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EU Regulatory Reads, 2017: Are We Heading Toward A 2018 Crisis?

by Amanda Maxwell

Since the EU's new Medical Device and IVD Regulations took effect in May 2017, progress toward implementation has been painfully slow. So, what is needed in 2018 to ensure the MDR and IVDR are viable?

The EU's Medical Device and IVD Regulations were *adopted*, *published* and finally entered into force just over seven months ago on May 25.

That means there are just over two years and four months to go until the MDR and IVDR fully apply – on May 26, 2020, for medical devices, and May 26, 2022, for IVDs.

By those dates, all new medical devices or IVDs coming onto the market since the date the MDR or IVDR entered into force will need to be in compliance with the new requirements. Also, by those dates, notified bodies will have to cease offering auditing against the current directives.

And while there is a potential extension of up to four or five years for some products beyond the date of full application, *manufacturers need to be extremely careful* that they are eligible to make use of this extension, and indeed that it is in their interests.

For the majority, a lengthy extension will not be practical nor desirable, or not legal, and certainly not for those *products that are being up-classified, or which are covered by the regulations for the first time*, or *those where any significant changes are being made*.

And even where an extension may be desirable, companies will need to

- Medical devices may continue to be placed on the market up until May 26, 2024, subject to conditions and depending on the type of certificate issued. Class I devices without certificates only have until May 26, 2020, and devices certified

cooperate closely with their notified bodies to maximize the extension period in their favor. But notified bodies are unlikely to have the capacity to be as flexible as companies would like and services could be slow as applications mount.

This could land some companies in deep water if they miscalculate and their CE markings under the current EU Directives run out before they are able to demonstrate CE-marking under the new regulations.

via the EC verification route only have until May 26, 2022.

- IVDs may continue to be placed on the market up until May 26, 2024, again subject to conditions. (Note: this provision is applicable only to a small percentage of higher risk and self-tests IVDs.)
- In addition, products legally placed on the market up until those dates can also legally be put into service for an additional year, i.e., until May 26, 2025.

No Organizations Designated To Audit For Some Time

So, just over 28 months to go and none of the EU's testing and certification bodies are ready – *nor will they be ready for a considerable time* – to actually audit manufacturers against the MDR or IVDR.

The reality is that the supposed three-year transition period for the MDR will be a *much shorter 12 to 18 months* – or even *as short as six to 12 months* some have speculated – for the majority of manufacturers.

Nov. 26, 2017, was the first date that notified bodies could even apply to become designated under the MDR and IVDR. But there were not as many applications on that first date as would be needed to ensure timely testing capacity among the notified bodies for all manufacturers that will need their services over the next couple of years and beyond to comply with the new requirements.

Notified Bodies Numbers Game

It is little surprise that about one-third of the pieces in *Medtech Insight*'s top 30 EU regulatory stories relate to notified bodies. The vast majority of products in the EU need to be audited by these organizations and the notified bodies are undergoing changes so fundamental that their survival in the medtech sector is challenged.

There are currently 58 notified bodies under the existing Medical Devices Directive (MDD). In addition, there are 22 under the IVD Directive and 14 under the Active Implantable Medical Devices Directive, many of which are the same testing organizations as those designated under

the MDD. Reports earlier this year that *notified body numbers were already dropping* (in the context of the current medical device directives), turned out to be wrong. Indeed, numbers have confounded predictions and have bounced back up from 55 in May 2017 to *58 under the Medical Devices Directive* now.

Nevertheless, the number of notified bodies that indicated their intention to *apply under the new MDR and IVDR* at the earliest opportunity was around just 20. Given how long designation will take to be achieved, this is highly concerning for the sector; any applications made later will still need to pass through *the lengthy application process*.

Industry is clearly concerned by how long this process is going to take. *Oliver Bisazza*, director of regulations and industrial policy at industry association MedTech Europe, told *Medtech Insight* in November: "We've been told that much of Q1 2018 will be spent simply reviewing the [paper] applications notified bodies start submitting, with onsite assessments starting in Q2 2018. We would like to see more ambitious timelines attempted."

In his view, authorities and regulators urgently need additional resources to tackle the challenges ahead. "We feel the timing will really depend on the amount of ambition and resources that are thrown at the challenge," he said.

No one knows exactly how many more notified bodies have applied, or, ultimately, will apply. More specifically, none of the approximately 35 notified bodies that operate in the EU but are not members of the European association of notified bodies, TEAM-NB, have publicly voiced an intention to apply for designation.

This means that the sector is facing huge uncertainties at one of the most critical times in its regulatory history.

For many manufacturers, they do not know if the notified body that currently oversees their products will continue under the new MDR or IVDR, and, if it does not, companies are faced with the reality that those notified bodies that have a more certain future in this sector are already almost all heavily oversubscribed and unlikely to be taking on new clients.

This creates uncertainty and a threat to the continuation of their products and indeed, in the case of smaller companies, their businesses. There are *fundamental questions over whether products affected by this scenario may continue on the market*.

When Will We See First MDR/IVDR CE Markings?

During 2018, some are optimistic that we may see the designation of the first bodies that are notified to audit medical devices and IVDs under the MDR and IVDR. But judging from *the guide produced by the Notified Bodies Operations Group (NBOG)* in November 2017, this may not happen

until 2019.

This big question, therefore, is when we are likely to witness the first CE markings of medical devices under the MDR and IVDR that have been audited by notified bodies.

This will be the year to find solutions to the problems of the timing of implementation and designation so that the vast majority of manufacturers can comply on time – although it is clearly going to be a challenging ordeal.

If the new CE-marking machinery does not make progress soon, there is a risk that many devices could need to be pulled from the market beginning on May 26, 2020.

It would be catastrophic if Brussels allowed this to happen, so solutions will have to be found, or, perhaps, a derogation will be allowed because of the failure of the implementation machinery. But many experts don't see exemptions as likely.

Of course, manufacturers of the *lowest-risk devices and IVDs* – class I medical devices under the MDR that do not have a measuring function or are not sterile, and class A IVDs – can self-certify their products in compliance with the MDR or IVDR. But it seems that none has yet chosen to do so, and a lack of infrastructure and guidance may be to blame.

Will Implementation Efforts Be Enough?

There is a hunger to have more information about how work is being rolled out to allow for implementation, and this has been reflected in the high positions in our top 30 articles focused on this topic.

While publication on May 25, 2017, revealed the final extent of the MDR and IVDR, this was, in practice, only the beginning. How the regulations are going to be implemented and managed in practice is now the subject of intense work carried out, mainly, by the European Commission and its working groups.

After months of delay, the so-called roadmap to implementation, *finalized on Nov. 10*, turned out, frustratingly for some industry experts, to be more of a roadmap to creating the actual roadmap to implementation. It was published nearly six months after the new regulations took effect, causing individual players in the sector to risk floundering about in uncertainty by heading off in the wrong direction in a bid to be compliant in time despite the lack of guidance.

One of the key items in this roadmap was the creation of the *new "Transitional Measures" Taskforce* to ensure the new regulations are introduced uniformly throughout Europe. This taskforce will have responsibility for a newly added work stream within the roadmap, titled "Over-arching & Cross-Cutting Priorities." The work stream includes a work item focused on

"transitional problems and uncertainties, and risks to continued supply of safe devices" that has been marked as high priority.

While the industry associations say they are doing their best to provide their own guidance, their work is done against a background of unfinished business, an environment where top-level guidance is needed, and where there are around a hundred delegated and implementing acts that still need drafting and adopting to implement key and critical aspects of the MDR and IVDR.

There is a great deal at stake, and the speed of the work being done in the context of this roadmap will be critical to ensuring that the structures and documents needed as foundations to build the new regulations are ready in time. If some are ready and others are not, then, like the proverbial deck of cards, the whole thing risks collapse.

Crucial Governance Structures: Embryonic At Best

The key governance structures on which the new EU Regulations are being built are also still mostly in very early stages of development or unformed.

The new Medical Devices Coordination Group (MDCG) – arguably the most pivotal group in implementation and oversight, and made up to competent authority experts reporting to the European Commission – was *set up at the end of the November*.

There was also news that the European Commission is looking more closely at *the organization of its working groups* and those needed in the future, but again, this seems at an early stage.

The expert panels and reference laboratories – critical for the review of higher-risk devices, including for clinical data and performance – have yet to be appointed, with guidance on how this is going to happen still pending.

And while experts are working in the background on the *new and updated version of the European medical device database, Eudamed*, there have been warnings of likely delays, especially if previous experience with the current version of Eudamed is a model.

The MDR and IVDR have built-in contingency plans for the scenario where the new database is delayed. But clearly if these are needed, it will impact the effectiveness of the regulations and likely involve additional work for all stakeholders.

Guidance, And Yet More Guidance

There was a time when the regulators excused the fact that there were substantially more pages in the MDR and IVDR than in the MDD (175 versus 60) and IVDD (157 versus 37) by explaining that the new regulations absorb much of what is in the guidance documents accompanying the current directives.

But, in reality, the new regulations are simply longer because they are more detailed and complex. And yet more guidance is going to be needed to assist in the implementation of the MDR and IVDR, and in helping manufacturers understand what is required. There will be vastly more paperwork to deal with, and this will be in addition to the hundred or so detailed delegated and implementing acts that have to be drafted.

MTI Guides Prove Popular

When the MDR and IVDR were being finalized and were first published, there was a dearth of information in the public view. During this time, *Medtech Insight* saw a surge in popularity of basic guides to the regulations. The result was that the top two articles of 2017 were *a guide to Clinical Evaluation and Performance Studies in the MDR* and *a guide to deadlines related to the new MDR*.

Also in our top 10 EU regulatory stories was *a useful guide to the basics of the new MDR and IVDR* – which provides comparisons in terms of numbers of pages compared with the directives and a listing and sequencing of all the main chapters and annexes.

Two further guides produced by *Medtech Insight* that readers found particularly useful were a *podcast produced just after the MDR and IVDR were published* on May 5, which advised companies how to prepare and avoid the hurdles, and a guide to the new IVDR, which features a *fairly comprehensive list of key dates and deadlines*.

Other Major Topics For 2018

No review of 2017 can fail to mention the UK's political upheaval. The uncertainty created by Brexit could barely come at a worse time for medtech regulations. Put very briefly, *no one yet knows whether the new MDR and IVDR will apply fully, and in the mid- and long-term, in UK law*. There continues to be contradictory statements.

There is hope for some clarity over the next quarter, or at the very latest, within six months. But, whatever the outcome, many organizations have already voted with their feet and set up offices in other European countries to avoid the catastrophic impact that a "hard," no-deal Brexit could have.

Medtech Insight conducted a popular review of *the extent to which Brexit has already impacted the medtech industry* toward the end of 2017.

Another key issue that has come at a particularly bad time for the medtech sector are questions around *standards* that underpin EU medtech and IVD regulations. If things are not made clearer in this area, and soon, this could lead to a serious undermining of the implementation of the MDR and IVDR. This will be a hot topic of focus in 2018.

EU regulatory articles accounted for 34 of the top 100 *Medtech Insight* articles in 2017, demonstrating how important this topic is to our global audience. The table below lists the top 30 pieces, ranked according to popularity.

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