**MDCG - EUDAMED Subgroup CAs and observers**

**9th December 2021 14:00 - 15:00**

A one-hour stakeholder session was organised as part of the MDCG EUDAMED WG meeting. Only NBCG-Med and MedTech Europe presented among all the participating observer stakeholders. MedTech Europe supported NBs also having M2M upload capabilities.

EUDAMED implementation timelines :

1. No major shift in EUDAMED timelines, though they talk about S2/2023 for the notice in the OJEU on a slide and Q3/2023 on another.
2. Next version of Playground + Production environment for ACT/DEV/CERT (2.3) planned for 13th January 2022; unknown when technical specifications will be made available and if Playground will be available before Production which is not foreseen to be the case before EUDAMED full functionality (conflicting with the [EUDAMED Implementing Regulation (EU) 2021/2078](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R2078&qid=1638155731516) Article 9: “EUDAMED M2M data exchange services shall first be introduced by it in the websites for testing and training”). MedTech Europe will continue to highlight to the EU Commission the compliance risk for Economic Operators when insufficient information is provided ahead of a new releases and insufficient opportunity to test and prepare systems is provided.
3. Market Info & Container DIs M2M upload are planned for end of Q1 2022. **See the list of all planned functionalities in the upcoming playgrounds for all modules in the Commission’s presentations that is embedded above.**
4. Development of EUDAMED MVP will be frozen at end of 2022 to be ready for the audit.
5. **The OJEU notice that declares the full functionality of EUDAMED is foreseen for May 2023,** which means that EUDAMED will be mandatory for use 6 months later, in Nov 2023. (Actor registration should be completed within those 6 months, by Nov 2023. **The remaining 3 modules (VIG, CI/PS, Market Surv) will be made available in production only 6 months after EUDAMED will be declared fully functional – released directly for mandatory use. Device and Certificate registration transition timeline will last for 24 months, until May 2025.**
6. Testing in Playground will stay limited to companies already having access as long as EUDAMED is not fully functional (mid-2023 earliest). Test environment is not stable and also functionalities could still change.
7. Notified bodies also need to make further testing (last August Playground only lasted 17 days for them).
8. The possibility for a second access point will be enabled when Vigilance playground is launched, but only for a 3rd party if the Economic Operator is already using their own direct access point, or a direct access point will be allowed if the EO is already using a 3rd party for a different module. One access point only for an SRN for its own use.
9. 75% of the Vigilance module requirements finalized. Locked down at 100% before year end, but likely to spill into January 2022.
10. MVP will only be amended if a legal requirement might have been missed.

MedTech Europe highlighted a number of issues with regards the use of EUDAMED Actor and UDID modules – for the details please see embedded presentation above.

SSCP translations, non-validated SSCPs, MTE requested again to enable manufacturers to control the upload:

1. Upload of SS(C)P is seen as a purely administrative action which adds to the workload of NBs. SSCP is required for implants but for 30% of IVDs (all class D, class C), which equates to roughly 12,000 IVDs. With only 6 IVD NBs available and a desperate lack of NB capacity to deal with the transition to the IVDR, allowing manufacturers to upload non-master SSP may be critical to relieving NB resources.
2. *COM*: Unlikely that manufacturer would get ability to control the upload of translated or non-validated SSCPs, that seems to be definitely for the NBs. It can be challenged but it means more time for EUDAMED development. EU Commission said it cannot be both NB and MF that have the ability. The Regulation does not specify who uploads the translations, so avoid debate the functionality is only granted to NBs.

Non-harmonised use of EUDAMED Actor registration module:

1. The EU Commission verbally stated that voluntary is voluntary and that member states could not mandate utilization during the voluntary period, but they could allow EUDAMED registration in lieu of National registration. MedTech Europe should ensure this be documented in meeting minutes.
2. They may make VAT/EORI/National trade registry fields are optional but non-editable after filled. Commission confirmed that they can be edited case by case after confirmation by the responsible CAs. They stated only fields that are truly non-editable are country and actor type.

Acquisitions/merger

1. SRN cannot be changed for a BUDI or UDI-DI.

Change management:

1. a proper change management foreseen to be implemented only after EUDAMED will have been reached its full functionality. Timeline will be agreed by MDCG for how long to have changes in playground first before its launch in production.
2. Malfunction rules will only be applicable when EUDAMED is fully functional. Until then [MDCG 2021-1 Rev. 1](https://ec.europa.eu/health/sites/health/files/md_sector/docs/2021-1_guidance-administrative-practices_en.pdf) applies.

Correction:

1. If too long to discard and correct, also the helpdesk can help.

Execution of data registration:

1. Commission confirmed that manufacturers fulfilled its legal obligation when he submitted the data to EUDAMED (even if the text of the [EUDAMED Implementing Regulation (EU) 2021/2078](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R2078&qid=1638155731516) says: *“submission of data shall be deemed executed at the date and time when the data is successfully registered in EUDAMED” and* even if the registration is competed upon the registration of the certificate by the Notified Body (manufacturers have no control).
2. Helpdesk gets 200 non-blocking tickets per week. Helpdesk escalation of issue: it is done internally. Helpdesk works on improving its services, learning curve.

Notified Bodies brought up the following issues – see NBCG-Med presentation embedded above:

Actor name/brand name in EUDAMED:

1. *Notified Body’s question:* There are names such “XY also trading as Z” in EUDAMED. Will NBs need to issue certificates using these entry names?
2. Actor registration FAQ question 2.7 **Can the same legal entity register several actors within the same role (manufacturer with different brand names/addresses)?** *Answer: the same legal entity may use several Trade Names (e.g. Company Medical Systems, Company Ultra-Sound, etc.) in this case they will enter separate registrations under their different Trade Names. This registration scenario will most likely trigger the duplicate check warning, requiring a justification. In the end it is up to the CA to assess your requests, EUDAMED provides only warnings, it does not define what the assessment criteria are.*
3. Commission’s answer: The name provided for Actor registration should be the one that is on the label and on the certificate. Competent Authorities who validate SRN requests should make sure that it is the case.

Registered data publicly available:

1. *Notified Body’s question:* When devices are visible to the public once submitted by manufacturer? Devices are already registered without completing a conformity assessment.
2. Commission’s answer: Only type examination certificates require the validation of Notified Bodies (those data will not get registered upon the data submission by the manufacturer in EUDAMED). If a technical document examination route is chosen, the validation of NBs is not necessary in EUDAMED. E.g. Class B not implantable for which technical doc is followed, no NB validation.