The Medical Device Regulation: Transitioning between old and new

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Introduction

In May 2017, the new Medical Device Regulation was published in the European Official Journal, initiating a three-year transition from the Medical Device Directive. This represented a culmination of eight years of significant work by ABHI and the European trade association, 'MedTech Europe', during which time we worked to protect the best interests of patients, clinicians and industry by creating a new 'gold standard' medical devices regulation.

But what are the critical elements of this new regulation that industry will have to be mindful of, in order to ensure compliance beyond 2020?

This document highlights the main areas of change, although it should be remembered that compliance is not an exact science. Each company should therefore assess the relative impact of each to their business. For example, clinical requirements will differ between product risk classifications and portfolios, and despite UDI/DI appearing generic, labelling needs and integration into supply chains, will be unique.

This document only touches those areas for which the majority of companies are seeking answers. It is important therefore, that this is not seen as the panacea for understanding all the issues; it is important for every company to assess and strategize what is critical to them.

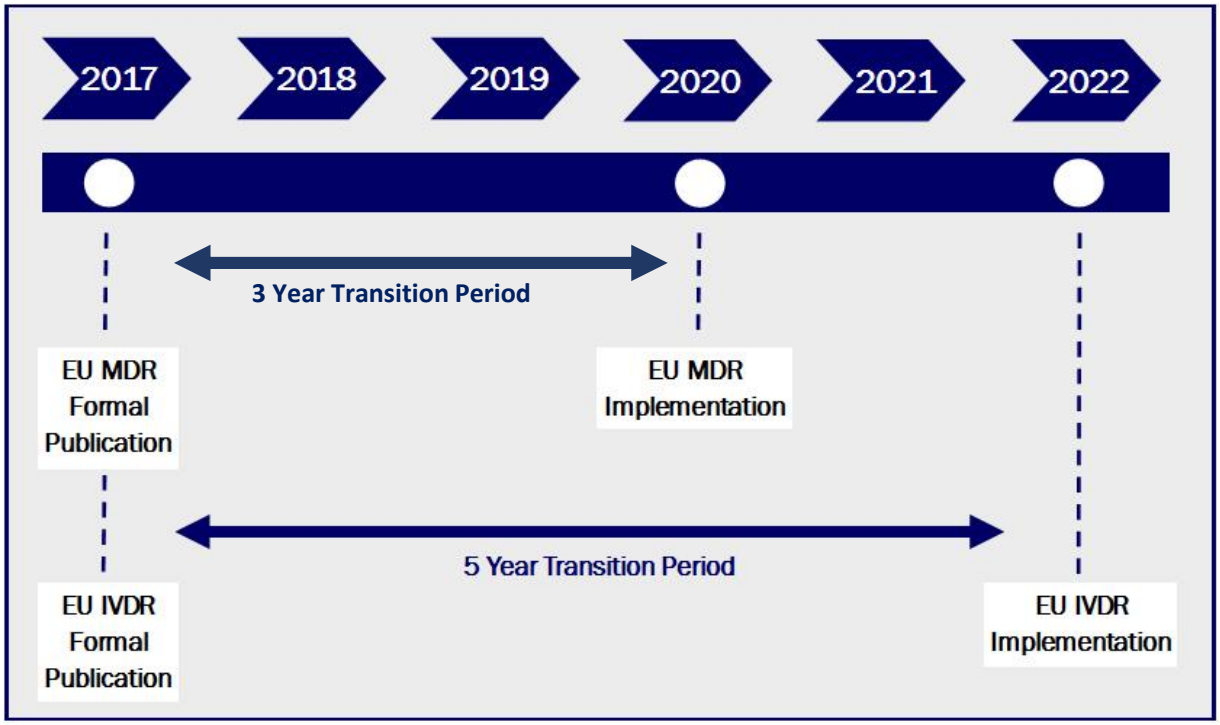
Association of British Healthcare Industries

ABHI is the UK's lead medical technology trade association. We are a community of over 260 members, and champion the use of safe and effective medical technologies to support high quality patient outcomes and health system efficiency.

Transition Period and Timing

Having been published on the 5th May 2017, Regulation 2017/745 (the Medical Device Regulation or MDR) will become fully applicable on the 5th May 2020. Up until this date, the Medical Device Directive (93/42/EEC) will continue to apply. This three-year transition therefore, will allow companies to introduce and strategize new procedures in line with MDR compliance.

It should be noted however, that the transition provisions will allow product to be CE Marked and placed on the market under the current Directive up to 4 years beyond 2020, assuming that they are not subject to further significant technical change, that they meet published Implementing and Delegated Acts and that their certification has not expired.



BDIA

The British Dental Industries Association

Established in 1923, the BDIA represents and supports manufacturers and suppliers of dental products, services and technologies. BDIA members gain access to a range of services designed to benefit them and promote the well-being of the industry as a whole, and the profession gains the reassurance of dealing with like-minded individuals who are committed to providing a high quality standard of service.

Transition Period and Timing

During the period between 2017 and 2020 however, the European Commission will be publishing and executing a number of MDR 'Implementing' and 'Delegated' Acts, which are likely to become effective alongside the current Medical Device Directive, resulting in an effective 'Medical Device Directive PLUS' compliance.

These aspects could include Notified Body operations, EUDAMED inputs, UDI/DI, Re-Processing provisions, further transition arrangements and 'Chemicals' to name but a few. In all there will be 18 'mandatory' Acts, which will be required in order to make the MDR work by May 2020.

Furthermore, as with industry, Notified Bodies themselves will have their own strategies for ensuring that they too have appropriate accreditation, enabling them to 'certify' manufacturers to the new Regulation.

There are many imponderables between May 2017 and May 2020. But rather than being a 'leap of faith', there are a number of key decisions that can be made now to mitigate future non-compliance issues.

RECOMMENDATION 1: Speak early to your Notified Body to validate your transition plan and to manage their expectations of your future Certification.

The Business Connection

The text of the MDR includes aspects of Quality Management, Risk Management and Post-Marketing engagement that were not included in the old Medical Device Directive. This is transforming medical device regulation into a 'business process' rather than a process of 'product control'.

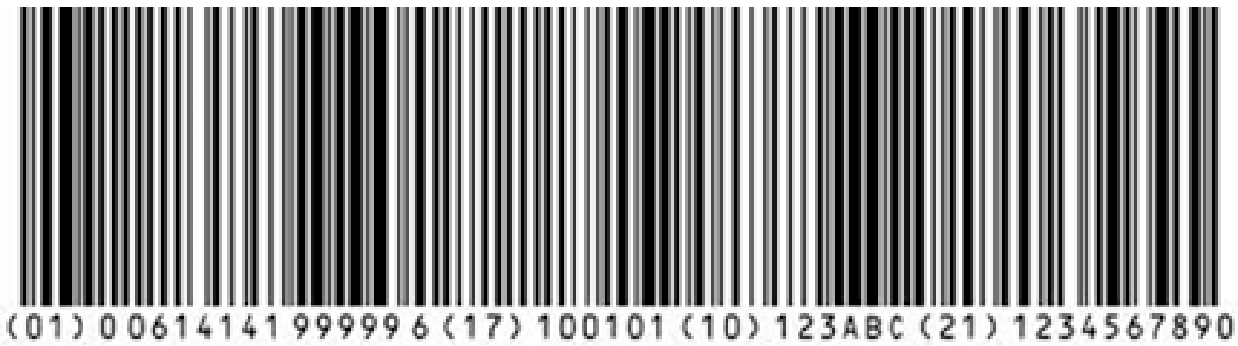
Do not fall into the trap of considering the MDR as an issue the Regulatory and Quality team can solve on their own – the MDR now demands joined-up thinking across the whole company.

How the Directive and Regulation Compare

- **Liability;** Release of specific product onto the market will now demand oversight by a 'responsible person', similar to that experienced in the drug world
- **Quality Management Systems;** Aspects of Quality Management have now been enshrined in the Regulation, in addition to standard EN ISO 13485. Audit will now be tied to Regulatory Compliance and Management responsibilities
- **Integration of Risk Management;** The MDR will now drive product lifecycle management through risk processes
- **Understanding of Supply Chains;** The establishment of auditable supply chains will change the responsibilities of distributors particularly with respect to compliance and post-marketing activities
- **Transparency;** Aspects of clinical performance, vigilance, adverse events, recalls and company registrations will become transparent through the application of a European-wide, publicly accessible database called EUDAMED.

RECOMMENDATION 2: Train the whole company and distribution network on the new MDR requirements. A holistic approach to compliance will drive economies of scale and ensure faster resolutions of issues.

UDI and Traceability



The MDR will require all medical devices in the future to carry a 'Unique Device Identifier' (UDI) – related to the device (UDI-DI) and it's production identity (UDI-PI). This information shall be visible on either the product itself or the labelling, depending on appropriateness and practicality.

In addition to manufacturer responsibilities, health institutions and economic operators will have a duty to store and keep these electronic records, particularly if those products are Class III's or implantable products. There will be a duty therefore, for manufacturers to work with their Economic Operators to ensure that their responsibilities are met.

Registration of products via UDI onto a central database is likely to subject to further implementing legislation, but all efforts will of course, be aimed at transparency in product identification and traceability of product within the distribution chain.

All efforts are being made to rationalise European and global content of the UDI components, such as the uniformity of nomenclature and applicable UDI standardisation, all of which still requires significant amount of negotiation and discussion. The requirements of the MDR however are unambiguous – very much a case of continued industry input.

RECOMMENDATION 3: Make sure your company continues to monitor and lobby nationally and globally on UDI issues to make sure industry requirements are appropriate and proportionate

Clinical Evidence

The MDR requires that the manufacturer, irrespective of risk classification of their product, reviews, analyses and documents clinical performance in a 'clinical evaluation report' (CER). The data, demonstrating a positive 'risk/benefit', is derived through review of scientific literature, clinical investigations or review of alternative treatments.

Class III and 'implantable devices' will have to be subject to specific 'clinical investigations', unless caveats apply. Indeed, these particular products now require a 'summary of safety and clinical performance (SSCP)' to be written in addition to the CER.

The Medical Device Directive allowed the assessment of clinical data using principals of 'equivalence'. The MDR however, places restrictions on the use of such equivalence, demanding technical, biological and clinical review to be conducted, necessitating the availability of supplier or competitor data.

As previously mentioned, Class III and implantable products will invariably require the generation of an SSCP. For new products under the MDR, this SSCP will be subject to further 'scrutiny' by a European expert panel prior to the CE Mark being affixed and will then be made publicly available through the EUDAMED database.

RECOMMENDATION 4: Although a degree of 'grandfathering' will apply, review your processes and procedures for assessing clinical performance, ensuring they include development of a clinical evaluation report (CER) and where applicable, a summary of safety and clinical performance (SSCP).

Post-Marketing Obligations

Demonstration of clinical performance is not a 'one-off'. The MDR requires that your product CERs and SSCPs are periodically updated according to a documented 'Post-Marketing Clinical Follow-up plan' (PMCF plan). PMCF can take many forms, from the pro-active collection of surveillance data, analysis of vigilance information, user experience or competitor literature. Whatever the source, this PMCF information needs to link directly to the updating of the CER, risk assessments and product lifecycle management.

Vigilance: Reactive

- The collection of adverse product experience that requires notification to the relevant competent authorities
- Subject to new reporting deadlines within the MDR, of 2, 10, 15 days, depending on severity
- Can result in 'Field Safety Corrective Actions', including recall
- Ultimately reportable through the EUDAMED database and linked through use of UDI and SRNs
- Manufacturers required to 'trend' changes to safety data particularly for those incidents that are expected or not reportable via vigilance processes

PMS: Proactive

- Manufacturers are required to implement Post-Marketing Surveillance systems (PMS) for the systematic collection of product experiences
- PMS generates a 'Periodic Safety Update Report' (PSUR)
- Frequency of PSUR generation dependent on risk classification and product novelty
- Class I products are not exempt – these too require a periodic Post-Market Surveillance Report
- Audited by the Notified Body

RECOMMENDATION 5: Ensure that your Quality Management System includes effective procedures for vigilance and 'Post-Market Clinical Follow-up'. All obligations, both reactive and proactive, are audited by the Notified Body and potentially critical non-conformities. Furthermore, ensure that PMS is linked to risk management processes and (where appropriate) product lifecycle assessments.

Supply Chain; Economic Operator Responsibilities

It will be incumbent on medical device manufacturers to fully understand and document their distribution chain. Furthermore, the stakeholders in this chain will have increased responsibilities, particularly with respect to the 'placing on the market' of CE Marked devices.

The Manufacturer

- EUDAMED Activities
- 'Person Responsible for Regulatory Compliance' release – ensuring compliance post-production
- Technical Files and Declarations of Conformity
- Vigilance and Post-Marketing Surveillance activities
- Product Lifecycle activities

The Authorised Representative

- 'Person Responsible for Regulatory Compliance' release – understanding of product and labelling
- Access to Technical Files and Declarations of Conformity
- Post-marketing and vigilance activities
- Liaison with Competent Authorities on technical matters
- EUDAMED activities (as appropriate)

The Distributor

- Regulatory knowledge to spot issues related to national non-compliance
- Able to prevent the 'placing on the market' in cases of non-compliance
- National competent authority liaison where appropriate
- Local assistance with manufacturer's Post-Market Surveillance activities

The Warehouse

- Stock control
- Regulatory knowledge to spot issues related to national non-compliance
- Adverse event and recall requirements

RECOMMENDATION 6: Ensure that your distribution network is fully contracted and understanding of their responsibilities, as your regulatory compliance is dependent on their actions.

Standard and Training

Standards

The Medical Device Directive is very much a product related document, requiring technical detail under-pinned by application of harmonised standards. Although standards are still part of the MDR, many aspects of compliance are now included within the legal text, making it more business oriented.

Training

- *Internally*
  Prepare your teams for the new requirements of the MDR, remembering that the regulation involves departments as diverse as senior management, marketing, sales, Quality, safety, and R&D. The integration of business functions is key to ensuring holistic regulatory compliance – irrespective of product classification.
- *Externally*
  Work with your Notified Body to understand the requirements of certification, conformity assessment and post-market commitments. The Notified Body assess many products in addition to yours and so by increasing their knowledge, you will re-assure them of your competence and ultimately your regulatory conformance. Note also that Notified Body auditing can potentially include your supply chain, so ensure appropriate training includes all of your economic operators.

RECOMMENDATION 7: Ensure that the MDR is understood as a business concept, as it not only focuses on product attributes

What Does the Future Hold?

The Referendum result in June 2016 has introduced an additional element of the unknown to the implementation of the MDR. What will the Brexit timelines mean for MDR Implementation? How can the UK maintain regulatory parity with European partners? Will the ABHI/BDIA's expectation that the MDR is the regulation of choice be realised?

The regulatory 'asks' of the ABHI and BDIA have been amplified in other documents and are constantly discussed through our lobbying efforts, to ensure;.

- Regulatory convergence
- Continued 'global' excellence of the MHRA
- UK Notified Bodies to continue within the CE Marking process

- UK Authorised Representatives to continue
- Clarity on MDR implementation, including timelines
- Input into European systems, such as CAMD and MDCG

RECOMMENDATION 8: Work proactively with ABHI and BDIA to shape the future of the UK Medical Devices and Dental Industry, ensuring that regulatory compliance is not about turbulence but more blue skies and plain sailing.

Useful Links

- Medical Device Regulation 2017/745
- In-Vitro Diagnostics Regulation 2017/746
- Medical Device Directive 93/42/EEC
- Active Implantable Medical Device Directive 90/385/EC
- In-vitro Diagnostics Directive 98/79/EC
- Medicines and Healthcare products Regulatory Agency (MHRA)

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