MEDTECH INSIGHT
CITELINE COMMERCIAL

01 Dec 2021 | **Analysis**

European Regulatory Roundup, November 2021: Eudamed Dominates News

by Amanda Maxwell

Updates and speculation surrounding the Eudamed medtech database has attracted significant attention in November. It was also an impactful month for IVDR news too, and for moves strengthening the medtech and pharma interface.

During November, there was good and not-so-good news when it comes to setting up the Eudamed medical device database to meet the information exchange needs of the medtech sector in implementing the EU Medical Device and IVD Regulations.

The good news was that not only are three of the six modules are now available on a voluntary basis - for actor registration, UDI/device registration and notified bodies and certificates, but that guidance was published in November to support users inputting their information into the modules.

The less-than-good news was that this guidance highlights how complex the processes are; *there are 95 pages of guidance on the UDI/Devices module* alone which will be daunting for many companies, especially SMEs. Furthermore, the *notified bodies user guide* is very lengthy at 78 pages. Like the UDI/devices module, it features screenshots of the database to assist users in making their way through the process. (The user guide is featured on the European Commission's *Notified Bodies And Certificates Eudamed web page* along with related technical documentation.)

The other bad news is that potential delays with two of the other three modules could *mean an overall delay in the readiness of the database,* although nothing has been officially confirmed.

Given concern over the timely availability of the modules on clinical investigations and market surveillance, there is new speculation that the database might be officially launched without these two modules. The other module that has not be made available yet at all, for vigilance

reports, is still expected by Eudamed's overall go-live date of 26 May 2022.

There is nothing official to suggest a delay in the launch of the whole *database*. But given increasing speculation about delays, Medtech Insight looked at what the *timelines for uploading information in the database are likely to be* if the current 26 May deadline remains in place for the entire database, and also if it is, or parts of it are, delayed until mid/late 2023.

Richard Houlihan, CEO of the EirMed consultancy specializing in Eudamed, explained to Medtech Insight *in an interview in early November* that it is important for manufacturers to upload information into the database at the earliest opportunity. This is not just because of demand for support services, but also because, while the current modules are voluntary, there is anecdotal evidence that importers, distributors and some notified bodies are already asking companies whether their devices are in Eudamed.

EMA Devices Role

Elsewhere,, the European Parliament and the Council of the EU *have reached a provisional agreement* on the European Commission's *proposed regulation for a reinforced role for the European Medicines Agency in health care crises*.

The document lays out the new role the EMA would play in overseeing various aspects of device management, as well as medicines, in the event of a health care crisis.

The agency would be involved in the management of two device functions: the medical device expert panels, already established under the Medical Device and IVD Regulations; and a new Executive Steering Group on Shortages of Medical Devices.

There are 198 mentions of the word "device" in the original commission proposal, an indicator of the extent to which the commission foresees the European medicines regulator playing a new role in oversight over the regulation of some products and their supply in the devices area.

Publication of the regulation, once adopted, is expected in the Official Journal of the EU before March 2022.

HTA Regulation

The medtech industry is also going to be impacted by another regulation that spans the medtech and pharma industries – the HTA Regulation.

The text that the Council of the EU adopted as its first reading position – in a move that is likely to see a straightforward path to adoption – retains aspects which were devised with both the pharma and medtech industry in parallel in mind, which MedTech Europe considers "add

another level of bureaucracy for medtech to overcome."

The industry has welcomed elements of the regulation that respond to the needs of the device sector. However, it remains concerned and hopes member states who will drive this new regulation, via the future HTA coordination group, could still correct shortfalls when defining future workplans.

"We very much hope assessments will only be planned and conducted when there is a clear and present 'need' for the exercise," the association said.

IVDR

The IVD industry, meanwhile, is still waiting to hear whether the new commission proposal to stagger implementation of the final compliance IVDR deadlines according to the risk class of *products will be signed off*. This contingency move would cut the sector some slack after growing fears that an overly tight deadline was going to prove a disaster for the industry and for product availability.

In the meantime, the commission's MDCG 15-page *updated plan on the implementation of the IVD Regulation, the Joint implementation and preparedness plan* shows what a challenge the sector has ahead of it in terms of compliance with the new IVDR.

The good news here is that *two long-awaited European Commission proposals have been published* which shed light on how EU reference laboratories will operate under the IVD Regulation and likely timelines. One sets out the tasks of and criteria for EU reference laboratories (EURLs) under the regulation, and the other lays down rules regarding fees the EURLs may charge. (EURLs are a new type of scientific body. Once designated, their main role is to carry out additional tests on the highest risk, class D, IVDs.

Looking Forward

Looking forward, the commission has published *a list of key medtech meetings* being held by the Medical Device Coordination Group up until February 2022.

Separately, for October's roundup, see: *European Regulatory Roundup, October 2021: IVDR Grace Period Proposals And Classification News*

Top 10 EU Regulatory Pieces

The most popular EU regulatory articles in November were as follows:

Rank	Title
1	***How To Register Devices In Eudamed: The Process And The Pitfalls***

2	*EU One Step Closer To Confirming EMA's New Pivotal Role In Device Matters*
3	*European Regulatory Roundup, October 2021: IVDR Grace Period Proposals And Classification News*
4	*How And When To Use Eudamed: The Challenges, Pitfalls, Surprises And Opportunities*
5	*How Does The Eudamed Module On Notified Bodies And Certificates Work?*
6	*Timelines And Deadlines For Stakeholders To Submit Information To EU's Eudamed Database*
7	*EU MDCG Meetings In The Pipeline: November 2021 To February 2022*
8	*Are Latest Challenges Threatening To Push Eudamed Launch Date Into 2023?*
9	*EU's Updated Plan Of Action To Plug The IVDR Gaps: All Hands To The Pump*
10	*EU HTA Regulation Adoption Now A Formality Despite Medtech Industry Concerns*