procedure is based on security reasons and is part of the draft Commission Implementing Regulation on Eudamed..

4. Actor module requests for changes/improvements/clarifications

The Actor module needs to be improved with 2 new functionalities regarding 1) Economic operators (EO) change of responsible CA after registration and 2) actor deactivation and clarifiy how to address the EO trade names.

The case of a country change is excluded, this is not possible in EUDAMED; if an EO changes country the legal entity changes and a new registration is necessary. The new registration will go through the normal validation path to obtain a new Actor ID/SRN.

If an EO changes address within the same country and falls under the responsibility of another CA, the solution will be to create a new version of its actor data specifiying the new CA and such new version will need the new CA approval. COM stressed that when the EO changing CA is an AR there are additional complexities. The idea is to avoid CA validationswhenever possible and only issue notifications to the concerned CAs

If an actor needs to be deactivated the LAA could have the possibility of indicating a deactivation date and the reason. The deactivation consequences as the users access, the status of the related items and the possibility of re-

activation have to be further analysed. COM clarified that deactivation do not means deletion, the data will remain available in EUDAMED.

About the trade names the general rule is that the EO name and address registered in EUDAMED must match with what is on the devices label and the name and address appearing in certificates. It is up to the MS to deal with the trade names according to their national rules, many MS only accept legal entities and check via their national trade registries and others accept trade names if all separately registered in EUDAMED.

A MS stressed that currently there are some Actor data fields that are non editable once the actor has been registered as the VAT and if there is an error to correct the actor is blocked. COM confirmed that the VAT field cannot be updated and said that in case a correction is necessary COM has exceptionally the possibility to correct it in the database but will only do it with the agreement of the responsible CA (a new Actor registration is not appropriate). If it would happen too often it should be considered to make this field updateable.

The COM will send a document with the new functionalies analysis and potential solutions for CAs consultation.

5. Ongoing work

Implementing Act.

The COM launched a first consultation within the Eudamed WG in March and informed the MDCG. When the EDPS consultation and public feedback consultation in the context of the Better Regulation were launched in May/June 2021, the COM informed the Eudamed WG and the MDCG of the procedures, and circulated the direct link to the draft Act. No major comments were raised by EDPS, nor in the public consultation, nor from Eudamed WG or MDCG. The draft has been adjusted to reflect inputs from those consultations.

Following stabilisation of the draft and dialogues with LS the COM will convene a regulatory committee meeting on 18 Oct, on the same date of the MDCG, with the aim of reaching an agreement on the draft from the committee.

Highly individualised devices

The COM is working alongside Industry, issuing entities and the UDI WG to find a feasible solution to the issue of UDI assignment for highly individualised devices, (e.g. contact lenses). Due to high variety of types and possible clinical parameters combinations, (e.g. lens material, dimension), the potential number of UDI-DI entries in EUDAMED is extremely high. The solution aims at avoiding disproportionate UDI-DI data entries in EUDAMED, with limited value for regulatory purposes and a negative impact on the database performance.
The solution would involve the assignment of special Production Identifiers (PIs) including a ‘Master UDI-DI’ (to group a product family or a range of types/models) and additional Production Identifiers (PIs) to capture the device

clinical specifications (clinical sizes). Discussion is in advanced stage and development of the solution is expected to start soon.

To avoid duplication of data, Position paper MDCG 2021-09, on the implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers, instructs manufacturers of the abovementioned products not to register in EUDAMED their devices (in the context of voluntary use) for the time being. EUDAMED will also technically prevent the registration of contact lenses and spectacle frames.

COM will put a warning or an explanatory text in the EUDAMED interface itself indicating not to register such devices.

The COM has organised technical discussions with the issuing entities to make progress on the master UDI solution.

6. AOB / Q&A

The COM closed the meeting thanking the participants for the useful discussions and summarized the meeting conclusions:

- The UDI/Devices module and the NBs & Certificates module will be put in production end of September
- The COM will focus on Bug fixing until end of the year
- The COM will send a document for CAs consultation about the Actor issues (Change of CA and discontinued actors)
- The COM will put a notice in the EUDAMED interface reminding not to register highly individualised devices as contact lenses.

The next meeting is scheduled 3 November and the COM will continue organising regular meetings to keep everybody informed about the progress and specific outstanding questions.

An MDCG will take place on 18 and 19 October.

7. List of participants

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

Observers: TR, NO, IS

Commission: SANTE B6, SANTE A4