MEDTECH INSIGHT
CITELINE COMMERCIAL

25 Aug 2023 | **News**

Should The EU Establish A Central Accountable Managing Structure For Medical Devices?

by Amanda Maxwell

Top regulatory experts are reacting to German industry calls for action over MDR/IVDR failures, including a proposal to have a centralized governance agency modeled on the European Medicines Agency but specifically for devices.

The question of whether there should be an EU centralized medtech agency to oversee the regulation of medical devices has come to the fore again because of what many consider to be a fundamental failure of the implementation of the Medical Device and IVD Regulations.

And this issue is dividing opinions.

The proposal for a central governance structure is not new. This matter was being deliberated at EU level a decade ago when the Medical Device and IVD Regulations were being drafted, with particularly heated debates in the European Parliament at that time. (Also see "*EU medtech reform vote delay: tensions over involvement of EMA*" - Medtech Insight, 20 Sep, 2013.)

But the notion has surfaced again; this time in a 55-page White Paper from the German industry association BVMed (medical devices) and its IVDs counterpart, VDGH, who are calling for simpler, more transparent and less costly solutions now, ahead of the scheduled evaluation of the MDR in 2027. The current legal framework, they argue, “is not practical.”

There is a need for “more transparency and efficiency, more predictability and speed, more international connectivity and competitiveness,” they contend.

The two German associations worked in cooperation with Erik Vollebregt, expert medtech regulatory lawyer and founding partner at Axon Lawyers, to draft the text.

The proposal dedicates some three pages to developing a case for the how such an agency could improve the EU medtech regulations, which it describes as currently "too complicated, bureaucratic and cost-intensive. It says this situation is as putting EU industry, and especially innovation, as well as patients, at risk.

A Daydream? Or Premature?

Gert Bos, managing director of Qserve consultancy, sees many advantages of implementing the paper's proposals. He told Medtech Insight that the "paper reads a bit like a daydream, but if we all dream in the same direction, some elements, or even all of them might come to fruition."

But other experts disagree.

Sabina Hoekstra-van den Bosch, global director regulatory strategy at TÜV SÜD and a spokesperson for notified body matters as chair of the notified body coordination group executive committee and vice-president of the Notified Body Coordination Group (NBCG), could endorse some of the observations in the White Paper (regarding rate of notified body designation and slow implementation of Eudamed, for example) but does not believe an EU central governance body is the solution.

It is far too early to conclude that the medtech sector needs a central body, she said, noting that the commission has instigated a Study on Regulatory Governance and Innovation in the field of Medical Devices in the framework of EU for Health.

This study is executed by Ernst & Young, started earlier this year and will last 18 months, she noted.

It really depends on what the central body would be tasked with and if there are guarantees that it would do a better job than the organizations that perform the task now, as a lot of the tasks require very specific knowledge and expertise, she told Medtech Insight.

Nevertheless, Hoekstra believes improvements are needed. "We think that the sector could benefit from solid coordination of certain tasks, e.g., guidance development. However, without sufficient resources this cannot be achieved anywhere, neither in a central body, nor in any other coordination structure," she said.

"So, let's await the outcomes of this study first," she emphasized, in which all stakeholders will be involved, "before drawing conclusions."

Bos' Arguments

Bos suggested that, being realistic, revising the supervisory structure alone might take a couple of years and it could take until 2030-2040 to get such a new structure as the two German

associations are proposing, operational.

In the meantime, energies need to be dedicated to progressing the MDR and IVDR assessments as fast as possible, he proposed, so that essential changes in products and (micro) innovations can start to be rolled out again.

Nevertheless, he credits the paper with good suggestions that could be implemented in the relatively short term such as transparency in pricing and clear conformity assessment timelines.

And the environment is potentially sufficiently mature now to consider such a concept. When the MDR and IVDR negotiations were being closed, Bos notes, many indicated a shift from notified bodies to a new and fully inexperienced agency would be too risky.

But since then, the sector has moved on, he asserted, And the European Medicines Agency has brought together groups of experts that might well feature in a supervisory way, where notified bodies might make certification recommendations to a central review board like EMA's Committee for Medicinal Products for Human Use (CHMP), he suggested.

He feels certain that a new and overhauled system would greatly benefit niche products for smaller groups of patients, both for diagnostics and medical devices. “Most critically,” he added, “it might bring back the earlier innovation that the European market historically has been known for, that now is fleeing to US, UK and Asia.”

How The White Paper Sees The Agency Operating

The authors of the paper dedicate three full pages to developing the argument of how a central governance structure could work for EU medtech regulations.

They believe the structure should be standalone and not a branch of the EMA and be responsible for EU medical devices policy and approval of certain high-risk and innovative devices.

They also consider that any medical device policy elements already administered by the EMA should be transferred to the accountable managing structure.

In terms of any comparisons with the EMA, Hoekstra-van den Bosch, noted that the pharma agency has a headcount of over 900 people and a budget of almost €300m. of which around a third is distributed to the national competent authorities for pharma products.

While cautioning that the two sectors - pharma and medtech - have quite different regulation and governance structures and so should not be compared, the TÜV SÜD global director, speculated how much could be done “to improve coordination and harmonization in the medtech sector with resources in the same order of magnitude.”

"You can only dream of it....", she said, adding to Bos's views that the proposals may be more the stuff of dreams than reality as they stand now.

More Details of What The White Paper Envisages

The German associations' White Paper is thorough and detailed. There is a lot of consider in the 55 pages of analysis and proposals, and it will be interesting to see what Ernst & Young make of it in considering their report.

The White Paper envisages:

- Restricting the competence of the proposed centralized structure for certification to a certain specific minority of devices, and/or specific roles in the approval process, such as high-risk and innovative devices currently subject of the clinical evaluation consultation procedure (CECP) and under the scrutiny procedure. (The remainder would still be subject, it suggests, to certification decisions by notified bodies.)

- Ensuring the patient voice is included in the different regulatory activities of a device's lifecycle to improve trust in regulatory decision and new devices, at the same time as allowing for engagement with other stakeholders, notably manufacturers and notified bodies.

It also foresees that a new governance structure could consolidate responsibility for "indispensable roles" and responsibilities for the regulatory system, such as:

- An administrative appeal process for appealing against notified body decisions regarding the non-granting, the suspension, restriction or revocation of CE-marking certificates.

- Taking over tasks from the commission, including guidance developments, harmonization of notified body auditing, notified body oversight, integration of process and development of the Eudamed medical device database.

- Overseeing the designation of notified bodies, as well as the coordination of notified body policy and relieving pressure from the "under-resourced processes of the Joint Assessment Team (JAT) which have "consistently posed a major, if not the biggest, bottleneck in the notified body designation process under the MDR and IVDR."

- Monitoring notified body fees and providing harmonization of notified body fees structures.

- Creating and running an SME office, like the EMA SME office.

- Broadening the range and type of products submitted to prior oversight and scrutiny following initial notified body assessments and prior to market launch so that the accountable managing structure could raise concerns which would have to be considered by the notified bodies.

Standing Still Not An Option

To motivate the sector to action, the authors of the paper warn that the "future of Europe as a medtech location and of patient care is at risk," adding that "standing still is not an option" and that the sector "cannot wait until the planned evaluation of the MDR/IVDR in 2027."

So, they are calling on the European institutions to enter a structured dialog with all relevant stakeholders in Germany and wider Europe to take the necessary measures as quickly as possible.

As a first step to encourage dialog, they have developed five concrete proposals in the White Paper.

They want to see:

- Use of post-market surveillance to eliminate recertification.
- Supplementary regulations such as fast-track procedures for innovations, orphan devices or niche products.
- Integration of the EU into the global Medical Device Single Audit Program (MDSAP) as well as mutual recognition agreements between the EU with Switzerland and Great Britain.
- Consistent harmonization and centralization of the EU administrative structure, including establishment of an SME office at EU level.
- Increased efficiency through the implementation of the European principles of good administrative practice, especially predictability of deadlines and costs, access to the system and transparency of the certification processes.

Marked Urgent!

In their White Paper, VDGH and BVMed emphasize the urgency of action to address shortfalls in the implementation of the MDR stating that:

- In 65% of cases, companies are forced to shift development resources to regulation, at the expense of innovation.

- 89% of medtech companies now prioritize FDA approval.
- Companies are increasingly shifting research projects to the UK or US because innovation access and data use are better regulated there.
- Even Switzerland, which has adopted CE marking for decades, is moving in the direction of the US and wants to recognize FDA approval for medical devices.