THINK TANK

# Are we MDR ready?

SUMMARY OF
RESEARCH FINDINGS
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eit Health

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# Contents

# Executive Summary

**In May 2017, the Medical Devices Regulation (MDR) entered into force, replacing the previous Medical Devices Directive (MDD). While the new MDR aims to increase transparency in the health sector, increase protection for patients, reduce potential liabilities for manufacturers, and create fair market access for entrepreneurs and healthcare professionals, the regulatory requirements of MDR are deliberately more stringent than under the MDD, placing a greater burden on all stakeholders involved in the regulatory process.**

Due to the shift in priorities arising from the coronavirus pandemic, in April 2020 the European Parliament and the Council of the European Union (EU) extended the transitional period for full implementation of the MDR by one year - until 26 May 2021, allowing stakeholders greater time to prepare.

In April and early May 2021, the EIT Health Think Tank explored the topic of readiness for implementation of the MDR in a series of virtual Focus Group meetings. The aim was to gain insight from the perspective of three key stakeholder groups involved in the regulatory process – innovators and manufacturers of devices (start-ups and SMEs), Notified Bodies (NBs), and National Competent Authorities (NCAs) – regarding to what extent the 12-month extension to the transition period had been beneficial, the levels of readiness of each stakeholder group, and where gaps still exist. In addition, the research also aimed to highlight if any of the recommendations arising from the 2019 Think Tank Roundtable Series *'Optimising innovation pathways: future-proofing for success'* that were proposed to address some of the concerns around implementation of the MDR had been mitigated or if perceived issues as described at the time, remained.

All three stakeholder groups who participated in the research identified challenges relating their MDR readiness. All groups considered that, at a European Commission level, several critical gaps still exist in the supporting infrastructure and resources necessary for effective MDR implementation, in particular the European Database on

Medical Devices (EUDAMED), which they believe is an essential tool currently missing from the new MDR process. Harmonised standards for medical devices are also needed, to include the definition of 'significant changes', particularly for new technologies that have regular iterations and updates.

Lack of designated NBs, as well as NB resource capacity, were identified by all stakeholder groups as challenges in both the short term to meet the increased MDR requirements and also in the longer term due to expiry of MDD certificates in 2023/2024.

However, there were also disparate views across these groups on certain topics. In terms of available information about transitioning from MDD to MDR and the new requirements, start-ups and SMEs felt that there was a lack of information and clarity on the requirements which created a barrier to their MDR readiness, while NBs and NCAs felt they had produced regular and comprehensive information targeted to medical device companies. It was suggested that many device manufacturers had not engaged sufficiently with the new MDR but focused instead on renewing MDD certification to extend the time for transition.

During the 12-month extension to the deadline for transition to MDR, response to the COVID-19 pandemic was the priority focus for both NBs and NCAs, which had a knock-on effect for start-ups and SMEs, although MDR readiness plans continued for all stakeholders where resources were available. The restrictions of the pandemic resulted in authorisation by the European Commission of the use of remote audits by NBs in certain cases. Both manufacturers and NBs were in favour of continuing this in order to streamline the certification process, but NCAs disagreed as they considered it was a temporary solution used in these extraordinary circumstances and not intended to replace face-to-face audits.

Some of the concerns raised at the 2019 Think Tank Roundtables re-emerged during the research as ongoing issues, including a lack of clarity for device manufacturers in several aspects relating to the new MDR requirements, in particular clinical evidence, and the need for greater specificity on the requirements for new technologies. The research also highlighted the challenges that small companies face in terms of financial resources to meet the demands of the new requirements, particularly the generation of sufficient clinical evidence, which links to the proposal made by the 2019 Think Tank Roundtables to create funding mechanisms to help start-ups offset the costs associated with becoming compliant.

Overall, this research suggests that MDR 'readiness' is not something that is finite but rather a dynamic process that will continue to evolve as time goes on, as was the case for MDD. The three key stakeholders groups have all made progress towards MDR readiness, recognising the challenges of the last 12 months and the impact of the coronavirus pandemic, but they also highlighted ongoing challenges that will require collaborative efforts to resolve. The research did identify several opportunities where EIT Health may have a role in facilitating the gathering and dissemination of key information on MDR implementation to help bridge the current gaps.

# The EIT Health Think Tank

The EIT Health Think Tank – our thought leadership forum – brings healthcare leaders together to prepare the ground for life-changing innovation and identify the next opportunity for a step-change in how healthcare is delivered. We collaborate across disciplines and borders to explore and assess the most pressing topics impacting health and the uptake and adoption of innovation. This allows us to make continual assessments of the environmental needs of our portfolio of projects and programmes.

These topics are explored through meaningful dialogue with both internal and external experts in their respective fields. To facilitate this dialogue and its findings, EIT Health drives a range of activities to generate knowledge and insight, including research, expert round tables, publications and dissemination of key information.

# Are we MDR ready?

## Background

Medical devices are products or equipment intended generally for a medical use and are regulated at Member State level. The Medical Devices Regulation (MDR) and the In-Vitro Diagnostic Devices Regulation (IVDR) have introduced new responsibilities for the European Medicines Agency (EMA) and National Competent Authorities (NCAs) in the assessment of certain categories of medical device.

Medical devices in the EU have to undergo a conformity assessment to demonstrate that they meet legal requirements to ensure they are safe and perform as intended. EU Member States can designate accredited Notified Bodies (NBs) to conduct conformity assessments. The conformity assessment usually involves an audit of the manufacturer's quality system and, depending on the type of device, a review of technical documentation from the manufacturer on the safety and performance of the device.

The adoption in April 2017 of Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In-Vitro Diagnostic Devices (IVDR) changed the European legal framework for medical devices, introducing new responsibilities for the EMA and for NCAs. Both regulations entered into force in May 2017, replacing the MDD and the In-Vitro Diagnostic Devices Directive (IVDDD), respectively, both being subject to a staggered transitional period. These regulations intend to adapt EU legislation to technological innovation, developments in medical science and changes in standards and laws. They aim to create a sustainable, transparent and internationally-recognised network of medical devices that can be efficiently identified and tracked, thus enhancing clinical safety and closing supply gaps.[1] To support implementation of the regulations, the European Commission is developing the European Database on Medical Devices (EUDAMED) that will function as a system for registration, collaboration, and notification, structured around 6 interconnected modules, and will be publicly accessible. While the registration function has been live since December 2020, the system is not yet fully operational. Two further modules are expected to be live by September 2021, and the remaining modules do not have a defined timeline for completion but are slated for May 2022.

As a result of the coronavirus crisis redirecting critical focus and efforts to emergent priorities, on 23 April 2020, the European Parliament and the Council of the EU adopted a proposal to extend the transitional period of the MDR by one year - until 26 May 2021. The revised MDR fully applies from this date. This relieved pressure off NCAs, NBs, manufacturers, and other pertinent actors, so they could focus on urgent priorities related to the pandemic and gave them additional time for MDR implementation.[2]

In October 2020, the number of designated NBs had fallen from 80 to 17. A total of 48 new companies have applied for designation as a NB, but certain criteria must be met, and this is a more complex and expensive process than for MDD. Several smaller companies aiming for NB designation simply cannot keep up and have decided to withdraw from the process.[3] At time of publication of this report, the number of NBs in the EU is 20.[4] At the outset, transition to the new MDR would have been considered a time-consuming and costly, but unambiguous, process. The COVID-19 pandemic and strict guidelines on NBs regarding performing audits for each device have made the transition increasingly complicated.[1]

The new MDR will offer possibilities of increased transparency in the health sector, increased protection for patients, reduce potential liabilities for manufacturers, and create fair market access for entrepreneurs and

healthcare professionals. NBs and companies will have to work together and allow partial liberties to each other in the transition phase. The coronavirus crisis has affected all players equally and the need to work closely and overcome setbacks is critical at this time. However, the regulatory requirements outlined by the MDR are higher than under the MDD, the new protocols necessitating greater aptitude and expertise.

MedTech companies are also scrambling to evaluate which of their devices under the former MDD are worth renewing under the MDR apropos of inventory, profits and sales. The new MDR will entail changes to regulatory documents, procedures, lifecycle components and labelling. The fundamental measures would include quality management systems' compliance and audit by an EU MDR-certified NB, revision of relevant documentation following a review by a NB, and the establishment of a continuous supply chain.[1] The MedTech sector is struggling with diminished NB capacity and lack of guidance information at its disposal, especially smaller manufacturers.[5]

This correlates with the concerns raised by the participants at the 2019 Think Tank Roundtable Series entitled *'Optimising innovation pathways: future-proofing for success'* which hosted national meetings with relevant experts across Europe and discussed existing digital health innovation pathways, from idea to market entry and reimbursement. These meetings raised similar concerns regarding transition to the MDR and its implications on the trajectory of health innovation on its way to benefiting European citizens. These Roundtables outlined potential solutions to be addressed at both national and European levels and recommendations were proposed. Some of these were:

- Clarification of the process for entrepreneurs.
- Assessment of the effects that the enforcement of the MDR will have on Digital Health.
- Awareness-raising and education campaigns on the MDR and its requirements.
- Utilising this shift to promote education and research on regulatory science and health technology assessment.
- Creating funding mechanisms to help start-ups offset the costs associated with becoming compliant.

# Research methods

The topic of MDR readiness was discussed in a series of virtual Focus Group meetings between 3rd and 10th May 2021 attended by representatives of three key stakeholder groups involved in the regulatory process – innovators and manufacturers of devices (start-ups and SMEs), NBs, and NCAs – as well as relevant umbrella organisations representing these groups. The Focus Group meetings were supplemented by individual interviews and written input from those who were unable to attend. Participants' views were gathered anonymously and are summarised in this report. All three focus groups were co-moderated by a regulatory expert and EIT Health.

The meetings aimed to provide a forum for these groups to convene and engage in guided discussion in order to take a deeper dive into identifying what actions have been undertaken over the full transition period to ensure adherence to, and compliance with, the new regulatory framework, and to ascertain the level of MDR readiness of those tasked with undertaking a regulatory submission, and those tasked with providing the review and necessary conformity assessments.

## Key objectives

- To ascertain the level of MDR readiness of three key stakeholder groups: (1) start-ups and SMEs, (2) NBs and (3) NCAs.
- To understand the actions they have undertaken over the full transition period.
- To identify where there are still gaps that need to be addressed, and whether these are educational, informational, resource- or capacity-driven.
- To highlight any areas of ambiguity or uncertainty.
- To revisit the recommendations arising from the 2019 Think Tank Roundtable Series to determine if these have been addressed or mitigated, where gaps still exist, and how these can be tackled.

## Contributor selection

### Start-ups and SMEs

The Focus Group for businesses, innovators and manufacturers of devices comprised start-ups and SMEs from France, Germany, Ireland, Portugal, Spain, Sweden and The Netherlands who have medical devices from varying class types at the early-, mid-, and late-stage of development. Contributors from within the EIT Health Network were suggested by EIT Health Regional Innovation Hubs. The final group was selected with a balance of geography, development stage and medical device class designation in mind.

### Notified Bodies

The Focus Group for NBs comprised representatives of NBs who were approached and invited based on knowledge and proximity to the MDR in their organisations. As not all EU countries have a national NB, the aim was to have a cross-section of countries ranging from those with only a few NBs to those with many.

### National Competent Authorities

The Focus Group for NCAs comprised representatives of the National Authorities who were approached and invited based on knowledge and proximity to the MDR in their organisations.

# Primary insights - Perceived readiness for MDR

## Start-up and SME readiness

Readiness for MDR was considered to be more of a challenge for start-ups and SMEs that produce higher-risk medical devices (Class IIa and above). Those that develop Class I devices do not seem to have as many issues with MDR as the process is much the same as for MDD and relatively straightforward, with limited requirements for NB involvement. Companies producing Class III medical devices are often developing products for global markets, so, the changes introduced for additional clinical evidence are already in line with the requirements of the FDA in the USA.

For companies that produce software-based medical devices, the MDR has had a significant impact since most have been upgraded from Class I to Class IIa or higher, and now require a NB for conformity assessment. However, not all EU countries have NBs (for example, Portugal does not have one), which makes it more expensive for smaller businesses to run audits in countries where no local NB is available. New products need to comply with these extra requirements, while existing products have until 2024 to transition as long as they don't make significant changes to the product.

Manufacturers perceived there was lack of appropriate guidance and clarity from NBs and NCAs on aspects of the MDR which were creating a barrier to readiness for them.

**Perceptions of Notified Bodies**

The perception of NBs is that there is a wide variation in the readiness of start-ups and SMEs, so it is difficult to generalise – some want to comply as early as possible while others want to delay for as long as possible. Some, especially newer, manufacturers seem to be unaware of the extended timelines needed for the certification process due to increased MDR requirements (particularly for clinical data) coupled with the finite resource capacity of NBs, and often have unrealistic expectations. When the remaining MDD certificates expire in 2024, this could be a big hurdle and not all manufacturers seem to have understood these implications or factored them into their timelines.

Applications from start-ups and SMEs have mainly been for MDD certification and not for MDR certification. Several companies have approached their NBs to renew their MDD certificates before the deadline so they can have a longer transition period.

**Perceptions of National Competent Authorities**

Despite regular provision of information, some device manufacturers still seemed surprised about the impending MDR implementation deadline. Start-ups and SMEs, particularly if new to the sector, need to engage with other key stakeholders involved in the regulatory process in order to develop a better understanding of the sector overall and the applicable regulations that are needed before a CE mark can be awarded, in particular clinical evidence requirements, technical documentation and timelines. Larger companies who have existing regulatory infrastructures seem to be better prepared.

## Key takeaways

> Start-ups and SMEs perceived that one barrier to their readiness was a lack of appropriate guidance and clarity from both NBs and NCAs on several aspects of the MDR. In contrast, both NBs and NCAs confirmed that they each produced relevant, accessible information and had been communicating it regularly in advance of the transition deadline.

> The perception of NBs and NCAs is that some smaller companies have not engaged fully with the transition to MDR and its increased requirements particularly for higher-risk medical devices or appreciated the extended timelines that will be required for certification. Many companies have focused instead on renewing MDD certification to extend the time for transition.

> Larger companies who often have, their own regulatory departments, appear to be more aware of the new MDR requirements and ready to adjust to the changes.

## Notified Body readiness

As of May 2021, only 20 NBs are designated under the MDR compared to 53 for the MDD. Over the next few years an increase to 40 NBs is expected. The process of increasing the number of NBs has been slower than anticipated, making it difficult for the sector to prepare medical device manufacturers for MDR. Similarly, only 4 NBs are designated for the IVDR compared with 22 for its predecessor. The IVDR introduces many additional requirements that will result in an increased role for NBs, so implementation of IVDR is even more of a concern in terms of capacity.

To increase resource capacity, NBs have been recruiting heavily, but are pulling from the same pool of people as other stakeholders, which can be a challenge. Some NBs have also experienced their existing auditors leaving their organisations for consultancies, which further drains the capacity of the NBs. Data on the Team NB website shows that NBs are continuing to increase the number of employees year-on-year but as they are difficult to hire, they also rely on subcontractors.

NBs, alongside other stakeholders, have been investing heavily in internal training and getting to grips with the MDR – it is a new way of working for everyone. However, some of the requirements still lack clarity, namely clinical evaluation and IT platforms: EUDAMED, which is key for implementing MDR changes, is still not fully functional.

**Perceptions of start-ups and SMEs**

Variations were reported in the perceived level of expertise and efficiency of different NBs across EU Member States. Although NBs have around 25 years of experience with MDD, they (along with other stakeholders) are still on a learning curve for MDR. For example, there seems to be a degree of uncertainty from NBs in terms of clinical evidence requirements and what constitutes sufficient (or insufficient) data. It can be difficult for manufacturers to get a clear answer from NBs prior to collecting and submitting the evidence. This uncertainty is a concern, especially for those working with innovative medical devices.

The experience of NBs' expert panels to review and assess the rapidly-evolving new technologies and innovations, for example artificial intelligence (AI) and digital health applications, was a concern. Building understanding and expertise at both the European Commission and NB level in these specialist areas is needed to ensure that knowledgeable standards are applied uniformly by all the various NBs.

NB's lack of capacity was suggested as a possible contributor to the long lead times to obtaining certification, which can have an impact on the development roadmap for start-ups and SMEs. Even products that are already certified but need incremental updates have to be put on hold until they can be reviewed by a NB, which can take more than

a year in some cases. Transparency in the timelines was needed so companies can assess likely time to market of new products.

**Perceptions of National Competent Authorities**

Although there are still resource challenges, readiness of NBs is relatively good, particularly in comparison with readiness for IVDR. As already noted, over the last few years, many NBs have been working on re-certification according to the MDD and not on MDR certification, in order to keep devices on the market as long as possible. So, for devices already on the market, things are OK; the challenge will be for new products that will need to go through the MDR process. This situation may change as existing MDD certificates expire in 2023/2024.

### Key takeaways

- An increase in the numbers of qualified auditors in NBs will be required to help reduce the long lead-times to certification with MDR and to manage the future workload when MDD certificates expire in 2023/2024. Efforts are being made to address this (recruitment, subcontracting), but it will likely impact certification timelines at least in the short-term due to the increased MDR requirements and need for re-certification of all devices in the longer term.
- Overall, there is a need for more talent in terms of regulatory affairs experts across the medical devices sector (companies, consultants, NBs, NCAs).
- The number of designated NBs and the resource capacity and expertise of individual NBs, particularly relating to innovative medical devices, was a concern for other stakeholders in terms of the MDR readiness of NBs.
- A particular concern of manufacturers was the current degree of uncertainty from NBs regarding clinical evidence requirements of the new MDR, particularly for innovative, non-traditional medical devices. Guidance was needed in advance of collecting the data.
- NBs themselves also felt there was a lack of overall guidance at the European Commission level, ranging from insufficient information on clinical evaluation to inadequate provision of necessary IT infrastructure facilitating MDR implementation.

## National Competent Authority readiness

Readiness for MDR is a continually evolving process, rather than one with a fixed endpoint. This was the same for MDD for which guidance is still being provided 20 years later. No stakeholders will ever be 100% ready. Most NCAs are as ready as they can be, but some countries are still lagging behind. The MDR is a market surveillance system, not an approval system, so there will always be imperfections and aspects that are unfinished.

Many NCAs have increased their resources in order to manage the MDR process but it has become clear that many aspects will require additional resources with a more centralised pan-EU system, which requires investment beyond those of NCAs. The challenges faced by NCAs mostly need to be addressed at a pan-EU level, as there is more than 500,000 different medical device types on the EU market.

**Perceptions of start-ups and SMEs**

NCAs are becoming more open to having interactive discussions with medical device manufacturers. Historically, NCAs have been perceived as primarily pharma-focused but their medical device functions have increased in recent years. However, the evaluations, and impact of interpretation, rely heavily on interaction with NBs, who cannot engage in consulting services, which restricts any in-depth preliminary discussions.

**Perceptions of Notified Bodies**

More NBs are needed so the process for designation by NCAs and the European Commission needs to be improved.

## Key takeaways

- Most NCAs are as ready as they can be, but readiness was recognised as a continually evolving process, just as it had been for MDD.
- NCAs would welcome a more centralised MDR infrastructure, much like the EMA in the pharmaceuticals sector, to help manage the high volume of medical devices on the market compared with medicines.
- NBs considered that NCAs and the EC needed to streamline to process of NB designation so that the number of NBs can be increased as a matter of urgency to keep pace with the increased requirements of the MDR.
- Manufacturers welcomed the greater openness of NCAs to interactive discussions with the medical devices sector.

# Additional insights - Factors influencing MDR readiness

## Existing resources to support stakeholder readiness

### Start-ups and SMEs

Information provided directly from the European Commission was suggested as the best resource for MDR guidance for device manufacturers. However, more information, guidance and support from NCAs would be helpful, particularly for innovative and non-traditional medical device technologies. Guidance on MDR has been issued by NBs but often different NBs have a different interpretation of the same topic/issue, so there is a lack of clarity and standardisation.

Trade bodies, such as COCIR, the association that represents the medical imaging, radiotherapy, health ICT and electromedical industries, were good sources of information for larger companies. It was recognised that it was valuable for start-ups and SMEs to build good networks or join existing ones, like RAPS and TOPRA, to help source the right information and advice to support their products.

### Notified Bodies

Remote audits were approved during the COVID-19 pandemic, although this was limited and done on a case-by-case basis. In addition, NBs had to report back to the NCA if they certified with full or partial remote audits. During this period, however, NBs gained experience with conducting the necessary audits remotely under the MDD/AIMDD and this provided valuable insights into what can be assessed remotely and where there is still a need for an auditor to visit on-site. Continued authorisation of remote audits (or even hybrid audits) by the European Commission would assist NBs in streamlining their auditing process. A survey undertaken by Team NB in September 2020 indicated that the number of non-conformities issued by remote audit was the same as for face-to-face audit, thus not impacting their assessment.

NBs have regularly communicated guidance to start-ups and SMEs to raise awareness of the extension to the deadline for MDR implementation and any increased requirements of the technical documentation that needs to be presented to NBs. They have also hosted webinars on readiness, how to improve submissions, and best practice for MDR and IVDR to support medical device manufacturers.

### National Competent Authorities

The role of NCAs is to provide an added-value service to customers, namely manufacturers and NBs, as well as undertaking surveillance. Awareness-raising communications to businesses, such as newsletters, are supported by more detailed technical advice in the form of webinars and also face-to-face meetings in several countries. Some NCAs generally have good links with medical device sector associations and academic institutions. Information is available if stakeholders wish to access it.

Remote audits were a temporary solution for the COVID-19 pandemic. For them to continue would require a change in EU legislation.

NCAs have also been developing functional systems to support the 'pre-market' aspects of the MDR, including clinical investigation, in the absence of tools and infrastructures, such as Expert Consultation on Clinical and Performance Evaluation, but this is not yet available.

## Key takeaways

> There was a difference in perception of start-ups and SMEs on one hand and NBs and NCAs on the other regarding the level of information available about the new MDR – start-ups and SMEs felt that clear, standardised information was lacking while NBs and NCAs both felt they provided a comprehensive range of different resources that could be accessed easily, including face-to-face meetings with NCAs in some countries.

> Continued authorisation by the European Commission of the use of remote audits in certain cases was considered by both device manufacturers and NBs to be beneficial and would streamline and speed up the certification process, although it was recognised that this would require a change in EU legislation. In contrast, NCAs did not consider continued use of remote audits suitable or appropriate beyond the pandemic – it was 'a temporary solution for a temporary problem'.

> In the absence of tools and infrastructures to support MDR implementation at a European Commission level, some NCAs have been developing their own functional systems to facilitate the 'pre-market' aspects of the MDR, including clinical investigation.

## Actions needed to improve MDR implementation and stakeholder readiness

**All stakeholders**

Implementation of the EUDAMED database is urgently needed to allow manufacturers to register their products in one central portal, and improve information exchange and transparency for healthcare professionals and other stakeholders, including patients and citizens.

Harmonised standards are needed for medical devices. Guidelines from the European Commission's Medical Device Coordination Group (MDCG) should be published as a matter of urgency to give start-ups and SMEs a better understanding of what is required. In particular, there is currently a lack of guidance regarding what is considered as 'significant changes' for digital health tools. Defining these for devices across all classes would benefit not only start-ups and SMEs (as they would not waste time reporting non-significant changes) and would also benefit the NB process.

**Start-ups and SMEs**

Start-ups and SMEs often do not always have sufficient funding to provide extended clinical evidence or conduct clinical trials for every modification or application. This could eventually lead to some products being discontinued and some start-ups going out of business because they cannot comply with the MDR due to lack of financial resources. A formalised clinical review process prior to undertaking clinical trials (as used by the FDA) would be extremely valuable, give greater clarity on the requirements, and avoid incorrect assumptions. At present, the perception is that while the regulatory burden on companies has increased, the infrastructure to support this process is lacking. NBs in the EU are unable to give advice which leaves them with no clear route for consultation if they have queries about clinical evidence requirements, or problems with their MDR submission.

In addition, timelines for review by NBs can be prolonged and this impacts product development. This is a particular problem for software applications that require regular incremental updates.

Manufacturers need to be innovative in the way they manage their compliance with MDR, namely using more online tools to reduce the internal resources they require to administer a quality management system, and to keep up with regulatory changes and documentation.

### Notified Bodies

NBs are facing competition from consultants as well as other NBs to hire competent auditors. Even if recruitment is successful, it will mean that a large proportion of staff are in training, a process that takes up to two years, and during this time their work has to be countersigned by qualified auditors.

NBs anticipated that the longer transition period would inevitably mean significantly more work for them in the coming years. Due to the limitations in NB capacity, there may be a new bottleneck in 2023/2024 when MDD certificates expire, alongside an increased burden up to this point to support the MDR transition. Added to this is the overlapping transition from the IVDD to the IVDR.

### National Competent Authorities

NCAs will need to ensure that they have sufficient resources in place to assess the post-marketing surveillance data arising from the MDR process. There will always be challenges related to the regulation of rapidly-evolving new technologies, but this is the same all over the world. For products, such as AI applications, standard definitions are needed that can be used globally. Technology-specific guidance for the products would also be helpful.

Implementation of the innovation support Clinical Evaluation Consultation and also Common Standards would likely provide clinical policy guidance and allow a more predictable market access pathway for manufacturers within the current decentralised system. Release of guidelines is a work in progress that may take several years (as it did for MDD), and Working Groups have prioritised those with the greatest patient impact.

#### Key takeaways

- Implementation of the EUDAMED database was identified by all stakeholders as an essential tool that is currently missing from the new MDR process.
- Harmonised standards for medical devices are needed from the European Commission, to include the definition of 'significant changes', particularly for new technologies that have regular iterations and updates.
- For innovative products, such as AI applications, global standard definitions are needed along with specific guidance on MDR requirements.
- Start-ups and SMEs suggested that a formalised clinical review process was needed prior to undertaking clinical trials so that the evidence requirements are clear at the outset and before expensive clinical studies are undertaken.
- Manufacturers need to take a proactive approach internally to engaging with MDR regulatory process and requirements.
- Although recruitment for NB auditors is progressing, other stakeholders need to be mindful that the training process is lengthy so MDR certification timelines may still be prolonged in the immediate term.

## Impact of the 12-month extension to the transition period

### Start-ups and SMEs

The extra time resulting from the deadline extension has generally not been deployed to increase extent of readiness, given the static nature of the available information and resources, and due to the fact that the NBs and NCAs were prioritising activities relating to the pandemic.

**Notified Bodies**

NBs have been prioritising work on COVID-19-related medical devices, which has meant the 12-month extension to the deadline for full implementation of the regulation was not only used to prepare for MDR, but also to help with specific products and companies with COVID-19-related products. Due to the one-year extension many companies that had applied for MDR certification for products, withdrew their applications and instead applied for renewal of their MDD certificates. There was a preference to use the directive rather than the regulation as this involves less time for review and is less resource intensive.

**National Competent Authorities**

During the past 12 months NCAs have primarily been focusing on issues related to COVID-19 pandemic (COVID-19 testing, face masks etc.). Postponing the deadline by a year did not make a substantial difference to NCAs. Plans for MDR readiness continued and NCAs attended all European Commission Working Groups as normal. They also continued to provide and communicate information about MDR to other stakeholders in terms of regular newsletters etc.

NCAs had already developed a roadmap which comprised over 150 different tasks that needed to be addressed. On that basis, workplans for MDR have been prioritised.

### Key takeaways

> During the 12-month extension, response to the COVID-19 pandemic has been the priority focus for NBs and NCAs, which has had a knock-on effect for start-ups and SMEs, although MDR readiness plans have continued alongside where resources have allowed.

## Impact of the coronavirus pandemic on the level of readiness

**Start-ups and SMEs**

During the restrictions that were in place due to the pandemic, remote audits were undertaken by NBs. The general perception was positive and that they worked well in most cases. In addition, for start-ups and SMEs they were cost-effective as there was no requirement to pay travel expenses. Others felt that in certain circumstances they added to the complexity, for example if a product was being re-certified, a face-to-face visit may be needed anyway, in addition to the remote audit which added to the costs. The relative benefits of a remote audit were also dependent on what was being audited, for example the technical file (suited to remote audit) or the quality management system (where the manufacturer is likely to need more direct feedback from the NB).

The pandemic has had a significant negative impact on data collection for some products, for example surgical devices where surgery has been postponed due to the pandemic, and this is still not back to normal.

**Notified Bodies**

Issuing of new MDR certificates requires an on-site audit and these were significantly disrupted during pandemic due to travel and other restrictions, meaning that this work had to be postponed.

**National Competent Authorities**

Over the last 12 months NCAs have been involved primarily in COVID-19 response initiatives where products were developed very rapidly under extraordinary circumstances. This impacted the capacity of the European Commission and NCAs to develop the infrastructure to support MDR (e.g. EUDAMED) and guidance on harmonised standards.

Remote audits were permitted during the coronavirus pandemic but this way of working is not something that should be used routinely to overcome any bottlenecks in the current regulatory pathway – the usual conformity route should be optimised and adhered to.

### Key takeaways

- For all three stakeholder groups, the COVID-19 pandemic has diverted resources from MDR-related activities.
- For start-ups and SMEs it has impacted clinical evidence collection in cases where clinical trials or surgical procedures have been postponed. For NBs, face-to-face audits were not possible, so remote audits were employed where possible. Key MDR infrastructure, such as the EUDAMED database, and guidance on harmonised standards were delayed.
- While it was recognised that many positive learnings and new ways of working emerged from the pandemic, it was stressed that this should not lead to efforts to 'shortcut' the usual conformity assessment route.

## Overall perceptions of the MDR

**Perceptions of start-ups and SMEs**

As the MDR requirements are more stringent than MDD, bigger companies have the advantage over start-up and SMEs in terms of managing the additional requirements and resources needed as they will generally have an existing regulatory infrastructure and personnel.

The MDR is designed for traditional hardware products, and is not sufficiently agile to accommodate the frequent iterations and updates that are common in continually-evolving newer technology products that employ software and AI, for example.

The MDR requires re-certification or provision of new clinical evidence for every change that may be significant, and this evaluation often needs to be undertaken by NBs, which can be expensive and time-consuming. Costs for submitting applications under the MDR have risen substantially compared with the MDD, and this can be a significant burden for start-ups and SMEs who are trying to comply with the regulation.

It was suggested that the protracted MDR process, where it can take years to obtain CE marking for some medical devices, was driving companies out of Europe and to the USA where the FDA process was reported to be much quicker, in some cases, mostly due to clearer guidance and advice, and rapid commercialisation afterwards (although this does depend on the particular type of medical device). Such delays can have a negative impact on a small business, and on attracting funding and investment.

**Perceptions of Notified Bodies**

The MDR will allow for better and more transparent regulation and the steps towards harmonised standards are welcomed. The new requirements are necessary changes which in most cases, other than the increased requirements for clinical data, are not substantially different from MDD. For manufacturers, the main changes relate to the transition from IVDD to IVDR.

Although EUDAMED has been delayed, it will be a very valuable resource once it is fully implemented. The possibility to undertake unannounced audit visits will also be a positive step forward in helping to identify fraudulent manufacturers.

The issue of assessing the iterations and updates that are common in continually-evolving newer technology products will partly be addressed in the product's post-market clinical follow-up (PMCF) plan. There will be an agreement on how often data should be submitted for review. Certification is granted on the provision that the data are collected (although NBs cannot advise how this is collected).

NCAs may need to step in and respond to some products leaving the market. Due to the global nature of the medical devices market, there may be some disruption as a single NCA does not have full control of all the products available in its own market since they are manufactured in other countries and supervised by other NCAs.

**Perceptions of National Competent Authorities**

While there are many stakeholders in the MDR process – the European Commission, manufacturers, NBs, and NCAs – ultimately patients and citizens are the customers for the medical devices being approved and they must be the driving force behind regulation. The MDR is deliberately more stringent than the MDD for very a good reason – to ensure a high standard of safety for patients and citizens. But, as clearly set out in the preamble to the regulation, it is intended to strike a balance between safety and innovation. The challenge for NCAs is to maintain independence in the regulatory process while also supporting innovation.

In recent years, the FDA has changed from being a 'closed shop' with a very high market access barrier to becoming more open to discussion with innovators and has developed a breakthrough devices programme. The EU has a much more decentralised system and would benefit from providing regulatory support to innovators in a more centralised way. MDR provides these tools.

## Key takeaways

- The overall goal of the MDR is to increase quality and safety standards of medical devices, so it is expected that some products will fail to continue in the market, or to enter the market in the first place, without improving their quality to meet these new standards. Companies need to understand the importance of following appropriate procedures for market access and compliance with the required steps for all types of medical devices.
- Although the MDR is designed to ensure patient safety, it was suggested that some ongoing issues may prevent timely access to potentially life-saving devices, as well as discouraging innovation.
- The MDR needs to be sufficiently agile to be applicable to continually-evolving newer technology products.
- More agile and standardised processes that will allow better ways of working between stakeholders were suggested. This does not mean less regulation but implementing easier and faster processes that do not hinder innovation and allow patients and citizens timely access to safe medical devices.
- The new MDR requirements may have a particular impact on small start-ups and SMEs who have resource limitations.
- There are many positive aspect to MDR, both now and in the near future – more transparent regulation, the implementation of EUDAMED, and the introduction of harmonised standards.

# Conclusion

**The overall goal of the MDR is to increase quality and safety standards of medical devices. However, the increased requirements of the new MDR mean that early engagement between stakeholders, clear communication of information, as well as understanding the realistic timelines for certification are essential for its successful implementation. Ultimately, all stakeholders have the same aim – a successful, smooth regulatory process, so greater collaborative communication will be beneficial.**

The research identified that all three stakeholder groups are facing their own specific challenges relating to MDR implementation but there were also commonalities. In addition, the coronavirus pandemic, and the restrictions that resulted, undoubtedly impacted each group in different ways and diverted resources that would otherwise have been directed towards MDR readiness.

All three groups suggested that urgent action was required at a European Commission level to fill critical gaps in supporting infrastructure and resources for full MDR implementation, including the EUDAMED database and agreement on harmonised standards for medical devices, particularly new technologies. To meet the challenges of the increased MDR requirements in both the short and longer term, it was suggested that NCAs need to streamline and accelerate the process of designating NBs, while NBs themselves need to continue to increase skilled NB resource capacity. Start-ups and SMEs developing medical devices need to ensure they engage sufficiently with the new MDR process, access relevant information and advice, and factor the extended timelines for the new MDR for higher-risk medical devices into their planning.

The restrictions of the pandemic changed some ways of working, including the authorised use of remote audits by NBs in certain cases. While this was welcomed by device manufacturers and NBs as a way of streamlining the certification process, it was opposed by NCAs who considered that the usual conformity assessment route should be adhered to and the remote option was not appropriate under normal circumstances.

Although the situation has undoubtedly improved since the publication of the 2019 Think Tank Roundtables report, some of the concerns raised then were also flagged during the research as ongoing issues which still need to be addressed, such as a lack of clarity for manufacturers on some MDR requirements, in particular for clinical evidence.

The results of this research will help inform EIT Health's internal planning and communications with its partner network. It has highlighted several opportunities where EIT Health may have a role in facilitating the gathering and dissemination of key information on MDR implementation to help bridge the current gaps. These could include liaison with the European Commission to determine guidelines/strategies for MDR assessment of new technologies (machine learning, AI applications, etc.) and signposting access to information/guidance for start-ups and SMEs: the information appears to be available (according to NBs and NCAs) but manufacturers are not always accessing or fully engaging with it.

It can be concluded that all three stakeholder groups who participated in this research are as MDR ready as they can be given the prevailing circumstances. There is still work to be done at all levels – the European Commission, NCAs, NBs, start-ups and SMEs – to optimise the regulatory process but it is apparent that for all stakeholders involved that MDR 'readiness' is not a fixed destination to be reached but a continually evolving pathway and a learning curve for everyone - just as the MDD once was.

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