

MINUTES OF THE MEETING EUDAMED 17 OCTOBER 2019

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

AGENDA

1. Tour de Table
2. Agree on agenda
3. Current activities of Business Team
4. Status Phase 1 (Realised, Issues, Risks, User Acceptance Tests ...)
5. Plans until Deployment of Phase 1

[REDACTED]

[REDACTED]

CONTEXT

OUT OF SCOPE

In this context, we have organised the first meeting among the units to ensure a smooth and efficient transfer of competencies from DG GROW to DG SANTE.

MINUTES

DG SANTE will commence responsibility for EUDAMED-MDR from 2020-01-01, and highlighted the importance of finding as much information as possible about the progress of the application at this stage.


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OUT OF SCOPE

[REDACTED]

DG GROW briefly outlined the current status of EUDAMED-MDR:

OUT OF SCOPE

- The application consists of six modules (Actors Registration, UDI/Devices, NBs & Certificates, Vigilance, Clinical Investigation and Performance Studies & Market Surveillance) and a data exchange component. The modules are grouped in 2 sets: the first one includes Actors, UDI/Devices and NB & Certificates and the second one Vigilance, Clinical Investigations and Performance Studies & Market Surveillance. At this stage the requirements of Actors' registration are mostly delivered and the biggest part of the UDI/Device module is done although the requirements of other modules should still require further work on Actor and UDI-Device modules. For the Public Site the functionalities related to Economic Operators search and view details are already available on test environment. The project team already delivered 2 versions in Playground (environment that allows external stakeholders to test the functionalities of the system).
-  OUT OF SCOPE
- The IT and the policy unit meet internally once weekly with the Project Managers and with each Business Analyst separately, and there are number of meetings per year with the different (7) EUDAMED WGs (so far between 15 and 20 meetings per year). Each module has a dedicated WG, plus the Data Exchange (only Actor and UDI/Device WGs have no more meetings foreseen). GROW.D4 also reports to Member States via the Medical Devices Coordination Group, (5-6 meetings/year, next meeting: 2019-12-13) with the collaboration of GROW.R3 for state of play and planning.

It was initially intended as required by Regulation to release all modules by March 2020. As from the beginning of 2019, COM suggested due to delays to release the modules in production gradually as of March 2020, starting with the first set of modules in March 2020 and some parts of vigilance module in November 2020. However, DG GROW recently received legal advice that the application may only be released once fully functional.

Full functionality will not be completed for another two years; release to production is now scheduled for May 2022. After May 2020, derogations foresee by the legislation will apply. This delay has not yet been communicated to Member States. DG GROW expects to send this communication soon. In the meantime the deliverables have been progressively released to the Playground environment for feedback from the end-users and to help them to prepare their systems accordingly.

OUT OF SCOPE



OUT OF SCOPE

