

Medical Device Regulation - Europe **UPDATE**

New Medical Device Regulation will be published by January 2017

(How is your business meeting the challenge?)



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So, what is going on?... It has been a long time in the making, but the long awaited Medical Device Regulation (MDR) is certainly going to pack a punch. After many published versions, the agreed final text was published by the commission in May 2016 with the intention that this text is published in the European Official Journal in the later part of 2016.

Key Consequences...

- **Tighter controls on the collection of clinical data and expansion of the definition of clinical investigations.**
- **Mandatory publication of data on the performance of Class III devices.**
- **Post Market Surveillance must be maintained over the whole of the device's life.**
- **Periodic Safety Update Reports for Classes II, IIb and III.**
- **Transition period for devices excl. in-vitro diagnostics: 3 years.**
- **Major organisational and financial impact on smaller companies.**

Clinical Evidence in a New European Regulatory Environment... There are many substantial changes to the new regulation including new controls on economic operators and the specific duties of Notified Bodies. But by far the most fundamental change has been to the definition of clinical evidence, the gathering of clinical evidence and, arguably, the maintenance and reporting of this evidence, particularly for higher risk classification devices. This has very much been driven by very public failures of Post Market Surveillance plans, particularly the well-publicised field failures such as the ASR metal on metal hip implant, which was not detected by the manufacturer in a timely manner.

Stringent Controls... The new regulatory regime dictates very stringent controls on the gathering of clinical data with the new Annex XIII defining requirements for clinical evidence and Post Market Clinical Follow-up (PMCF). Many of you will already have been challenged by your Notified Body to provide a documented rationale as to why you are or are not actively running PMCF protocols for your products. We also see a greatly expanded definition of Clinical Investigations in Annex XIV of the proposed regulation, which features very defined approval processes and a level of transparency regarding studies not seen to date in Europe. For class III products this can clearly be seen in article 26 which requires manufacturers to provide summaries of safety and clinical performance which will be published via Eudamed.

Article 60 of the text requires a system of PMS to be established throughout the entire lifetime of the product. This should incorporate risk management assessments, literature reviews (MEDDEV 2.7.1 rev 4) and a documented Post Market Surveillance Plan (PMSP) which will be part of the technical documentation for the device or family of devices. The output of this process will be reported in a Periodic Safety Update Report (PSUR) which for class IIb and II devices will be published annually (see Annex IIa) with reports for class III products being submitted to the European Commission.

As you can clearly see, there will be huge amount of work associated with generating this data, its analysis and periodic reporting of these activities. This will be a resource intensive process which requires support from trained and experienced staff.

The Challenge... The message is clear; as we transition into the enforcement of this new regulation how we systematically collect, maintain and analyse clinical evidence will be one of the major pillars supporting the continued CE marking and distribution of products in Europe. For those products with a weak historical evidence base and few published reviews, this will have to be a major focus of organisational efforts over the brief transition period to this new regulation.

The Opportunity... As is often said; “never waste a good crisis”. The challenge for smaller companies is how to turn this increased focus on performance data into an opportunity.

Post Market Surveillance systems should be and can be run as part of a coherent and continuous plan to collect evidence of clinical and economic outcomes, which evidence can be used to justify the position of the company’s product on wound care formularies and tenders, and to support the sales effort.

Historically, wound care has seen a heavy reliance on case studies and case series to satisfy post market surveillance requirements but these are not always managed consistently and so do not always produce data which will satisfy clinicians and budget holders looking for credible justification of cost-effectiveness.

Contact us today to discuss how we can make complying with the New Medical Device Regulation “Less of a Pain and more of a Plus” by...

- ✓ **Designing Clinical Evidence Programmes to satisfy regulatory, reimbursement and post-reimbursement sales objectives.**
- ✓ **Project Managing Clinical Evidence Programmes from A – Z.**