The state of EU Medical Device Regulation (MDR) readiness in UK SMEs

A threat to the UK medical device sector. Time to act!

This report describes the readiness of the UK SME and Micro Medical Device Sector for the new EU Medical Device Regulation (MDR) which came into force in 2017 and for which the transition period ends in May 2020.

Contents

1 Executive Summary

This report was commissioned by Innovate UK to provide evidence of the readiness of the UK small and medium size enterprise (SME) medical device companies for the Regulation (EU) 2017/745, commonly referred to as the EU Medical Device Regulation (MDR).

The scope of the assessment was the UK medical devices SME sector, which is required to be compliant with the MDR on the 26th May 2020.

It was widely acknowledged that there were opportunities to revise the Medical Devices Directive (MDD) (Council Directive 93/42/EEC) and Active Implantable Medical Devices Directive (AIMDD) (Council Directive 90/385/EEC) that date back to 1993 and 1990 respectively.

The MDD and AIMDD offered guidance that has been open to interpretation by both Manufacturers and the Notified Bodies. In recent years, the sector has had to deal with a number of high profile product issues and withdrawals. These past events, coupled with new devices incorporating complex technical innovations such as nanomaterials, digital apps and 3-D printing, created a need to revise the certification standards. Consequently, the MDR is not only being introduced as a regulation, it provides greater levels of definition of compliance. This reduces subjectivity in interpretation by Manufacturers and Notified Bodies alike. MDR also brings greater control to the global trade in products into the EU market from manufacturers outside the EU.

Transitioning to MDR is costly, MedTech Europe[1] estimates compliance costs of 8-15% of revenue from certified devices, that's £800K - £1.5M for an SME with revenues of £10M. Perhaps more critically, MDR is a complex change program. It requires significantly more in terms of clinical evidence, risk assessments, post-market surveillance, supply chain obligations and IT and data for the Unique Device Identification (UDI) system and the new EU Eudamed database.

Medical Devices companies in the UK are largely (almost 95%) SMEs and Micro Manufacturers. In recent months and as May 2020 approaches, anecdotal evidence suggested that the SMEs are unprepared for the MDR.

Innovate UK, commissioned ISO Life Sciences and Medilink UK to conduct an assessment of the sector's readiness for MDR to provide an informed platform for discussion. The intent by Innovate UK is to raise awareness of the issues, challenges and needs of the SMEs and Micro Businesses and to engage critical stakeholders to formulate action plans to help mitigate a crisis within the sector and more importantly across the UK Healthcare systems.

[1] MedTech Europe website

As part of the assessment, a survey was sent to 1,350 UK SMEs and responses were received from 110. Whilst the SME sector is known to be difficult to engage, the number of respondents is considered to be a representative sample of the sector. The results confirmed and validated both ISO Life Sciences' and Medilink's informal assessments whilst adding considerable depth and detail and were supported by in-depth Case Studies conducted after the survey.

The survey found that the majority of the UK SME medical devices sector was severely underprepared with many lacking an understanding of the extensive changes required for MDR compliance.

Case studies give real insights into the business impact, which inevitably ends up as patient impact. The assessment found that revenues are likely to fall as a result of the significant financial cost of compliance with MDR. The cost of compliance will likely result in companies discontinuing products and the financial impact may fundamentally threaten the viability of SMEs beyond May 2020.

There is a so called 'grace period' beyond May 2020 where products can remain certified under existing MDD certificates for up to 4 years. However, this only offers partial respite since many aspects of the MDR, such as the Eudamed database, post-market surveillance and new supply chain obligations must be in place by May 2020. There is no evidence that these aspects are being prioritised to enable the 'grace period' to be utilised and so the risks remain.

Until the recent corrigendum, Class I products were unable to benefit from the grace period. Under the corrigendum, those with self-certified Class I products will be required to achieve full compliance on the Date of Application. For those with Class I re-useable surgical instruments, there will be the added challenge of finding a Notified Body.

Manufacturers with portfolios containing Class Is/Im, Class IIa, Class IIb and Class III devices may have a grace period with product recertification up to a further 4 years under the MDD or AIMDD but only if they are confident that they can operate to MDR Article 120.3.

In addition, the many up-classified Class I products, including significant numbers of the standalone digital health products, will need to be recertified to the MDR by the date of application and this will require a Notified Body certification assessment. The unintended consequence is that failure to do so will result in product withdrawal.

Whilst this survey did not provide the data to quantify the impact on patients, it is expected to be significant with real poor-health outcomes. The consequences will be that many existing 'legacy' devices will be taken off the market, in fact 35% of the Manufacturers in this survey believed that a reduction in the size of their

product portfolio was inevitable. Additionally, some new devices, offering state of the art, therapeutic benefits will either no longer be developed or will be launched outside the UK/EU.

The recommendations to support the UK SME medical device sector address the fundamental issues identified by this report. Action is needed in the following areas:

1. Education: Beyond awareness to product and business specifics.
2. Funding: Supporting compliance activities and program design and delivery.
3. Acceleration: Guided implementation and access to specialist expertise.
4. Mitigation: Urgent action planning with the MHRA, BEIS, OLS, DHSC & NHS organisations.

This report details the very real and concerning lack of readiness of UK medical device SMEs for MDR.

Disruption to the access and supply of medical devices in the UK/EU will impact on NHS organisations, health care professionals and patients. For example, this could mean having to adapt to replacement products, service delivery redesign if key products are not available.

What is required is a call to action. The sector has declared its needs to address this pending ‘cliff edge’.

2 The Significance of Medical Devices

It is widely recognised that medical devices are indispensable to the functioning of our healthcare systems. Consider the impact on our daily lives of a possible loss of supply of any of the following; thermometers, hypothermic needles, spectacles, x-ray images, cardiac pacemakers, hearing aids, LED phototherapy machines, prosthetics and implants, drug eluting stents or blood glucose monitors. In May 2020 because of a major change in the regulation of these devices we maybe faced with the loss of many of these and the other >500,000 medical devices used across our health systems today.

2.1 Medical Devices Explained

A medical device is any device intended to be used for medical purposes.

Medical devices benefit patients by helping health care providers diagnose and treat patients, helping patients overcome sickness or disease, improving their quality of life.

Medical devices vary in both their intended use and indications for use. Examples range from simple, low-risk devices such as surgical instrument containers, medical thermometers, disposable gloves and bedpans to complex, high-risk devices that are implanted and sustain life.

One example of high-risk devices are those with embedded software such as pacemakers, and those which assist in the conducting of medical testing, implants, and prostheses.

Today, with the rapid emergence of technology including innovations such as nano-materials, 3-D printing and of course digital apps, the medical devices sector is a highly complex sector within the Life Sciences industry.

Furthermore, the use of medical devices in combination with either medicines e.g. insulin pumps designed to deliver reliable, consistent doses of insulin to help people with their medication management and diagnostic devices such as wireless blood pressure cuffs which, via Bluetooth technology, takes a reading and sends it to an app on an iPhone, adds to the complexity.

It also indicates the vast role which medical devices play right along the patient wellness pathway including prevention, diagnosis and treatment of illness and disease, as well as rehabilitation.

Significant potential for hazards are inherent when using a device for medical purposes and thus medical devices must be proved safe and effective with reasonable assurance before regulating governments allow marketing of the device in their country.

As a general rule, as the associated risk of the device increases, the amount of testing required to establish safety and efficacy also increases. Further, as associated risk increases the potential benefit to the patient must also increase. The classification of medical devices in the European Union is outlined in Article 51 of the Medical Devices Regulation (EU) 2017/745. There are basically four classes, ranging from low risk to high risk.

- Class I (including Ir, Is & Im) *Low risk*
- Class IIa
- Class IIb
- Class III *High risk*

The authorization of medical devices is guaranteed by a Declaration of Conformity. This declaration is issued by the manufacturer itself, but for products in Classes Ir, Is, Im, IIa, IIb or III, it must be verified by a Certificate of Conformity issued by a Notified Body.

A Notified Body is a public or private organisation that has been accredited to validate the compliance of the device to the European Regulation. Medical devices that pertain to class I (on condition they are not re-useable, require sterilization or do not measure a function) can be marketed purely by self-certification.

The European classification depends on rules that involve the medical device's duration of body contact, invasive character, use of an energy source, effect on the central circulation or nervous system, diagnostic impact, or incorporation of a medicinal product.

Certified medical devices should have the CE mark on the packaging, insert leaflets, etc. This packaging should also show harmonised pictograms and EN standardised logos to indicate essential features such as instructions for use, expiry date, manufacturer, sterile, single-use, etc.

In May 2020, with the introduction of the MDR, all medical devices used in the care and rehabilitation of patient care across health and social care, in our homes and hospitals will need to conform with the new regulations or we risk them having to be withdrawn.

2.2 An Overview of the UK SME Medical Devices Sector

The UK Medical Devices Sector is significant in terms of terms of revenue, employment, patient care and innovation.

Turnover in the UK Medical Technology market is £22.2 billion and is the third largest in Europe. There are over 3,500 Medical Devices businesses in the UK, 95% of which are SMEs. They employ 122,000 people which is 15 employees per 10,000 inhabitants and attract 6.5% of healthcare spending. The medical technology sector is also highly innovative and, in the EU as a whole, files the largest number of patents for any sector, over 12,000 in 2016[2,3].

The sector is heavily dependent on sales from CE marked devices, not only in the UK and EU but also in countries which accept and require CE marking such as Australia, Saudi Arabia, Singapore and Argentina.

This is an important sector and, as this report shows, it is vulnerable to changes in the EU regulatory environment, particularly for SMEs and Micro businesses.

[2] The European Medical Technology Industry – in figures 2018
[3] MedTech Europe UK Medical Technology Sector: Strength and Opportunity 2017. HM Govt. OLS

3 Objectives and Approach

The objectives of the assessment were to:

1. Present the assessment survey to a broad selection of the UK SME Medical Device Sector

2. Analyse the findings and guide recommendations for improving the MDR readiness of the sector.

Businesses invited to participate were SME and Micro Medical Device Manufacturers and Pre-market Innovators.

The assessment approach was based on:

- An in-depth understanding and experience of the technical, business and programme management requirements for MDR compliance, provided by ISO Life Sciences.
- Access to and in-depth understanding of the UK SME Medical Device Sector and the related regulatory environment, provided by Medilink UK and

- Access to and engagement with key stakeholders and oversight and direction provided by Innovate UK.

The principal tool was a bespoke, online survey distributed by email utilising Medilink's UK SME database and promoted on sites such as LinkedIn and by email reminders. Candidates for a limited number of Case Studies were selected from the survey respondents. These were undertaken by face to face, structured interviews to explore issues and potential support needs in more depth.

The approach, methodology and tools are described in detail in the appendix.

4 Assessment Findings

4.1 Participant Information

Our initial set of questions to the survey participants sought, by understanding their businesses, to establish an understanding of the potential complexity facing UK SMEs in transitioning to the MDR. Such is the pervasive nature of the changes in the MDR that it touches all products and most aspects of a business across the value chain.

The respondents to the survey fell into one of two categories; a Manufacturer or a Pre-market Innovator.

Manufacturers
Of the 110 respondents, 73 were categorised as Manufacturers. Within this category, approximately 70% employed more than 10 employees, with the remaining 30% employing fewer than 10 employees. The majority of the businesses had been established for over 10 years with 80% termed the Legal Manufacturer of their products i.e. they were responsible for the design, manufacture and certification of their products.

For 55% of the Manufacturers, greater than 70% of their revenue is generated from their CE marked devices. This figure raises to 80% of the Manufacturers who generate more than 30% of their revenues from their CE marked products. The 70% of Manufacturers that sell into EU markets do so using 3rd party agents and distributors.

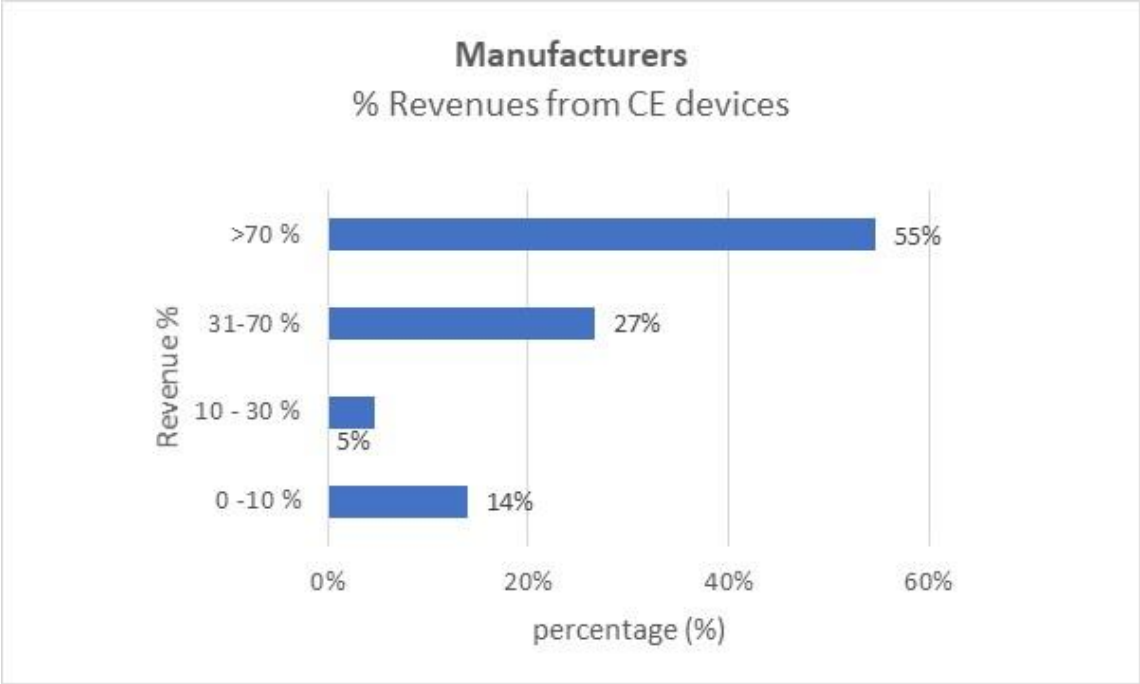


Fig 1: Manufacturer % Revenue from CE marked devices

The typical structure of a Manufacturer's portfolio comprised single class products, with a small percentage having a multi-class portfolio. A significant proportion of Manufacturers had portfolios comprised of either Class I or Class IIa products.

Fig 2: Manufacturers' Portfolio Classification

One of the major impacts of MDR on large multinationals was the resultant reduction in the product portfolio. This was due to the prohibitive cost of remediation of legacy 'aged products' to bring them into compliance. Not surprisingly, 35% of the SME Manufacturers in this survey believed that a reduction in the size of their portfolio was inevitable. The consequences would be the patient impact of the removal of products from the market, loss of revenue to the Manufacturer with reduced investment for the future and potential job losses across the business. For a proportion of the respondents, portfolio rationalisation was not always seen as a negative with comments from several that rationalisation was overdue and would be of benefit to the business.

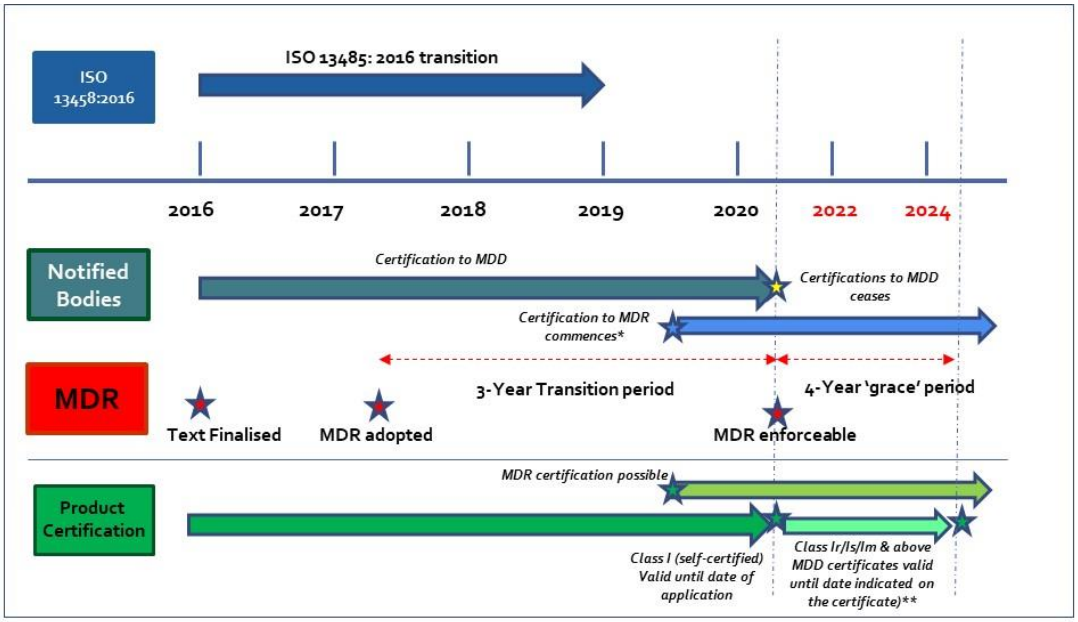
It was concluded from this data that many of these Manufacturers were faced with sizeable MDR transition programs. All Manufacturers will have to conduct work to varying degrees to transition to the MDR. This work will be required across the value chain: In R&D, due to changes in design validation, risk management and restrictive substances, in clinical and safety data due to enhanced post market clinical follow up and safety reporting, in technical documentation and product labelling, post market surveillance, product traceability and in changes in the regulatory obligations of operators across each product supply chain.

Importantly, for those Manufacturers with Class I (self-certificate) products, product compliance under MDR will be required by the 26th May 2020. For all other products, MDD certificates will be valid beyond 26th May 2020 to the date of expiry on the certificate and/or they may use the 'grace period' enabling them to seek renewal of their MDD certificates prior to May 26th 2020 and hence extending their period of transition out to May 2024. However, caution needs to be exercised here, as Manufacturers will need to be sure that the conditions of MDR article 120.3 (no significant changes in design and /or intended purpose) will apply.

The remediation efforts required for Class I products cannot be underestimated. Many products in this class were self-certified and required no Notified Body assessment under MDD. Under MDR, those Class I products which are placed on the market and are re-useable surgical instruments will be subject to a conformity assessment by a Notified Body. Products with software functionality will be up-classified to Class IIa. These changes are one of the reasons why this segment of the SMEs will be worried by the lack of Notified Body capacity for approval by the application date.

There are also significant aspects of the legislation which will apply on the date of application, including vigilance and post-marketing obligations, registration of economic operators and devices in EUDAMED etc., no matter the status in recertification of products and so significant compliance work will still be required.

The consequences of not being ready by May 2020 would be 'temporary' loss of supply continuity of products, until such time as the products were certified under the MDR. Doubtless for many of these Manufacturers, potentially a major threat to their future. The MDR Transition Timelines are shown in Fig. 3, below:



Notes : * subject to NBs designation to MDR
**Class Ir/Is/Im & above product certificates will be valid until the date indicated on the certificate, the transition period may be extended by renewing MDD certifications prior to 26th May 2020 which would extend the transition period until 26th May 2024, however subject to the conditions set out in MDR Article 120.3

Fig 3: MDR Transition Timelines

In our work with the multinationals, we have experience in the financial planning for MDR compliance. The budgets for MDR transition need to be planned and are of a size, certainly for the larger publicly quoted manufacturers, which demanded CFO attention and the attention of company boards. In our experience budget estimates of between 8-15% of impacted revenues are the norm.

For an average £10M turnover SME, the cost of compliance provision required could be between £800,000 and £1.5 million.

With less than one year to go to the date of application of the MDR, 60% of the Manufacturers had not as yet budgeted for the MDR. Of the 40% who had, only 12% had provisioned between 8-15% of their impacted sales revenues

Looking beyond the short term, we asked the Manufacturers if they intended launching new products into the EU market, requiring CE certification, within the next 3 years. 73% of the respondents confirmed that this was their intent. Coupled with the response that 85% of Manufacturers intend to continue to do

business in the EU under the MDR, we concluded that compliance was a significant imperative for UK Manufacturing SMEs.

Pre-Market Innovators

The second category of respondents, the group we termed Pre-Market Innovators, consisted of those businesses focused on product design and development, who in the future intended to launch a product certified to MDR and/or sell on their innovations to established manufacturers. What is common amongst this category tends to be an environment where funding of the product design and development is the priority and regulatory readiness is left until later.

To assess this category's MDR readiness, we needed to establish the class of products to be launched, the timescales to launch and their intent to launch into EU markets and hence the need to certify under the MDR.

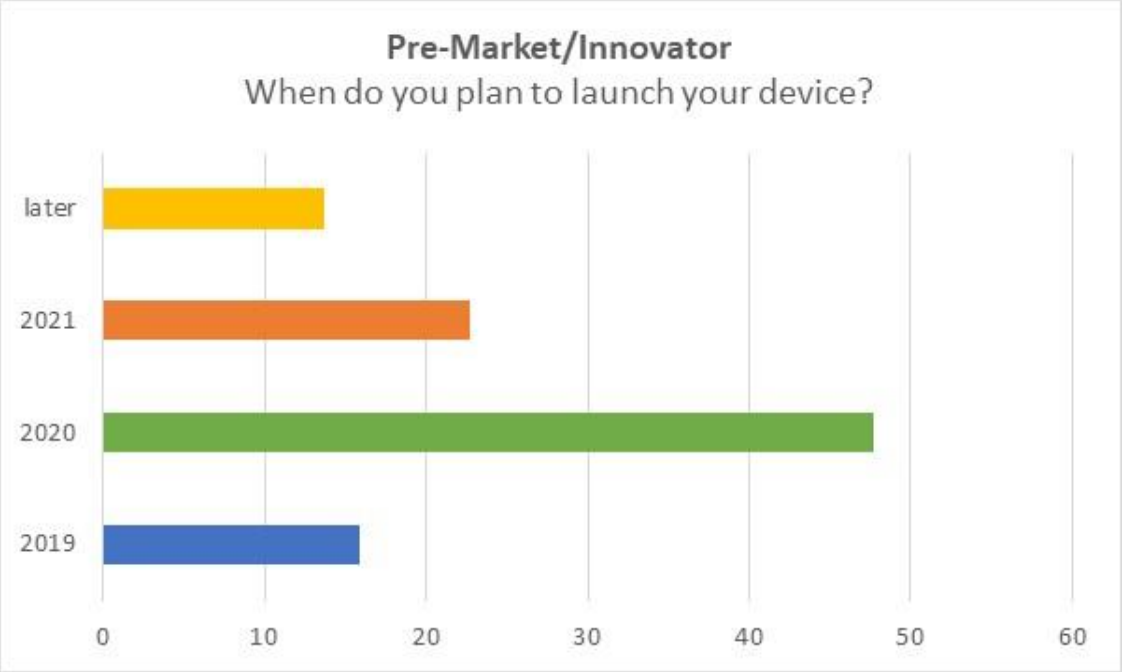


Fig 4: Pre-Market/Innovators market launch timelines

The data show that over 80% of devices were intended to be launched in the critical transition period prior, on and immediately after the date of application of the MDR and for the many devices, which will be Class I, certification to the MDR may be required by the date of application.

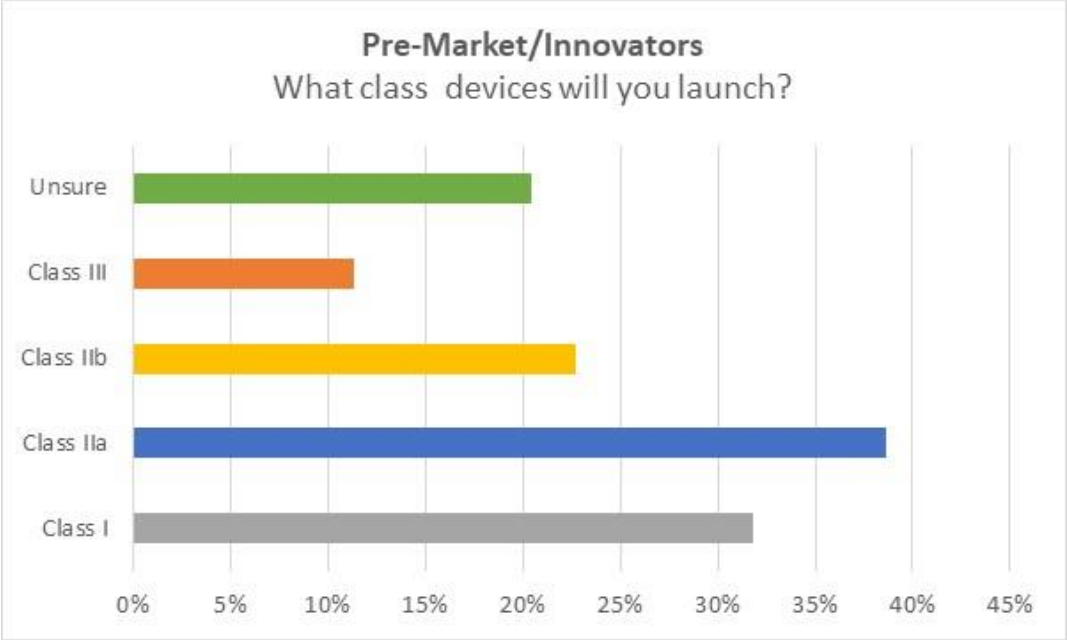


Fig 5: Pre-Market/Innovators launch device classifications

We also confirmed that the intent for this category was to launch in the EU market.

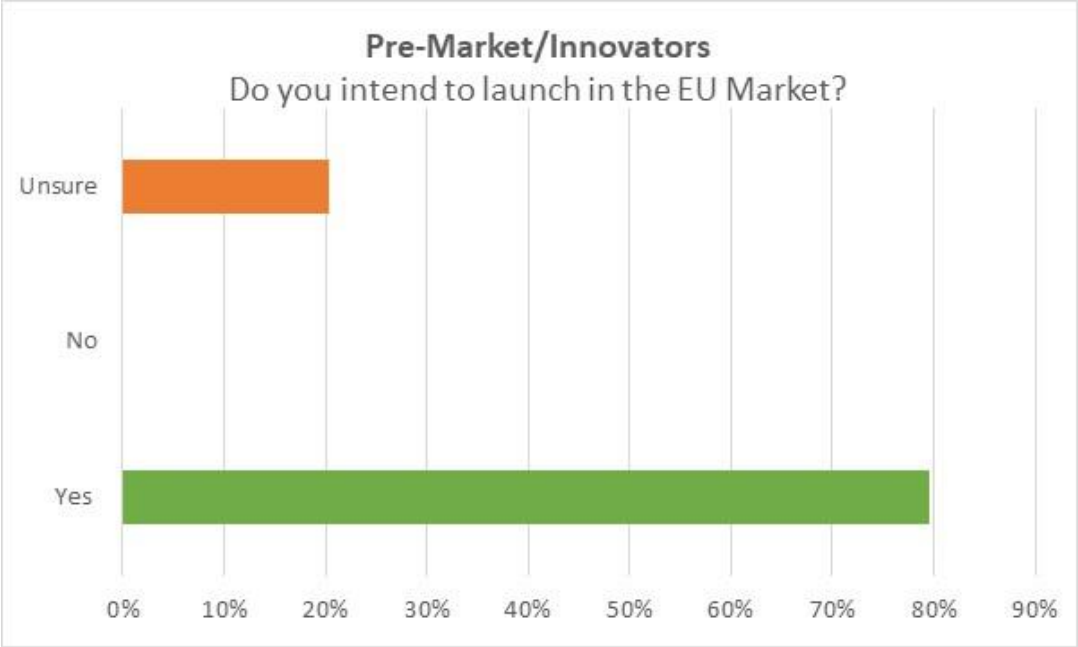


Fig 6: Pre-Market Innovators launch markets

We concluded that what this particular category of UK SMEs clearly needed was to embrace and work to the MDR. What we have experienced over the last few years, working with the larger multinationals, was their intent to steer away from launching new products into the EU markets. There were three key reasons. Firstly, was the expected disruption and uncertainty they were anticipating in the EU in the run up to the date of application and likely for some years beyond. Secondly and much quoted was that the EU was a much less attractive launch market because of the enhanced compliance requirements under the MDR. Finally, they expected launch timescales to be protracted under the MDR, again because of the protracted compliance requirements.

4.2 Readiness Assessment

Having established that UK SME Manufacturers needed to undertake sizeable MDR transition programs, and hence provision necessary financial investment and resourcing needs, we sought initially to establish an understanding of how they were running their MDR programs. On the assumption that programs were underway, we then sought to establish progress in relation to remediating products and the various operating model changes to meet MDR compliance. This section of the survey utilised the 'Competency Model' approach described in Appendix 6.2.

The results are colour-coded to signify the range of readiness encountered:

Purple minimum readiness level
Blue mode (most common) readiness level
Green maximum readiness level

The Readiness Maturity Levels represent:

0. No awareness
1. Minimal awareness of the MDR
2. Awareness and understanding of the MDR
3. Gap assessments undertaken for my business and products
4. Gap closure solutions defined and programme in place
5. Compliance solution implementation in progress

The Descriptors are examples of the level descriptors and here show only Level 1 and Level 5 to represent the readiness range for each category.

MDR Readiness Survey Results
Category: Manufacturers

Maturity Parameter	Descriptor	0	1	2	3	4	5	Descriptor
Business Readiness								
Leadership /Management Alignment on MDR	• MDR understood by the Leadership /Management teams							• Leadership/Management are confident MDR transitioning is on track
Regulatory Compliance Status	• Business operating under MDD compliance							• MDR transition program underway with progress on long lead activities • Alignment with Commission timetable/NB readiness, Implementing Acts etc being managed
MDR Financial Planning	• Finance/Commercial teams aware that there will be Revenue and Cost impacts to the Business under MDR							• Financial Management in place • Financial reporting to Leadership/Management teams in place
Notified Body Engagement	• Position of current Notified Body authorisation is understood							• NB engaged and aligned
Product/Portfolio Readiness								
Product Design & Dev	• Design and Development undertaken to MDD							• MDR technical File/DHF available for recertification submission
Clinical Evidence	• Current certification based on competitor equivalence claims • CER compliant to MDD							• CERs compliant to MDR • Revised PMS Plans/PSURs updated into MDR Technical Documentation • EUDAMED ready
Product Labelling	• All labelling and marketing materials up to date							• Product labelling updated to MDR • Packaging operations updated to accommodate UDI printing/pack changes and Implant Card insertions
Hazardous Substances	• Compliant with REACH							• Product labels updated including warnings etc. • Redesigned product substitution planned • Commercial management of retired products agreed
Operating Model Readiness								
Quality Management System	• ISO 9001 and/or • ISO 13485 and/or • GDP compliant							• Train and roll-out new SOPs • MDR compliant QMS recertification
Post Market Surveillance, Vigilance and Market Surveillance	• Post Market Surveillance & Vigilance processes in place							• Implementation of MDR compliant PMS, Vigilance and Market Surveillance
Economic Operators	• Commercial agreements formalised across the supply chain							• Roll-out and re-negotiation of MDR compliant technical agreement
Product Registration/Product Traceability	• Systems in place to support product identification (UDI-DI) and production identification (UDI-PI)							• UDI implementation in process • EUDAMED ready

Fig 7: UK SME Manufacturers MDR Readiness assessment

The summary conclusion of MDR Readiness in this category is that it is far from where it needs to be. In order to achieve compliance within the time available, manufacturers would be expected to be identifying against levels 4 and 5 for the majority of the maturity parameters, and especially those that have Class I products where MDR compliance will be required in May 2020. This is clearly not the case.

Fig. 7 shows the manufacturers' worst, mode (most common) and best case MDR readiness. If we take the mode readiness, the majority of survey respondents are still working on understanding the differences between compliance under the MDD and the MDR and where they have potential gaps. This conclusion is further substantiated by the low scores (typically Level 1) in MDR Financial Planning, which indicated that the businesses had yet to assign budgets for remediation projects, the most likely reason for which is a lack of definition on what compliance gap solutions would be required.

It is also evident from Fig. 7 that the business leadership and management teams believed they had some level of awareness of the MDR. Similarly, it is evident that there is less than necessary progress in the typically initial areas of investigation, i.e. product compliance to the revised GSPR (General Safety and Performance Requirements) and clinical evidence gaps. These tend to be the most onerous and to have the longest remediation lead-times. These factors appear conflicting in that if the awareness and understanding of the MDR at the leadership and management team level was sufficient, then much greater progress would already have been made to the GSPR and clinical work. Progress across other aspects of compliance remediation would also be evident.

However, many SMEs have reported on a new rigor adopted by Notified Bodies from 2016 resulting in 'new' non-compliances being identified. One of our respondents experienced this for the first time in over twenty years. The resource implications of this were compounded by Notified Bodies withdrawing their services. One SME reported that it would be difficult to achieve MDR compliance in the required time due to resources being diverted to transferring their Notified Body on three occasions in four years. They also experienced that identification of their third Notified Body proved extremely difficult due to lack of capacity within the remaining NBs to take on new business.

Notwithstanding the above, the observed profile of maturity across all of the parameters highlighted a common weakness in the approach taken by many businesses. We believe that, were businesses to understand earlier the full impact of the MDR across the whole business, and with that the full extent of all of the changes needed, MDR would be a priority initiative driven by informed leadership and management teams. Irrespective of the product portfolio size and structure and business size and structure, placing products on the EU market with the CE mark under the MDR will impact every function within the business;

commercial, engineering, quality, clinical, production, packaging and labelling, regulatory, procurement, legal, and supply chain. The extent of the impact is however business specific, driven by its specific MDD-MDR gaps, and requires product portfolio and business specific analyses to determine the appropriate compliance program.

Finally, it should be recognised that MDR has a disproportionate impact on SMEs because they need to respond to the full weight of the MDR but have fewer resources. Whilst they may have smaller portfolios, in many cases single site operations, limited budgets and resources, they could have best met MDR compliance by starting early, thus remediating within the constraints of their resources and finances over the full 3-year transition period. Unfortunately, almost all have left it very late and many have yet to grasp the full implications of the very significant change from the MDD to the MDR

In conclusion, SMEs unfortunately have lost a critical lever available to successfully transition, that of time. The consequence of this is that it will now require higher levels of support with specific MDR expertise and of financing in the remaining transition period, if MDR compliance is to be achieved.

Pre-market Innovators

The survey results revealed that the Pre-market Innovators are less advanced in their MDR readiness than the Manufacturers. Of concern, as evidenced in Fig 8, is that the minimum was largely at Level 0 and the mode (most common) was largely at Level 1. These levels indicate the MDR to be largely unknown or only superficially understood.

MDR Readiness Survey Results
Category: Pre-Market/Innovators

Maturity Parameter	Descriptor	0	1	2	3	4	5	Descriptor
Business Readiness								
Leadership /Management Alignment on MDR	• MDR understood by the Leadership /Management teams							• Leadership/Management are confident MDR transitioning is on track
Regulatory Compliance Status	• Business operating under MDD compliance							• MDR transition program underway with progress on long lead activities • Alignment with Commission timetable/NB readiness, Implementing Acts etc being managed
MDR Financial Planning	• Finance/Commercial teams aware that there will be Revenue and Cost impacts to the Business under MDR							• Financial Management in place • Financial reporting to Leadership/Management teams in place
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Clinical Evidence	• Current certification based on competitor equivalence claims • CER compliant to MDD							• CERs compliant to MDR • Revised PMS Plans/PSURs updated into MDR Technical Documentation • EUDAMED ready
Hazardous Substances	• Compliant with REACH							• Product labels updated including warnings etc. • Redesigned product substitution planned • Commercial management of retired products agreed
Operating Model Readiness								
Quality Management System	• ISO 9001 and/or • ISO 13485 and/or • GDP compliant							• Train and roll-out new SOPs • MDR compliant QMS recertification

Fig 8: UK Pre-Market/Innovators MDR Readiness assessment

What differentiates this sector from the Manufacturers is that they are likely to be dealing with a single product and they will be less concerned with certain aspects such as; post market surveillance and clinical follow-up reporting, supply chain and distribution. Nonetheless, with many anticipating product launches in 2019/20, to demonstrate this lack of preparedness for the MDR, will we believe, pose significant risks and challenges for these businesses and their plans.

Again, what we believe has occurred here is a weakness which relates to the poor communication and understanding of the extensive requirements of the MDR. Many see it purely as a regulatory and certification issue. It is our observation that Regulatory has played a part in failing to adequately communicate the scope and breath of the changes to their businesses. Wherever Regulatory have failed to communicate to businesses that MDR is a business program to be implemented by the business facilitated by Regulatory or indeed retained by Regulatory as their program, we have observed similar lack of progress and readiness.

In mitigation, the size of the Regulatory resource within these businesses tends to be a 'part-time' resource. It is also widely acknowledged that a regulatory plan tends not to be where efforts are focused in the innovation cycle and is more likely to be considered as launch nears. Unfortunately, with the significance in the changes now legislated for under the MDR in the weight of performance, clinical and safety data, and the levels of scrutiny required for truly innovative products, this approach is very unlikely to succeed.

In conclusion, for UK Pre-market Innovators prepared to this level, we believe the lack of progress in MDR readiness will manifest in two significant ways. They will require significant remediation in their submissions resulting in a delay in launch timelines, additionally the lack of access to an already over-subscribed pipeline of re-certifications at the Notified Bodies will very likely point the way to launching in non-EU markets.

4.3 Key Challenges

Survey respondents were offered a list of 12 potential key challenges and the opportunity to add their own. Respondent ranked the challenges as 1st (top), 2nd and 3rd.

Manufacturers and Innovators are shown separately and have different concerns.

Manufacturers

Small and micro manufacturers had common views on the most significant challenges and these are reflected in the chart below for SME Manufacturers: All Respondents. The top 3 were commonly agreed to be;

1. Access to Notified Bodies
2. Access to expertise
3. Access to finance

Below this there was some slight variability but this chart can be taken as representative.

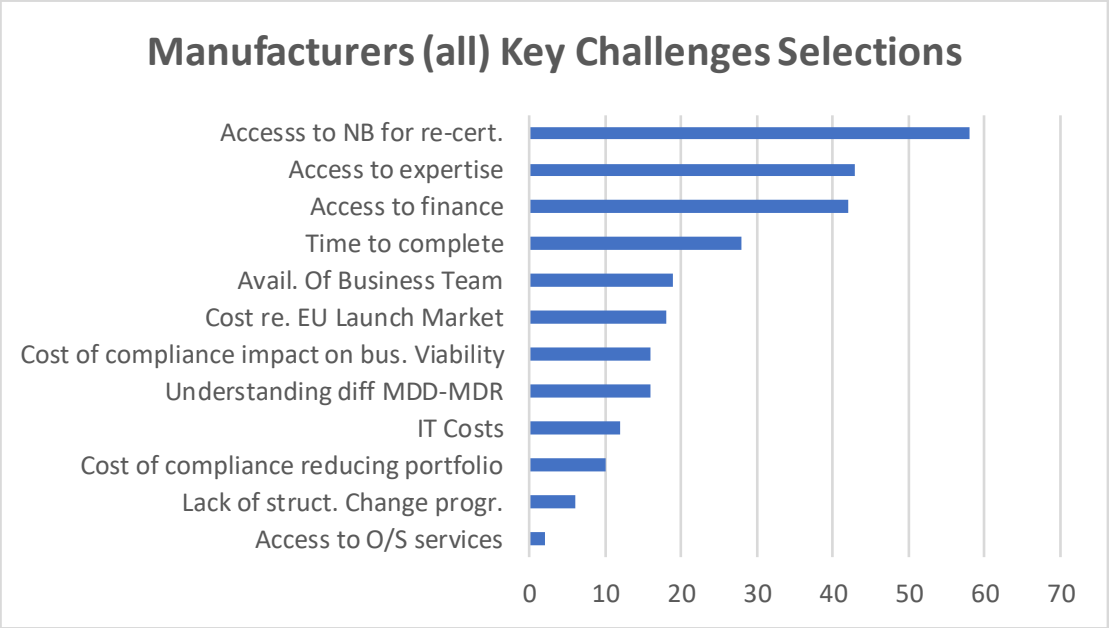

Fig 9: Manufacturers key challenge selections

Medium sized manufacturers had a much greater concern over access to Notified Bodies as is shown in the chart below:

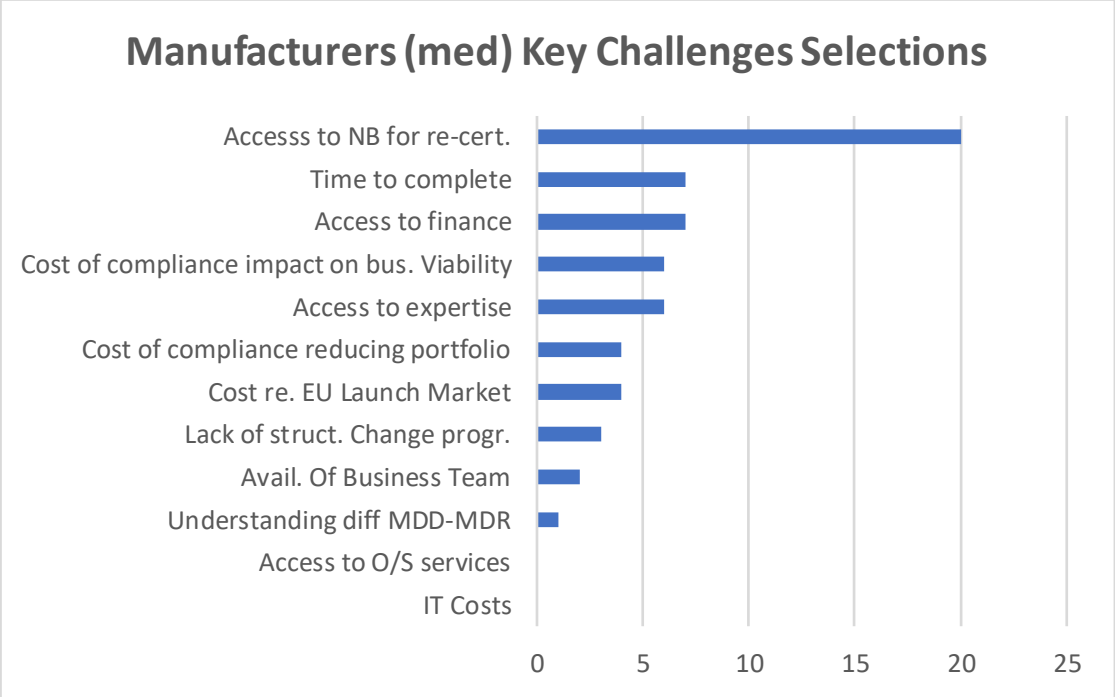

Fig 10: Manufacturers (Medium) key challenge selections

In the readiness assessment we observed that the larger the business the more ready they are and it is likely that Notified Body issues are more pressing because the larger companies are closer to submission to the NBs.

Whilst there are broad industry concerns with the availability and readiness of the NBs, it is unlikely that any direct mitigating actions are possible in this regard. See Section 4: EU MDR Status and Challenges, below.

Business viability was also of greater concern for the medium sized manufacturers. For the Small and Micro enterprises which typically have a limited product portfolio, their focus is on compliance. As was observed earlier in the report, they are also a very long way from being ready and it is unlikely that they fully comprehend the challenges that compliance presents and so 'business viability' concerns have yet to manifest themselves. This will be different for Medium sized enterprises which have larger portfolios, better access to Regulatory expertise and a more developed view of the challenges they face in the limited time still available before the MDR date of application on May 26th 2020.

Pre-market Innovators

It is to be expected that Pre-market Innovators will be smaller companies and the majority had fewer than 10 employees (micro).

In this case there are significant differences between micro and small innovators and these are evident in the charts below:

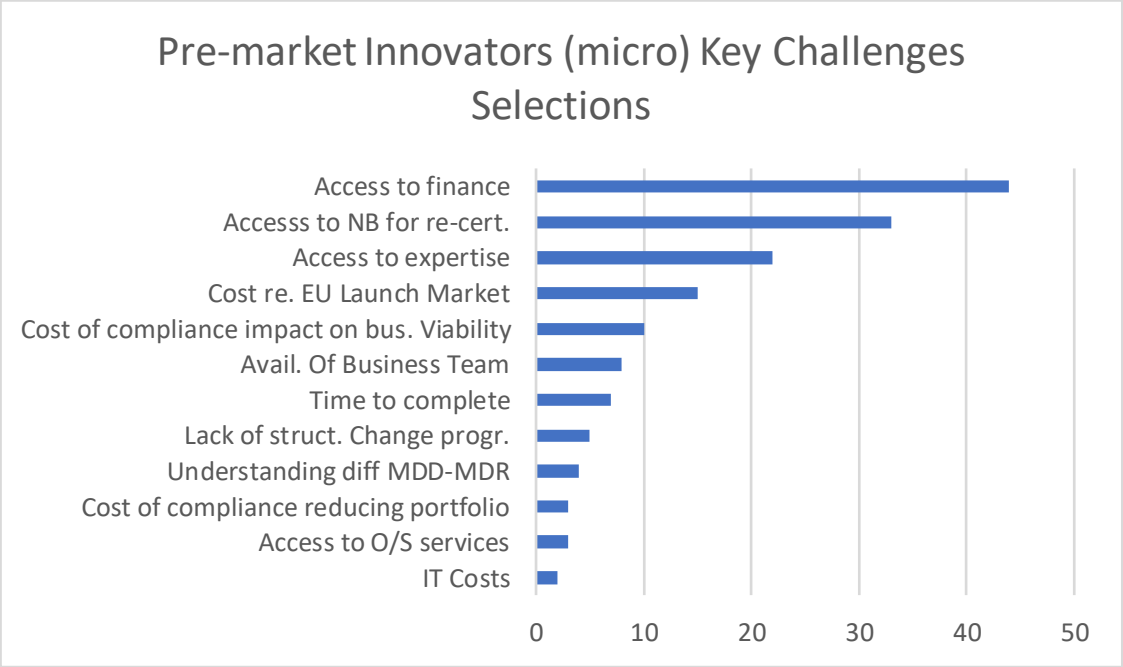

Fig 11: Pre-market Innovators (micro) key challenge selections

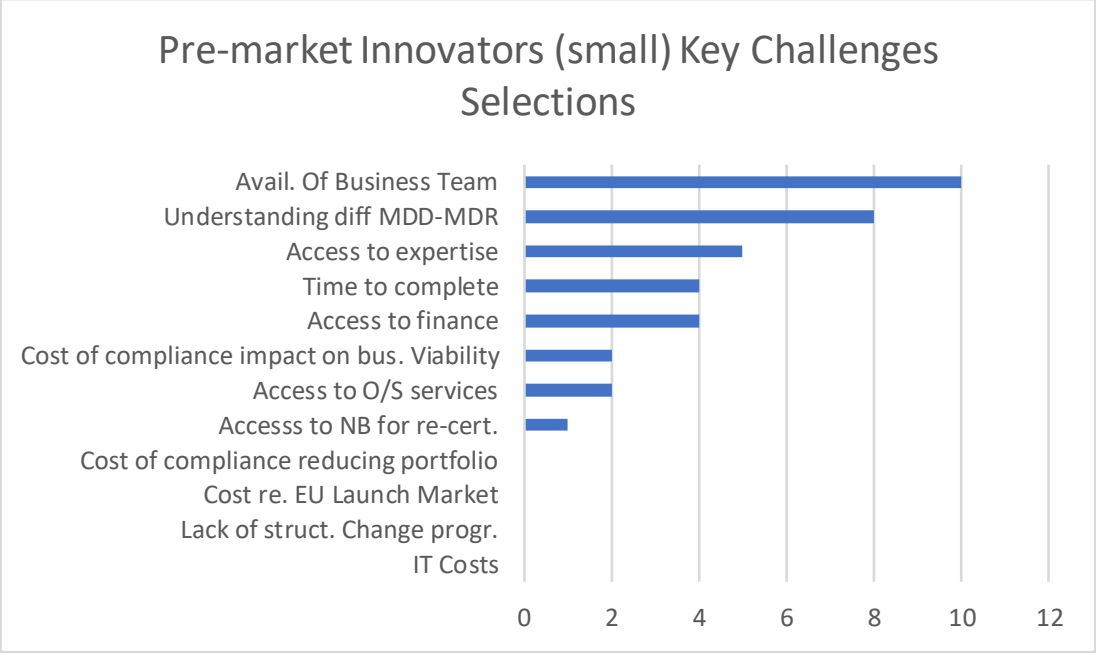

Fig 12: Pre-market Innovators (small) key challenges selections

The data show a marked difference between micro and small Pre-market Innovators in that small businesses expressed a concern over their business team's engagement with and understanding of the MDR.

This further supports the view expressed in Section 3.2 Readiness Assessment that focus of is on innovation and consideration of regulatory pathways are commonly disregarded until late in the development process.

By contrast the micro businesses are simply too small to leave any group disconnected. Otherwise the issues are held in common, especially access to expertise and access to finance.

The concern remains with the pre-market innovators that they have not engaged with the MDR because they don't have sufficient understanding and have yet to face the cost and complexity inherent in compliance.

4.4 Case Study Corroboration

We spoke to a number of the survey participants, generating Case Study corroboration of what we had concluded from the survey results.

Case Study 1: Medium-sized Manufacturer

We selected a medium-sized manufacturer, which has 87 employees and has been established in the UK for 26 years. This company is a manufacturer of specialist surgical instruments with a complex portfolio of products, running to 1000's of SKUs which it makes available for ENT and ophthalmology applications. The business sells their products internationally in 72 markets, 25% in the EU. However, it also needed CE marking for access to many non-EU markets e.g. Middle East, Far East and Africa.

This company has benefited from starting its transition to MDR in 2016. Having done so, it quickly realised the prohibitive cost of compliance of MDR and undertook a review of the viability of the business under MDR. The leadership concluded that in order to balance the costs of compliance, it would be necessary to significantly increase its sales. To achieve this expansion it required significant levels of investment. The decision was taken to sell the business, which it did to a US company. And whilst R&D and manufacturing remains in the UK presently, the leadership confirms that the sale of the business was almost certainly brought on by the enhanced effort and cost of MDR compliance.

This same company reported that MDR was also impacting on product development investment decisions. This particular business presented a case where it had been asked by a University about the use of its technology to

develop a product. Under MDD, such a request would have been fulfilled by a 6 month development cycle. However, regulatory advice had suggested that under MDR it could have taken 7 years to get to market. Consequently, the opportunity was not pursued.

Case Study 2: Pre-market Innovator

Case 2 is a Pre-market Innovator, which has 9 employees and has been established for 10 years. Their development portfolio included a 'next generation' polymer bioresorbable cardiovascular stent, which has reached 'first in man' trial stage. The business also had a stent device for other applications under development. Moreover it was engaged in discussion with a number of major corporations to exploit its technology in other areas.

Currently, MDR is adding considerable cost to the development budget. As an example, they quoted an increased testing budget around biocompatibility, costed at £120,000, which had to be found. However, of real consequence to this business was the threat of delayed launch resulting in the benefits of this innovative product not being realized by patients or the NHS.

Coronary artery disease is the leading cause of death both in the UK and worldwide, with enormous and far reaching social impacts. Access to this innovative product by the NHS it is claimed could significantly reduce treatment time and costs and could replace imported bioresorbable stents, benefitting both patients and the taxpayer.

This business also outlined the very real prospect of MDR driving the decision to first launch products away from the EU market. It quoted looking to the US, where it was stated that the FDA was becoming relatively easier to launch with, given the onerous requirements of compliance under MDR.

Case Study 3: Micro Manufacturer

The final case served to illustrate the issue faced by manufacturers who outsource aspects of their business to third parties. We spoke to a micro manufacturer, employing 6 and established for 11 years in the UK. The nature of their business was based on a machine, with proprietary technology developed by the founder, which along with accessories, is used in applications where blood plasma and platelets require separation. The business uses two different manufacturers, one for the machine and the second for the accessories. Over 70% of their sales are in the EU (excluding the UK).

Of concern for this manufacturer, was its dependency on its third party manufacturers to meet MDR compliance needs. The business spoke of limited progress in MDR transitioning by its third party manufacturers and the consequential impact that posed on its business.

The consequences for this business would be significant loss of sales and market position in the EU and in other markets which reference the CE mark for issuance of a certificate of free sale.

Also, this particular case indicated that the third party manufacturer would pass on the increased MDR costs. This will erode margins in what is already a particularly tight margin business. It also expected to have to contribute to the third parties' transition costs.

The consequences of MDR are clearly illustrated in our Case Studies. The impact on patient access to current and future products is a very real threat.

4.5 Assessment Findings Summary

The changes from the MDD to the MDR are so significant that they require a paradigm shift in the relationship between business and the regulatory function.

Under the MDR, compliance costs and complexity have increased significantly.

All business functions need to engage with their compliance obligations within an integrated, complex program. The timescales are reducing and levels of expertise required for compliance have increased.

Regulatory pathways should be a key focus for companies with specialist advice being integrated within the business rather than acting as an 'advisory add-on' as has typically been the case in many organisations under the MDD.

The UK SME medical device sector is heavily dependent on sales to the UK, EU and related markets and still considers this market as its primary target for new product launch.

It is evident from the readiness assessment that, with a few notable exceptions, SME manufacturers do not fully comprehend the MDR. This is evidenced primarily by their lack of budget provision and also by their lack of readiness overall.

At the time of writing there are only 5 months remaining for UK SMEs to become compliant to the MDR. To state again, there are many aspects of the MDR which

will apply on the date of application no matter the structure of the product portfolio.

For those with self-certified Class I products, full compliance will be required on the date of application.

For those with Class I re-useable devices, there will be the added challenge of finding a Notified Body.

Manufacturers with portfolios containing Class Ir/Is/Im, Class IIa, Class IIb and Class III devices may have a ‘grace’ period with product recertification up to a further 4 years under the MDD and only if they are confident that they can operate to MDR art 120.3.

Unfortunately, as has been evident for a long time and compounding the situation, very few Notified Bodies have yet been approved and there is little capacity in the system for a last-minute surge of applications. The risks are clear.

For Pre-market Innovators few have engaged with the MDR and, when they do, we believe that many may reconsider launch in the UK/EU. Unusually, the ‘easier’ route to market is now through the US and the FDA.

The consequences for the SME sector as a whole are likely to be reductions in the size of product portfolios, particularly for legacy devices, a reduction in the employment through both surviving but smaller businesses and business failure or sale of UK businesses into non-UK ownership.

What can’t be ignored is the extreme likelihood that the impacts to patients will be both extensive and unavoidable as longstanding devices become unavailable, as some businesses close and as product launches occur outside the UK/EU. This might not only be detrimental to patient outcomes but could have a cost implication for the NHS.

5 EU MDR Status and Challenges

Implementation of the MDR by the European Commission is not without its own challenges.

Concerns have been raised repeatedly by the Med Dev sector about the readiness of the Commission for MDR, particularly over issues such as the approval and readiness of Notified Bodies and the EUDAMED database. These have been documented in a recent report by MedTech Europe, the seven critical areas from which are listed below:

Extracts from: Industry Perspective on the Implementation Status of the MDR/IVDR by MedTech Europe Publ. 7th June 2019.

Critical infrastructure building blocks are incomplete:

Infrastructure Building Blocks	**Status**
Notified bodies	So far only 5 are designated under MDR out of nearly 60 and one of these is BSI UK which may soon be outside the EU
Quality Guidance	Some are done but most are yet to do
EU Reference Laboratories	There are none yet
Implementing Acts	So far only 2 are published and at least another 16 are needed
Expert Panels	There are none yet
Common Specifications	There are none yet

According to MedTech Europe, industry has expressed concerns in several ways this year: Concerns have been expressed and immediate action urged at the highest institutional level (Commission Vice-President and national Ministers of Health) and there has been a joint medical technology community statement expressing urgent concerns.

MedTech Europe has issued a call for action to the member states

Area of Critical Concern	**Solution-focused plan for accelerating implementation:**
Notified Bodies	Designate them faster
Re-certification	Ensure the procedure works for all products
EUDAMED	Deploy the new database with workable IT specifications and implementation timelines
(Quality) Guidance	Publish it in the most urgent areas
Scientific Bodies	Rapidly establish the new expert panels and EU reference laboratories
Delegating and Implementing Acts	Publish the most-needed ones, including certain 'system-critical' common specifications
Harmonised Standards	Ensure they are available in the highest-priority areas first

It is beyond the scope of this report to review the readiness of the EU Commission with respect to the implementation of the MDR and it should be noted that there is currently no indication that the Commission will deviate from the published date of application of May 26th 2020.

However great the concerns about Notified Bodies from the UK SME Med Dev sector, there is a strong argument that focus should not be on negotiating for delay. Essentially there are many examples of medical device manufacturers that have understood the implications for their business and products of the transition from MDD to MDR and acted in good time.

The fact that the survey respondents did not raise any of the other critical areas highlighted by MedTech Europe is likely to be a consequence of the general lack of readiness of the UK Med Dev SME Sector in that they have yet to come up against these issues in any significant way.

6 Recommendations

Detailed recommendations are to be developed in conjunction with key stakeholders and are not offered in this report at this time.

We do however offer a number of areas for consideration based on the readiness, challenges and consequences identified in this report:

1. **Education**
   The majority of the UK SME Med Dev Sector does not understand the reality of what the MDR means for their specific business in terms of compliance time, complexity, cost or risk. Similarly, this has not translated into an understanding of the impacts on patients, HCPs and the NHS.

2. **Funding**
   Compliance costs for both Manufacturers and Pre-market Innovators range from challenging to prohibitive with risks (and proven outcomes) that include discontinued current and future products, employment loss and business non-viability.

3. **Acceleration**
   The majority of the sector has started late, is progressing too slowly and lacks a clear understanding of where they are going. They lack access to the broad spectrum of specialist expertise necessary to accelerate their compliance and would benefit from external support.

4. **Mitigation**
   It may already be too late for many companies to meet the date of application but some mitigations may be possible. Urgent re-certifications under the MDD (where permitted) and mitigation discussions with the MHRA (The UK Medicines and Healthcare products Regulatory Agency), BEIS (The UK Gov. Department for Business, Energy and Industrial Strategy) and OLS (The UK Gov. Office for Life Sciences) should be pursued.

END

7 Appendix: Assessment Approach

Businesses invited to participate were SME and Micro Medical Device Manufacturers and Pre-market Innovators. The assessment approach was based on:

- An in-depth understanding and experience of the technical, business and programme management requirements for MDR compliance, provided by ISO Life Sciences.
- Access to and understanding of the UK SME Medical Device Sector, provided by Medilink UK and
- Access to and engagement with key stakeholders and oversight and direction provided by Innovate UK.

The principal tool was a bespoke, online survey distributed by email utilising Medilink's UK SME database and promoted on sites such as Linkedin and by email reminders. Candidates for a limited number of Case Studies were selected from the survey respondents. These were undertaken by face to face, structured interviews to explore issues and potential support needs in more depth.

The survey was sent to 1350 UK SMEs and responses were received from 110. Whilst the SME sector is known to be difficult to engage, the number of respondents was believed to offer a representative sample of the sector. The results confirmed and validated both ISO Life Sciences' and Medilink's informal assessments whilst adding considerable depth and detail and were supported by the in-depth Case Studies conducted after the survey.

Online Survey

A bespoke survey for MDR Readiness Assessment was developed based on ISO Life Science's knowledge and experience of the MDR and of compliance work with many large corporate Med Dev manufacturers over the last three years.

The survey comprised three sections:

1. Company information to enable understanding of the level of change for a business
2. Readiness assessment to enable understanding of the current transition status
3. Key challenges to enable understanding of where support needs to be provided

Company information included size, maturity, regulatory resource, revenue from CE marked products. Product Portfolio information included product classification, the number of technical file and ownership in addition to information on budgets for MDR compliance. This was in sufficient detail to segment analysis on readiness and key challenges.

This section was common for all respondents.

Readiness assessment used a long established competency assessment methodology in which several dimensions are described at increasing levels of competency and respondents identify the level they have achieved based on descriptors for that level.

The high level areas assessed were:

- Business Readiness
- Product Portfolio Readiness and
- Operating Model Readiness

Each of these areas was detailed in several dimensions. An example is shown below:

UK SME MDR Readiness Survey : **Operating Model MDR Readiness - Manufacturers**

	Level 1	Level 2	Level 3	Level 4	Level 5
Quality Management System	• ISO 9001 or, • ISO 13485 or, • GDP (Good Distribution Practice) compliant	• ISO 13485 : 2016	• QMS gap assessment completed against Article 10.9	• Develop new Standard Operating Procedures (SOPs) including • GSPR (General Safety & Performance Requirements) • Risk management • Clinical Evaluation • PMS	• Train and roll-out new SOPs • MDR compliant QMS recertification
Post Market Surveillance, Vigilance and Market Surveillance	• Post Market Surveillance & Vigilance processes in place	• Post Market Surveillance system includes PMS Plans, PMS Reporting • Complaint handling, vigilance reporting and trending system operational • Investigations /Serious Incidents system operational	• PMS gap assessment completed • Complaint handling, vigilance reporting gap assessment completed • Market surveillance gap assessment completed	• Updated PMS processes & templates including MDR compliant PMS Plans and PSURs, PMSR (Class I devices) • Process efficiencies to support reduced reporting timelines to CA (Competent Authority) designed	• Implementation of MDR compliant PMS, Vigilance and Market Surveillance
Economic Operators	• Commercial Agreements formalised across supply chain	• Technical Agreements between 3rd parties along the supply chain available	• Economic Operators (EO) re-classified across supply network • MDD-MDR Gap assessment of Technical Agreements for all EOs completed	• Appointment of Authorised Rep/Importer for 3rd country manufactured products • New Technical Agreement templates agreed (Third Party Manufacturers, AR, Importers, Third Party Distributors, Distributors)	• Roll-out and re-negotiation of MDR compliant technical agreements
Product Registration/ Product Traceability	• Systems in place to support product identification (UDI-DI) and production identification (UDI-PI)	• Recording and maintaining of product *supplied from and by* the Business to enable traceability	• End to end Supply Chain traceability gap assessment completed against Article 25 • Gap assessment to support product Registrations and required EOs by the Business to EUDAMED	• SC traceability process solution agreed facilitated by UDI system • EUDAMED reporting requirements designed	• UDI implementation in process • EUDAMED ready

Fig 13: MDR Readiness Competency Framework – Operating Model transition maturity

The descriptors were designed to ensure objectivity in the self-assessment and enable the results to be aggregated and compared with significantly more confidence than a simple self-assessment of the type:

How ready are you: 0 (not at all) – 10 (completely)

The readiness maturity levels represent:

0 No awareness
1 Minimal awareness of the MDR
2 Awareness and understanding of the MDR
3 Gap assessments undertaken for my business and products
4 Gap closure solutions defined and programme in place
5 Compliance solution implementation in progress

This section was customised for respondents depending on whether they were manufacturers or pre-market innovators since their experience under the MDR will be different.

Key Challenges were proposed as a list based on experience of issues and challenges with MDR programmes elsewhere. A free text box was available for respondents to add their own challenges if they were not already included.

Respondents were invited to rank challenges as High, Medium or Low and then to identify their 'Top 3'. This Top 3 list was used to assess common challenges and to understand variations based on company or product portfolio differences. In presenting the data the results were weighted; 1st (top) challenges scored 3, 2nd scored 2 and 3rd scored 1. This allowed the challenges to be equally represented in a single chart. Sensitivity testing by reducing the weighting did not change the order of the challenges.

This section was common for all respondents.

Survey respondents were accessed through Medilink's contacts and relationships with the UK SME Med Dev sector. The survey was piloted at a Medilink MDR event in Liverpool on the 9th July 2019 at which there was a positive response and support for the assessment. The survey was modified based on feedback from the event and published online using SurveyMonkey.

Case Studies

Case study candidates were selected on the basis of their survey responses. In particular we were looking for representative companies (medium, small and micro manufacturers and innovators) with credible and complete responses.

The case studies were undertaken by face to face interview with preferably both business and regulatory representatives using a structured interview form. The interview form revisits the business and MDR transition information and explores in depth the critical challenges and possible support needs.

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