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# European Regulatory Roundup 2021: Extensive Reshaping Of Underlying Medical Device And IVD Structures

by Amanda Maxwell

2021 witnessed a landmark event in May when the new Medical Device Regulation first applied. The medtech sector will experience a similar milestone this year with the new IVD Regulation coming into force in some four months' time. Medtech Insight reflects on the broad and complex swathe of changes that took place in 2021, putting industry under considerable pressure, and predicts no let-up this year.

During 2021, a great many updates occurred in parallel to support implementation of the new MDR and IVDR. This against an ever-shifting political backdrop and a time of health policy change.

The top 20 most read regulatory pieces in Medtech Insight in 2021 show a particularly interesting picture. What is striking is the diversity of topics that have generated the highest level of interest.

This, of course, reflects the numerous important changes that are taking place in the context of the implementation of the Medical Device and IVD Regulations, to help manage the COVID-19 pandemic, and that are a consequence of political shifts among certain countries relating to their relationship with the EU.

But it is a difficult and complex regulatory scenario to follow, let alone manage at ground level, not least by an industry that is dominated by SMEs.

Before looking at the top 20 articles, here is an overview of the most significant news in 2021.

## Deadline Changes - MDR

To put 2021 in context, it is worth remembering that the outlook last calendar year was altered by the 11th hour postponement of the date of application of the MDR by a year to 26 May 2021, as well as an expansion of the scope of products eligible to benefit from the grace period.

While all new or significantly changed products had to either be compliant with the MDR by the new deadline or removed from the market, only 502 conformity assessment certificates had been granted by EU notified bodies in the context of the MDR (and just 31 under the IVDR) by September 2021).

All other devices either made use of the grace period or were removed from the market.

The vast number that have made use of the extension period could result in bottlenecks at notified bodies, particularly in 2023/2024 as the MDR 26 May 2024 grace period deadline approaches.

## Deadline Change – IVDR

In addition to the delayed MDR deadline, changes to deadlines for the full enforcement of the IVDR were adopted at the end of 2021. This has taken considerable pressure off IVD manufacturers, most of whom will be using a notified body for the first time. It also alleviates the work of notified bodies who had anticipated an unmanageable demand for their services had the 26 May 2022 IVDR deadline persisted for all products.

These IVDR changes did not involve a wholescale delay in implementation, however, as had happened with the MDR. The IVDR will still apply from 26 May 2022.

But *new transition provisions have been introduced for the majority of IVDs*. These will spread the end of the grace periods out according to the risk profile of the products beyond the previous 26 May 2024 deadline. The new grace period deadlines are: 26 May 2025 for class D IVDs, 26 May 2026 for class C, and 26 May 2027 for class B devices and class A devices placed on the market in a sterile condition.

No change, however, is proposed for the 26 May 2022 original compliance deadline for CE-marked IVDs that do not require notified body involvement under the IVDR (i.e. class A non-sterile devices which represent around 20% of the market) or for devices that are “new”, (i.e. devices that have neither a notified body certificate nor a declaration of conformity under the current IVD Directive).

The changes to the MDR and IVDR deadlines were in part a response to the challenges brought about by the ongoing COVID-19 pandemic, but also a response to repeated warnings from the industry and notified bodies that the previous 26 May 2022-2024 deadlines would have been

untenable.

## Remote Audit Issue

The fact that the initial notified body audits for conformity assessment certificates for products under the MDR and IVDR must be conducted physically rather than remotely has been a particular and ongoing challenge due to the pandemic creating social distancing and travel barriers.

But many believe the medical device and IVD industries are still heading for trouble. The medtech notified body industry association, TEAM-NB is among them. At the end of 2021, it published a *position paper* calling for remote initial and surveillance audits to be allowed—when justified by a documented risk-based approach.

It has also requested that notified bodies be allowed to develop best practice themselves, where important documents, such as guidances, have still to be made available.

On the IVDR front, meanwhile, while acknowledging the benefits of the staggered grace period deadlines, industry association MedTech Europe has expressed concern that half of all IVD manufacturers do not yet have a notified body; and the essential infrastructure to implement the IVDR has yet to be put in place. With 32,000 IVDs currently on the market, the sooner the structures are in place the better.

## Commission's Hugely Productive Year

There may still be a way to go in terms of guidances needed but no one should deny that 2021 was an extremely productive year in terms of new guidances published by the European Commission's Medical Device Coordination Group. This is in addition to many other targets being reached, for example in the context of standards, the Eudamed medical device database, expert panels and more.

During 2021:

- Some 34 new or revised medical device and IVD guidance document were published bringing the *total MDCG endorsed document and other guidance available* on the commission's guidance pages to 90.

- The number of designated notified bodies rose from 18 under the MDR at the end of 2020 to 25 by the end of 2021 (and one more has been appointed since in the New Year);

- By the end of the year, a total of just six notified bodies had been designated under the IVDR; and

- The commission has told the sector to expect more announcements in the Nando medical device database in coming weeks and months.

While still on the topic of guidances, the issue of *whether they are legally binding*, especially where they applies to notified bodies, was analyzed in April at the annual MedTech Forum organized by MedTech Europe.

Information was particularly highly sought by readers when the commission invited comments on a *draft Implementing Regulation on labelling*. This essentially brings the former version of the labelling regulation, *EU 207/2012*, into the framework of the Medical Device Regulation and updates it. EU 207/2012 applies to electronic IFU for products that comply with the medical device directives.

This implementing regulation on labelling was then *published in December*.

## Handy Guide

With the output of new documents being very high, Medtech Insight put together a *handy list of vital links* to what are arguably the 10 most useful EU regulatory documents, including the texts of the MDR and IVDR, as well as to notified body lists and an overview of the Eudamed medical device database.

## Standards

The urgent need for harmonized standards under the MDR, in particular, as well as under the IVDR, has meant that several articles on standards are featured in MTI's top 20 EU regulatory stories of 2021. They include one published in December revealing that *EN ISO 13485 has been linked to the MDR and IVDR*. Since then - in January 2022 - news emerged that this latest version of *EN ISO 13485 has been officially harmonized under the MDR* along with other standards.

This is the second batch of standards to be harmonized under the new regulations. The *first batch* was published in July. The intention is for newly harmonized standards to be published every quarter in the Official Journal of the EU; the next batch should include the risk management standard, EN ISO 14971.

It was only back *in May that the legal basis came into force* for the EU to start publication of references of harmonized standards in the context of the new regulations.

The news followed the EU standards organizations, CEN and Cenelec, accepting the commission's mandate to revise some 200 existing standards that had been listed under the current medical device directives and draft 27 new standards to underpin the implementation of the new regulations.

## Eudamed Medical Device Database Developments

By the end of November, three of the six Eudamed modules were available on a voluntary basis - for actor registration, UDI/device registration and notified bodies and certificates and guidance (albeit lengthy and complex) *had been published to support users* inputting their information into the modules.

It also emerged that that potential delays with two of the other three modules could *mean an overall delay in the readiness of the database,* although nothing has yet been officially confirmed.

## Expert Panels

2021 saw the publication of the *first EU expert panel opinion*.

An expert panel advice is provided in the context of the clinical evaluation consultation procedure (CECP) or of the performance evaluation consultation procedure (PECP), which requires notified bodies to go through an additional procedure for specific high-risk medical devices and IVDs.

Class III implantable devices and class IIb devices for administering and/or removing medicinal products are earmarked under the MDR to undergo this process if it is considered necessary, as are class D IVDs.

This first opinion, related to a xenographic bone graft material, a class III implant intended for use in a variety of surgical procedures in maxillofacial surgery and dentistry. The opinion challenged certain aspects of the notified body's assessment of the manufacturer's clinical study and was subsequently removed from the commission webpages at the request of the notified body involved.

Since then, the *first IVDR expert panel opinion* was published relating to a hepatitis E virus (HEV) test and an opinion has also been published on *Class III implantable polyethylene acetabular inserts* to be used with or without bone-cement fixation in total hip replacement. This second case was a particularly tricky one for the orthopedics, traumatology, rehabilitation, rheumatology expert panel involved as several different devices were included in the dossier.

## EU Breakaways - UK

The fall-out from Brexit was felt by the medtech sector in 2021 as a number of changes came into effect on 1 January 2021. These included the new UKCA marking for placing devices on the market in Great Britain and the need to register all products with the Medicines and Healthcare products Regulatory Agency before placing them on the UK market. Additionally, manufacturers outside the UK wishing to place a device on the Great Britain market must appoint a single UK responsible person for their devices.

The UK is slowly transitioning to new regulations after30 June 2023. Certificates issued by EU recognized notified bodies will continue to be valid for Great Britain until then.

But the EU no longer recognizes UK notified bodies, and they are not able to issue CE certificates, having become UK approved bodies instead.

At present, devices are regulated under the *Medical Devices Regulations 2002* (SI 2002 No 618, as amended) (UK MDR 2002) which, prior to the end of the transition period, gave effect in UK law to the EU's medical device directives. But the new UK rules must be signed into law before 30 June 2023. That is the date the UKCA marking will have sole validity in Great Britain, the grace period for continued validity of the CE marking in the UK having ended that same day. (Also see "*Medtech Industry's Wishlist For MHRA's New UK Regulatory Structure*" - Medtech Insight, 2 Dec, 2021.)

A 10-week consultation on the UK's standalone rules, incorporating 465 questions, closed on 25 November.

## Switzerland

Switzerland is already part way through transitioning from EU rules to its own rules due to the breakdown in its mutual recognition agreement with the EU at the end of May 2021.

The impact of the breakdown of the MRA is that Swiss manufacturers are now regarded as third-country companies in the EU. This means that Swiss manufacturers, and those manufacturers who used Swiss notified bodies or authorized representatives must, therefore, have certificates issued by EU notified bodies and have an authorized representative in an EU country.

In an update to the Swiss Medical Device Ordinance (MedDO), the Swiss equivalent of the EU Medical Device Regulation, published one week before the EU MDR was implemented on 26 May, *three transition period deadlines* were set for Swiss imports of CE-marked and labeled devices from the EU:

- 31 December 2021 for class III devices;
- 31 March 2022 for class II devices; and
- 31 July 2022 for class I devices.

After these dates, the continued export of devices into Switzerland by foreign manufacturers will be subject to their appointment of a local Swiss-based authorized representative (CH-REP), or use of their own local company in Switzerland, should they have one. This will necessitate

*product label changes*.

Their break-away moves mean that neither the UK nor Switzerland have access to, nor are part of, the Eudamed medical devices database.

## Turkey

It looked like Turkey was going to head in the same direction as the UK and Switzerland. But good news arrived just as the MDR took full effect in late May that the EU/Turkey Customs Union would remain and Turkey's medical device regulatory framework would continue to be aligned with the EU.

## Further news

In other news, readers heard *how the EU Artificial Intelligence Regulation will overlap with the medical device regulations*. While this is potentially yet another hurdle for the medtech industry, and a draft Regulation of 108 pages to absorb, the new rules could take years to process, and will only apply 24 months after publication in the Official Journal of the EU. The medtech industry, however, needs to assess how it will be impacted and to keep up-to-date with developments on this new text.

## Pharma Creep?

Additionally, the European Parliament and the Council of the EU *have reached a provisional agreement* on the European Commission's *proposed regulation for a reinforced role for the European Medicines Agency in health care crises*.

The EMA's traditional remit is pharma and not devices. However, it has long been involved in the regulation of drug/device combinations and drug/IVD combinations, but not beyond this. But things are changing and the medtech sector would do well to monitor EMA medtech-related developments closely in 2022.

The proposed regulation lays out the new role the EMA would play in overseeing various aspects of device management, as well as medicines, in the event of a health care crisis. The agency would be involved in the management of two device functions: the medical device expert panels, already established under the Medical Device and IVD Regulations; and a new Executive Steering Group on Shortages of Medical Devices.

This is one to follow. The European Parliament is expected to formally adopt the proposed regulation at its plenary session in January 2022, followed by adoption by the council around mid-February, under the EU's ordinary legislative procedure. Publication in the Official Journal of the EU is expected before March 2022.

This proposed regulation is also the vehicle through which the commission is proposing the EMA supports the medical device expert panels "to provide independent scientific and technical assistance to member states, the commission, the Medical Device Coordination Group (MDCG), notified bodies and manufacturers."

With the HTA regulation having finished the legislative finish line *now the European Parliament has formally adopted it*, this will also see the medtech industry more impacted by pharma-related decision making . MedTech Europe has expressed mixed feelings about this text. MT144709

## The Humble Swab

Finally, as a reminder of just how complex medtech regulations can be, the piece concerning the intriguing situation of *how the humble swab could be a seriously disruptive element in the MDR and IVDR* was also very popular. It serves to remind the industry of how multi-faceted and interwoven the medtech industry is. In this case, it emerged that swabs, for example those used in COVID-19 test kits, are medical devices and had to comply with either the medical devices directive or the MDR from 26 May 2021 if they were not sterile.

The following is a list of Medtech Insight's top most popular European regulatory pieces in 2021:

| Rank | Title |
|---|---|
| 1 | ***EN ISO 13485 Linked To MDR and IVDR At Last*** |
| 2 | ***European Regulatory Roundup, September 2021: EN ISO 13485 Updated And More Key Implementation Developments*** |
| 3 | ***European Commission Gives In On IVDR Delays: Proposal For New Transition Periods*** |
| 4 | ***EU Regulations At A Click: Top 10 Most Useful MDR/IVDR Webpages*** |
| 5 | ***Good News For Medtech Regulation In The EU As Turkxit Is Avoided*** |
| 6 | ***Device Firms In Non-EU Markets Using The CE Mark Should Expect Some MDR Disruption After May*** |
| 7 | ***Open The Champagne! EU Go Ahead For Standards Needed For New Medtech Regulations*** |
| 8 | ***First EU Expert Panel Opinion Challenges Notified Body Assessment*** |
| 9 | ***Harmonization Of The EU Regulatory Compliance Role: Many PRRC Issues To Be Clarified*** |

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| 10 | *How The EU Artificial Intelligence Regulation Will Overlap With Medical Device Regulations* |
| 11 | *First Harmonized Standards Published For Both MDR And IVDR* |
| 12 | *EU Extends Scope Of Electronic IFU To Medical Device Software In First Update In Nine Years* |
| 13 | *The Unintended Consequences Of The Swiss-EU Medtech MRA Failure* |
| 14 | *EU MDR Guidances: Can Stakeholders Be Punished For Not Applying Them?* |
| 15 | *New MDR And IVDR Implementing Acts Due Imminently* |
| 16 | *IVDR Amending Proposal And New Transition Provisions Due To Be Formally Adopted On 21 December* |
| 17 | *EU Notified Bodies Advise Manufacturers To Think Hard About Regulatory Strategy Timings* |
| 18 | *Why The Humble Swab Could Be A Seriously Disruptive Element In The MDR And IVDR* |
| 19 | *EU Prioritizes Risk Management And Quality System Standards Now Legal Basis In Place* |
| 20 | *Lobbying For A One-Year Delay To The EU IVDR: Solution Or Forlorn Hope?* |