

Medical Device Regulation is changing. Why, when and how will it affect Tissue Viability?

Richard Forder. Head of Clinical Affairs, Talley Group Limited, UK

Introduction

The Medical Device Directive (MDD) 93/42/EEC historically directed medical device classification and regulation in Europe. This has now been superseded by the Medical Device Regulation (MDR) known as (EU) 2017/745 which sets higher standards for quality and safety.

The new MDR entered into force on 25th May 2017, and becomes fully applicable on 26th May 2020. Therefore medical device manufacturers have approximately 2 years to transition to the MDR.

During this transition period devices can be placed on the market under the current EU Directives, or the new Regulations (if they fully comply with the new Regulations) however, it is expected that manufacturers should be actively working towards the new MDR.

Medical devices placed on the market after the transition period (i.e. from May 2020 onwards) will need to fully comply with the new MDR, unless they wish to make use of the extended period of CE certificate validity which allows for CE certificates issued under the current Directives and within the transition period to remain valid for a maximum period of four years after the date it was issued.

It is anticipated that the new MDR will achieve the following objectives;

- Allow industry to bring safe, effective and innovative products to market quickly and efficiently
- Give increased confidence to healthcare professionals and patients in the devices that are being routinely used every day.

Why change?

The existing MDD has come under criticism in recent years and the new MDR is intended to overcome perceived flaws and divergences. It has therefore been designed to strengthen patient safety via a robust and transparent 'fit for purpose' regulatory framework.

Manufacturers must demonstrate MDR conformity and clearly show their products have an acceptable benefit-to-risk ratio i.e. devices are safe and achieve the claimed performance which must be proven with supporting clinical evidence (i.e. clinical evaluation report and where necessary a clinical investigation).

What is changing?

The introduction of the Medical Device Regulation results in multiple changes from the previous MDD. The key changes are listed in Table 1.

* Scope of regulated medical devices *
Pre-market scrutiny procedure
* Person responsible for regulatory compliance *
* Identification and traceability *
* Vigilance and market surveillance *
* Supervision of Notified Bodies *
* Clinical investigations and evaluation *
Timetable for introduction and transition

TABLE 1.
Key changes as a result of the Medical Device Regulation

The impact on manufacturers

The MDR should be welcomed by manufacturers who prioritise patient safety, device effectiveness and process transparency.

However, every asterixed line in Table 1 will result in the need for manufacturers to increase funding and resource in order to meet the new MDR requirements.

Three good, practical examples where manufacturers will need to make significant investments are highlighted in yellow in Table 1. For many small to medium size enterprises the need to have a **person responsible for regulatory compliance** is likely to mean recruiting a new person into the organisation and for some companies this will be a major undertaking. This person will be required to possess expert knowledge in the field of medical devices and have either;

- University degree or equivalent + a minimum of 2 years medical device experience in regulatory affairs or quality management systems.

OR

- 5 years medical device experience in regulatory affairs or quality management systems.

Device identification and traceability relates to devices having a UDI or unique device identification. The UDI system must be based on internationally recognised principles, including definitions that are compatible with those used by major trade partners.

The benefits of having a UDI system are listed in Table 2.

Clinical investigations and evaluation will play an increasingly important role in the MDR. Every medical device will be required to have a clinical evaluation report behind it in order to substantiate manufacturers claims of device safety and performance and this report will be closely scrutinised for any medical device being audited by a Notified Body.

Enhanced traceability, which should significantly improve the effectiveness of the post-market safety of medical devices
Better incident reporting, targeted field safety corrective actions
Improved monitoring by the MHRA (The UK Competent Authority)
Reduction in medical errors
Reinforcement of the fight against counterfeit devices
Improved purchasing and waste disposal policies and stock-management by health institutions and other economic operators

TABLE 2. Benefits of the Unique Device Identification system

With the role of the Notified Body becoming increasingly involved as a result of the MDR this is likely to result in;

1. Costs to manufacturers increasing as Notified Bodies have to spend far longer interrogating documentation to a much more granular level AND
2. A potential delay in the time required to move new devices through the development and registration process.

The Notified Body will only issue a CE certificate to show that the medical device meets the requirements, once it has determined a manufacturer has conformed to the relevant assessment criteria. The manufacturer then signs a Declaration of Conformity and applies the CE mark.

Implications for Tissue Viability

To conform to the new regulations and ensure their devices are fit for purpose and meet the new MDR safety and performance requirements all manufacturers will need to increase their level of investment in the area of Regulatory Affairs and Quality. In some cases for smaller companies the level of investment required to meet the MDR will be very significant.

Between now and May 2020, and potentially beyond as the MDR 'beds in', Tissue Viability is likely to see some subtle changes as manufacturers begin working to the new regulation. These changes will be likely to include;

- **Product price increases.** It is unrealistic and commercially naïve to expect manufacturers to absorb all additional costs incurred as a result of the increased spend required to ensure conformance with the new MDR. Whilst overall, devices will become more tightly regulated and safer, nothing comes for free and some products such as dressings and support surfaces will potentially become more expensive as manufacturers look to recoup the additional investment required to meet the MDR. With a healthcare system that is often looking to trim budgets and reduce costs there are likely to be some uncomfortable conversations between manufacturers and customers during tender processes and contract negotiation.

Manufacturers with strong existing Regulatory and Quality credentials are likely to already be performing the majority of the 'new' tasks

that will be mandatory under the new MDR, therefore in some cases the cost increases will be negligible, however this is likely to be the exception rather than the rule.

One potential benefit that may be seen is that in some cases the new MDR may 'level the playing field' in terms of regulatory requirements for some product classes. In this instance you may see cheaper, less well-regulated products increase significantly in price while similar, more highly regulated products see far smaller price rises.

- **'Toning-down' product claims.** The current MDD classifies devices by risk, however the new MDR will also classify devices by claim. To ensure some current Class I devices are not reclassified as more highly regulated Class IIa devices (thereby incurring far greater spend on regulatory submission and conformance assessment) manufacturers may opt to 'tone-down' product claims to keep their devices as Class I products.

It is therefore quite possible that Class I products which currently have very bold overarching claims suddenly start removing some of these or at the very least dumbing them down to a very low level. Look for changes on product literature, websites, exhibition stands etc. and don't be afraid to challenge manufacturer's claims. If they appear too good to be true then they probably are!

- **Products disappearing... Companies disappearing!** Registering a Class IIa medical device costs tens of thousands of pounds for each product. Therefore some manufacturers may withdraw product lines that would not justify the investment.

In addition, some smaller companies may have insufficient resources or infrastructure to meet the new requirements and the MDR may be a step too far for them so they may have to cease trading altogether.



Conclusion

The medical device landscape will change as a result of the new MDR, however it is ultimately positive for Tissue Viability as it tightens regulations around medical device safety and performance and therefore helps providers and clinical staff provide safe and effective harm free patient care.