

From: [REDACTED]
Sent: Wednesday, 23 October 2019 18:04
To: RYS Andrzej Jan (SANTE)
Cc: PETTINELLI Carlo (GROW); [REDACTED]
Subject: Eudamed - state of play
Attachments: NOTE_EUDAMED_3_CLEAN.docx; ANNEX_REV3_CLEAN.docx
Categories: AZ

Dear Andrzej,

OUT OF SCOPE

From: [REDACTED]
Sent: Wednesday, October 23, 2019 5:44 PM
To: RYS Andrzej Jan (SANTE) <Andrzej.RYS@ec.europa.eu>
Cc: PETTINELLI Carlo (GROW) <Carlo.Pettinelli@ec.europa.eu>; [REDACTED]

Subject: Eudamed - state of play

Dear Andrzej,

I would like, with Carlo's agreement, to inform you about the latest developments in the preparation of the new Medical Device data base – Eudamed.

After informal discussion with the Legal Service, it has emerged that the option we had considered to have a progressive release of the different sections (modules) of Eudamed, between May 2020 and May 2022 would not be legally workable. This is due to the fact that the Regulation foresees that Eudamed becomes operational (only) when “fully functional”.

As it will not be possible to have the IT establishment of the whole database by May 2020, then we have to postpone its functioning to a later stage (the target date is May 2022, which is the deadline for the implementation of the IVD Regulation).

You will find attached a document (composed of a general message + a more technical annex) which is meant to be addressed to Member States to inform them about the latest developments and the postponement of the release of the whole data base at a date later than May 2020. They need to be aware of that in order to get prepared and take the appropriate measures. After the information to MS, the one to stakeholders will follow.

We wanted to make you aware of all this important update which will of course impact the future progress of this huge IT project (as you know managed in-house – by the way we had a first, very useful meeting with both IT Units in GROW and SANTE last week).

On the more positive side, one has to note that the MD Regulation itself explicitly provides for the case where the database is not yet ready by May 2020 without impeding the application of the MDR; and that operators will have more time to prepare themselves for (and actually do prefer) the scenario of a later functioning of the entire Eudamed in one go rather than an immediate but partial release of the database.

Happy to discuss and to respond to your possible queries on this and of course other topics.

Best regards



European Commission

DG for Internal Market, Industry, Entrepreneurship and SMEs
Health Technology and Cosmetics
Unit GROW D.4



B-1040 Brussels/Belgium

