MEDTECH INSIGHT
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European Regulatory Roundup, August 2022: EU On Cusp Of Big Implementation Push

by Amanda Maxwell

The EU had arguably hit a crisis point when it came to the implementation of the new EU medtech regulations by the end of July. But now there are signs of a turnaround. Will it happen, though?

Unsurprisingly, after two years of COVID-ravaged summers, many were keen to make the most of the month-long traditional summer break. Nevertheless, there has been some important news and stock-taking.

The European Commission's Medical Device Coordination Group (MDCG) drafted, adopted and published *its 19-point action plan* over the EU's summer months to address obstacles to the timely implementation of the EU's Medical Device and IVD Regulations. The fact it worked over the summer on this file reflects how urgently these measures are needed after months of stark warnings from industry, notified bodies and competent authorities.

It is not just the implementation of the MDR and IVDR that is severely challenging many in the medtech industry. It is also a "perfect storm" of increased regulation in general and decreased availability of certain staff that is becoming overly burdensome, particularly for SMEs.

Indeed, one expert lawyer in the medtech sector, Shuna Mason of international law firm, CMS, suggested to Medtech Insight *in an interview* that the EU regulatory system may need "some structural changes or flexibilities and pragmatism". She even questioned whether the EU may have to "ditch the notified body model and go for a different kind of regulatory structure?".

Notified Body Capacity

There are certainly still concerns over the rate of notified body designations and over the capacity of these testing and certification organizations to audit all products so they comply in

time with the 26 May 2024 final deadlines for the MDR. The rate of designation for IVDR notified bodies is equally concerning; while there are new staggered deadlines for compliance with the IVDR, the number of products that will need to make the initial 26 May 2022 deadline is concerning.

While the *European Commission's new MDCG timelines chart* did nothing to reassure the sector over the rate of designations of new MDR and IVDR notfieid bodies, there are now hopes that the 19-point action plan, which does much to address the pace of notified body work and designations, will make a significant difference.

Other important developments related to the implementation of the two new regulations during August included the announcement of the *32nd notified body under the MDR*, Bureau Veritas Italia, based in Milan.

Further Implementation-Related Developments

In addition, the European Commission published new draft rules to address member state concerns about the under-classification of certain products that fall under the MDR but that do not have an intended medical purpose. These are the so-called Annex XVI products. The *draft addresses the risk classification of non-medical active products* such as laser/intense pulsed light devices for hair removal or skin treatment, liposuction equipment and brain stimulation devices. Feedback is invited by the end of 8 September.

Also in August, and this time in the context of the IVDR only, the European Commission sent a call for applications to member states to submit bids for European Reference Laboratories (EURLs) for eight categories of products classified under the IVDR's class D. These organization are pivotal when it comes to the review of these highest-risk IVDs and yet have been absent so far despite the initial application date of the IVDR having been 26 May this year.

The next step is for candidate laboratories to contact the relevant authority in their member state for further information.

Raising The Reimbursement Profile

During August, Eliza Slawther joined Medtech Insight's EU regulatory team as a senior writer, working with Amanda Maxwell to expand regulatory coverage beyond the Medical Device and IVD Regulations to other associated developments in the field of artificial intelligence, for example, and crucially in funding, reimbursement and HTA.

In *Slawther's first podcast with Maxwell*, she spoke of her experience in life sciences writing and her passion for the topic. She is familiar with pharma regulations, is doing a Bachelor of Science (BSc) in biomedicine in her own time, and addressed the issue of reimbursement for investigational cancer therapies in her Masters in journalism.

This first podcast was also an opportunity to review the basics of EU medtech regulation with the aim of supporting readers new to our area.

Reimbursement In UK And France

In one of her first articles for Medtech Insight, Slawther reported on how the UK's Association of British Healthcare Industries (ABHI) is concerned that the *UK's NICE is requiring developers of digital technology based on artificial intelligence and adaptive algorithms* to have generated "an extremely high bar of evidence". NICE is the UK body that produces health technology assessment guidance for England and Wales.

Reimbursement strategies are formed on a country-by-country basis. And in a separate article that has proved very popular with Medtech Insight's readers, Slawther interviewed Hubert Galmiche, head of medical device assessment at the French National Authority for Health (HAS), to report on the *factors that impact reimbursement and funding decision-making in France*. Proving clinical added value is a particularly important step when it comes to price setting.

New UK Medtech Regulations

In the UK, meanwhile, companies await with increasing impatience news of progress on the UK's new statutory instrument (SI) for medtech products.

In an *interview with Medtech Insight*, regulatory affairs manager at the British In Vitro Diagnostics Association (BIVDA), Ashleigh Batchen, was not convinced that the UK's draft regulation will be ready by the end of the current year.

There are certainly still multiple hurdles ahead. The EU may have already had experience with its medical device regulations from which the UK can learn. But the interview suggested the UK is likely to have a similarly tall regulatory mountain ahead to climb.

Also during August, we reported on the sad news that former Clinica editor and mainstay of our publications for three decades, Maureen Kenny, had passed away. (Clinica was the former name of Medtech Insight.) Maureen was well-known in the forums where life sciences issues were being discussed, especially regulatory topics.

For July's European Regulatory Roundup, see: *European Regulatory Roundup, July 2022: Threat Of Ongoing Hurdles Masks Progress*

Below is the list of our 10 most popular European articles in August:

Rank	Title
1	*European Regulatory Roundup, July 2022: Threat Of Ongoing*

	Hurdles Masks Progress
2	Latest Italian Designation Means Germany And Italy Are Home To Half EU's MDR Notified Bodies
3	European Commission Publishes Draft Rules In Bid To Reclassify Non-Medical Active Products
4	Why EU Regulations Are Changing The Face Of Innovation And May Be Unsustainable
5	UK's NICE Outlines Standards That AI And Data-Driven Medtech Should Meet For NHS Uptake
6	No Quick Fix When It Comes To EU Medtech Notified Body Designations
7	Vibrant IVDs Innovation Climate At Risk From Poor UK System Readiness
8	French Medtech Reimbursement – How Added Value and Clinical Benefit Sway Decisions
9	Introducing Medtech Insight's New EU Regulatory/Reimbursement Writer
10	EU Reference Laboratory Candidates Invited To Apply In Context of IVDR Regulation