European Medical Device Regulation and CE Transition Strategy

On 26 May 2017, the European Union's new Medical Devices Regulation (MDR)entered into force, which replaces a decades-old legislation, will require manufacturers to make significant changes in product development, data reporting and their quality management system. This long awaited regulations brings with it more scrutiny of technical documentation, including clinical evaluation and post-market clinical follow-up, and traceability of devices through the supply chain. Manufacturers of currently approved medical devices have a transition time of three years until May 26th 2020 to meet the requirements of the MDR.

So why did the European Commission revise existing legislation on Medical Devices Directive (MDD) and Active Implantable Medical Devices Directive (AIMDD) into a single Medical Devices Regulation (MDR)? Well, there are multiple reasons stemming from an ill-managed expansion of the EU impeding the governability, dis-harmonization in the implementation of the MDD and AIMDD. This led to differences in interpretation of the MDD, discrepancies between Competent Authorities (CA) which resulted to a non-level playing field for Notified Bodies (NB). In addition, the rapid development of technologies made it difficult to apply the requirements of the MDD and AIMDD. Finally, at least for the EU Commission, the 2010 PIP breast implant fraud scandal in France expedited the process of the MDR.

Compared to the MDD, the MDR is a shift from the pre-approval stage (i.e. the path to CE Marking) to a life-cycle approach. This approach is similar to the life-cycle view promoted by the US FDA and by many international standards.

So what are some of the major changes?

- The definition of medical devices is extended to include products for cleaning, disinfection or sterilization.
- Specific group of devices that do not meet the exact definition of medical devices may have a "medical character" as the MDR brings products intended without a medical purpose under it's scope such as coloured contact lenses and cosmetic implant devices and material
- A medical device incorporating an in vitro diagnostic medical device (IVD) will be governed by the MDR, although the requirements of the IVDR will apply to the IVD part of the device. This would imply that a Class I medical device incorporating a Class B, C or D IVD requires notified body involvement.
- Reprocessing of single-use devices may only take place where permitted by national law and under strict conditions.
- The number of Essential Requirements and the level of detail has increased. The new Essential Requirements Checklist under the EU MDR have more than 220 items to review.
- Mandatory Unique Device Identification (UDI) is introduced with the intention to facilitate the traceability of devices.
- EUDAMED databases established under the new EU MDR will be publicly accessible and will contain comprehensive data on the devices themselves, including the Unique Device Identification (UDI), data on all the economic operators, data on clinical investigations conducted in Europe, vigilance and post-market surveillance data as well as data on the Notified Bodies and the certificates issued
- Part of the data in EUDAMED require "summary of safety and clinical performance" for all Class III and implantable medical devices.
- Technical documentation elements specified in Annex II is largely based upon the GHTF STED guidance.
- Technical documentation on post-market surveillance (PMS) in Annex III requires manufacturers to be proactive in their efforts to systematically gather and analyze post-market data. More precisely, the technical documentation under MDR must contain a PMS plan that complies with the obligations of the manufacturers, a Periodic Safety Update Report (PSUR) for devices greater than class I, or a PMS report for devices of class I.
- Greater emphasis is placed on clinical data and the clinical evaluation. Equivalence, currently used to justify referencing to studies done with other devices, is more rigorously interpreted for clinical evaluation report. The MDR imposes tighter pre-market controls on high-risk devices, and apply a more rigid approach to the conduct of both clinical evaluation and the clinical investigation of clinical trials

- Notified Bodies (NB) will now move from an industry partner to an extension of the CA market surveillance program.
- NB must conduct audits and assessments at least yearly, on the quality management system and post market surveillance. Additionally, the NB is to perform unannounced inspections of manufacturer and manufacturer's suppliers or subcontractors at least once every five years. The NB will be mandated to test samples from the production or manufacturing process. NBs are also encouraged to analyze samples from the market.
- NBs would be placed under a strict regimen of supervision by the CA: the qualification requirements for auditing and reviewing NB staff are sharply increased.
- Under the MDR, all currently CE Marked devices must be recertified in accordance with the new requirements. There are no "grandfathering" provisions.

What is the potential impact to your business?
Translates to higher costs, longer lead time for technical documentation reviews and audits by NBs impacting market growth and product launches, increased scrutiny of technical documentation causing delays in product approval (or renewal) and EC Certification.

- Increased requirements and detail for Clinical Evaluation including MEDDEV 2.7.1 revision 4
- Structuring of technical file to STED
- Increased requirements and detail for Essential Requirements
- Updates to labeling to include new MD symbol
- Incorporation of products that are not currently subject to the MDD but will be under the MDR
- Requirements for Class I devices that may now be subject to NB involvement
- New reporting for Class III and implantable devices in EUDAMED
- New restrictions and responsibilities for AR
- Increased oversight and mandates for NB
- Increased documentation associated with post market surveillance
- The potential elimination of Own Brand Labeling as the requirements for conformity assessment and the technical documentation that needs to be available will effectively eliminate the position of the Own Brand Label manufacturer (viz. companies that rebrand existing medical devices and sell them under their own name)

How we can assist you to maintain compliance with minimal to no interruptions to your business?

- Conduct gap assessments with your current technical documentation to the MDR and remediate
- Create Clinical Evaluation Reports to the MDR and MEDDEV 2.7.1 revision 4 requirements
- Establish Post-market surveillance system (process, plan, effectiveness, PMCF and results)
- Create technical documentation (technical file, design dossier) to MDR requirements
- Provide training to staff to MDR, CER requirements
- Assess product portfolio to determine if subject to MDR
- Liason with the Notified Body and Authorized Representative to CE marking
- Risk Management File Review

It is important to note EN ISO 13485:2016, which was released in March 2016, is now mandatory from March 31, 2019. The new QMS along with the Medical Device Single Audit Program (MDSAP) which provides a global approach to auditing and monitoring of manufacturing of medical devices, it would be prudent to look at all of these initiatives strategically and holistically and not as separate efforts. This can allow you to leverage the efficiencies of the programs and minimize/eliminate business interruptions.