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Eudamed is delayed, a positive move

Published on October 25, 2019 - Richard Houlihan

I would prefer to wait for confirmed information however as the internet is going wild with speculation it is only right, that I share what I know.

At the Certificates working group yesterday (24th October 2019) the EC announced there will be a delay of two years for MDR Eudamed, deployment happening in 2022 with a two-year transition to 2024. However, neither the EC nor the MDCG have publicly announced anything. This delay discussion, so far, is all based on one man's comments at a working group. The official communication will come from the MDCG, most likely in December 2019.

There are several reasons for the delay, firstly not all the MDR Eudamed modules are ready. Secondly, the disruption resulting from move of medical devices from DG GROW to DG SANTE, and the negative effect this is having on the IT resources i.e. not all IT staff will remain with the project, is a major and prudent reason for the delay.

The EC are going to use the provisions in Article 34 to delay delivery the go-live.

Article 34

Functionality of Eudamed

1. The Commission shall, in collaboration with the MDCG, draw up the functional specifications for Eudamed. The Commission shall draw up a plan for the implementation of those specifications by 26 May 2018. That plan shall seek to ensure that Eudamed is fully functional at a date that allows the Commission to publish the notice referred to in paragraph 3 of this Article by 25 March 2020 and that all other relevant deadlines laid down in Article 123 of this Regulation and in Article 113 of Regulation (EU) 2017/746 are met.

2. The Commission shall, on the basis of an independent audit report, inform the MDCG when it has verified that Eudamed has achieved full functionality and Eudamed meets the functional specifications drawn up pursuant to paragraph 1.

3. The Commission shall, after consultation with the MDCG and when it is satisfied that the conditions referred to in paragraph 2 have been fulfilled, publish a notice to that effect in the Official Journal of the European Union.

The MDCG will have to communicate the delay before it is a reality. I believe the MDCG will have some tough questions for the EC before they agree to any full delay.

Some of these questions will or should include:

- What is ready?
- Can the modules already completed be deployed? Actors and UDI Devices.
- Even if the mandatory requirement for economic operators to populate the database may not be enforced until 2022 when the system is fully functional, can the operators who are ready and have invested heavily in preparing start using the system?
- Is there any reason why the SRN's cannot be issued in March 2020 and the device module start working?
- The actor and Device modules will be ready for March 2020 so it is possible these could be released?

A positive for the MedTech Industry

This is **a real positive for the industry.** Companies with regards to their MDR Eudamed projects should view this delay as an opportunity.

The industry representatives at the working groups have constantly stated that companies need 18 months from receipt of final specifications to prepare their systems. This delay gives that time.

The US RAPS asked for a 3-year transition period for the North American companies to prepare. If this delay is endorsed by the MDCG then you have your requested delay.

The one thing we can all be sure of is that the Actor and **UDI device** modules are ready. The data model for the most part and **data requirements will not change**. If you have prepared your data groups, Basic UDI and UDI DI's, heavily invested in training, and IT developments this is not wasted time or effort.

If you are only starting your projects, keep going, the delay does not change what will be required of you and your companies. The only change is that you have an opportunity to perfect your preparation and you have time to take a breath. Do not waste this opportunity.

A very wise man said to me last week "If the EC do delay, I hope companies use the time better than the British did with Brexit."

This sentiment I have to agree with, there is no reason to slow down or postpone projects. As things stand you have enough information to proceed with your UDI Device developments. By the time the Vigilance forms and requirements are ready you should be ready with your UDI Device data and you will have a good understanding of the MDR Eudamed needs.

Based on feedback I have received directly from economic operators and from participants at our training sessions, a lot of companies have underestimated the size and complexity of the required MDR Eudamed projects. So my final words, do not under estimate the size, nor the required time required to complete or complexity of your MDR Eudamed projects.

View this delay as a gift.

If you need support, training, or software to help with your data preparation and submissions then Eudamed.eu are available to assist you.

About the author

Richard Houlihan is international keynote speaker on Eudamed. He is the CEO of Eudamed.eu, a company in a unique position to help the MedTech industry with their Eudamed preparation, training, and support. This unique position is because of Richard's direct involvement with MDR Eudamed within European Commission. The company provides several services from Data preparation software, Training, Support, and Consultancy.