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First Public Discussion On How EU Medtech Regulatory Governance Structure May Evolve

by Amanda Maxwell

Does the EU need a medtech agency for the first time in its history? Nothing can or should be decided too quickly but five high-profile experts broadly agreed that change is now critical.

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Should the EU replace the current oversight of medtech products with a new regulatory governance system at the earliest possible opportunity to ensure more harmonization and predictability and a better environment for innovation?

That was the question that Medtech Insight put to five EU medtech regulatory experts in a recent vodcast focused on "What the future governance and oversight of the EU medtech regulatory system is likely to look like and whether the EU needs a medtech agency."

This was one of the very first, if not the first public discussion on the EU governance system, Petra Zoellner, director of regulatory affairs (IVDR and MDR) at trade association MedTech Europe, acknowledged.

Also on the call were: Bassil Akra, CEO of Akra Team; Olga van Grol-Lawlor, senior global regulatory intelligence and advocacy manager at Boston Scientific, representing industry. Representing EU notified bodies was Graeme Tunbridge, senior vice-president, global regulatory and quality at BSI regulatory service; and Royth von Hahn, senior vice-president, global medical

and health service at TÜV SÜD product service division.

The five experts broadly came out in favor of having an improved governance structure in the EU, but no one appeared wedded to the idea that this should necessarily be a medtech agency, like the European Medicines Agency for example.

They highlighted the potential that such a structure could have in improving the EU medtech marketplace, especially in terms of innovative products reaching patients.

But they cautioned that sufficient time is needed to get any new governance system right.

They also recommended learning from the mistakes associated with the implementation of the Medical Device and IVD Regulations, noting that changes were made without accurately assessing their long-term impact.

Topics discussed included: the need for the medtech sector to have stability; building expertise within the current system; speculation over timelines for an improved governance structure; the future role of notified bodies and competent authorities within a new structure; how a new structure could offer so much more including in terms of innovation and specialized pathways to market for certain product groups.

A Guide To The Vodcast

Below are indicators where you will find answers to key questions during the vodcast:

1. How optimistic are you on a scale of 1 to 5 that positive change is on the way in the EU over the next 24 months when it comes improving the regulatory environment for medtech products? 2.47

2. How important is a central governance structure to oversee the implementation of medtech regulations in the EU given the status of the implementation of the MDR and IVDR? What would be its the primary roles? 7.43

3. How important is the need for improved harmonization among notified bodies? 9.35

4. To what extent does industry consider more harmonization is needed between notified bodies and how they operate? 12.41

5. Does MedTech Europe feel there is a growing impetus to bring about the change that it would like to see? 15.21

6. What form could this agency take? Who would run it? Where would it be based? How soon could such an agency be up and running? And how would notified bodies foresee such a structure working? 21.48

7. What sort of role might notified bodies have in a new governance structure? 23.22

8. Would an agency or governance structure make industry communication with regulatory authorities more straightforward? 24.52

9. What can be done now ahead of establishing such a structure, including to improve opportunities for innovation and ensure patients in Europe have access to innovative products earlier than is currently happening? Do notified bodies have sufficient capacity now, including to work on innovative products?

10. Is industry more likely to launch its most innovative products in the EU or be more inclined to go to the US or other markets first? 36.23

11. Are notified bodies getting sufficient experience working with innovative products to retain the necessary expertise given so many innovative products are being launched in other markets? 39.29

12. What would be needed as building blocks in terms of talks, decision-making and, importantly, legal steps and instruments to create a new structure? 42.26

13. In summary, are each of the speakers in favour of having a new governance structure in the EU as soon as possible. 51.51