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EU Regulatory Round-Up, September 2024: Change Is In The Air

by Amanda Maxwell

Those working in the medtech sector returned from their traditional August break to a growing sense that the EU is more collectively aligned about the need to improve the medtech regulations and soon.

September 2024 was a critical month for manufacturers of legacy medical devices wanting to keep their products on the market. They had to ensure there was a written agreement by the 26th of the month transferring the responsibility for the surveillance of relevant legacy devices from the notified body they had used under the former EU Medical Devices Directive and Active Implantable Medical Devices Directive to the notified body assessing them under the EU Medical Device Regulation.

Without such an agreement, they were required to remove their products from the market.

It was also a landmark month for me. I celebrated 40 years of reporting on the medtech industry and took the opportunity to reflect on how far we have come in that time, and whether the EU's increasingly complex and stringent regulations have, indeed, actually improved patient care. *This was our number one read* among subscribers this month.

I also celebrated this occasion with an *in-depth, and very popular, interview* with two renowned EU medtech regulatory gurus, Tom Melvin, associate professor of Medical Device Regulatory Affairs at Trinity College Dublin, and Erik Vollebregt life sciences specialist lawyer and partner at Axon Lawyers. Neither expert shied away from giving strong opinions about the elements they believe should be urgently corrected within the system.

They also offered solutions that should be relatively easy to accommodate within the current EU rules, including introducing more reproducibility of efforts within the system to make it more efficient.

New Commission, New Policies

The European Commission is in a state of flux at present following the European elections. President Ursula von der Leyen, has listed *Olivér Várhelyi, as the commissioner-designate for Health* and Animal Welfare in the new European Commission.

In doing so, she has called on him to "step up the implementation of the current framework [for medical devices] and evaluate the need for potential changes" while keeping the availability and competitiveness of medical devices high on the agenda.

Some experts are already suggesting that the ground is now well prepared for the possible take-up of the proposed amending regulation by the commission which was the initiative of MEP Peter Liese.

Don't Forget The IVDR!

In response to von der Leyen ambitions, industry associations *MedTech Europe and COCIR issued a statement* saying: "It is essential that the scope of this priority area covers both medical devices and diagnostics, including diagnostic imaging technologies and in vitro diagnostic medical devices."

Innovation

It is no secret that innovation has taken a particularly hard knock because of the complexity of the EU's regulations, and the lack of sufficient preparedness at every level.

Interested parties now have until 10 October to respond to the Innovative Health Initiative's call to *present a proposal for model regulatory sandbox mechanism*s and enable their deployment to support breakthrough innovation in the EU.

Additional News

In other news, members of the TEAM-NB association of notified bodies have adopted an agreement specifying the terms of the transfer of the appropriate surveillance activities for legacy IVDs from one notified body to another. The deadline for IVDs is a year later than that for medical devices and comes on 26 September 2025.

Furthermore, the same association issued the latest version of its code of conduct which features a useful page on what can and cannot be provided in the context of a "structured dialog".

Separately, a new notified body, *ISS, was designated* under the IVD Regulation. This was Italy's first and the EU's 13th under the IVDR.

UK

While no longer part of the EU, there was *big news from the UK this month* as it announced a consultation on a pre-market statutory instrument to be completed by the end of 2024.

- For last month's highlights, see: *EU Regulatory Roundup, August 2024: Need For MDR Changes Continues To Absorb Sector*

Rank	
1	*Opinion: Is The EU Recreating A Different Monster Of A Regulatory Labyrinth?*
2	*Video: How To Efficiently Patch A Medtech Regulatory System 'Set Up To Fail'*
3	*EU Regulatory Roundup, August 2024: Need For MDR Changes Continues To Absorb Sector*
4	*Ursula Von Der Leyen Calls For EU Medtech Regulatory Framework To Be 'Stepped Up'*
5	*How To Transfer Surveillance Oversight For IVDs From One EU Notified Body To Another*
6	*Updated Notified Body Conduct Code Explains Permitted 'Structured Dialogue'*
7	*Urgent Action Needed To Address Deficiencies In EU's IVD Regulation – As Well As MDR*
8	*ISS Named As Italy's First Notified Body Under The EU's IVD Regulation*
9	*EU Launches Call For Regulatory Sandbox Initiative To Accelerate Medtech Innovation*
10	*UK MHRA Keeps Up Momentum For Change With 'Pre-Market SI' Devices Consultation*