EU MEDICAL DEVICE REGULATION:

6 THINGS EVERY DEVICE LEADER NEEDS TO KNOW

1 CHANGES ARE COMING.

The EU is proposing updated regulation for medical devices — from contact lenses to X-ray machines, pacemakers to HIV blood tests — to establish transparency into patient safety and product quality. Regulations are expected to come into force by mid-2016 with a three year window for compliance.

2 THAT IMPACT THE WHOLE BUSINESS.

Beyond obvious impact to the quality and safety functions, the regulations will impact the entire value chain, including supply chain, clinical development, portfolio management, and commercial.

3 THERE IS MUCH TO LOSE.

We expect that all CE marked products will have to be re-certified under the new regulations. Non-compliance will potentially result in a loss of business anywhere a CE mark is utilized. As Notified Bodies are flooded with submissions, companies should also expect delays to market for existing and future products.

4 BUT ALSO MUCH TO GAIN.

Beyond driving potential improvements in quality and patient safety, companies that are first in line to recertifiy will be first to market. Also, this could create a wave of opportunistic M&A deals as some companies choose to divest products versus bringing all products up to the new standards themselves.

5 THE TIME TO START IS NOW.

The queue for Notified Bodies will begin immediately upon Notified Body certification and the line will start forming quickly. Additionally, given the breadth of functions impacted, many large, multinational companies will need to act now to drive compliance by the 2019 deadline.

6 BEGIN WITH AN IMPACT ASSESSMENT.

To begin quickly, clients can engage YourEncore's EU MDR team to conduct a cross-functional gap assessment of your current organization to the future regulatory requirements. One option is to limit the initial pilot to a few products to make it more manageable. This type of assessment can be completed in as little as 3-4 months.

For Help Getting Started

Contact **Mary Ellen Schipp** to discuss YourEncore and EY's EU Medical Device Regulation workshop and proprietary assessment framework.
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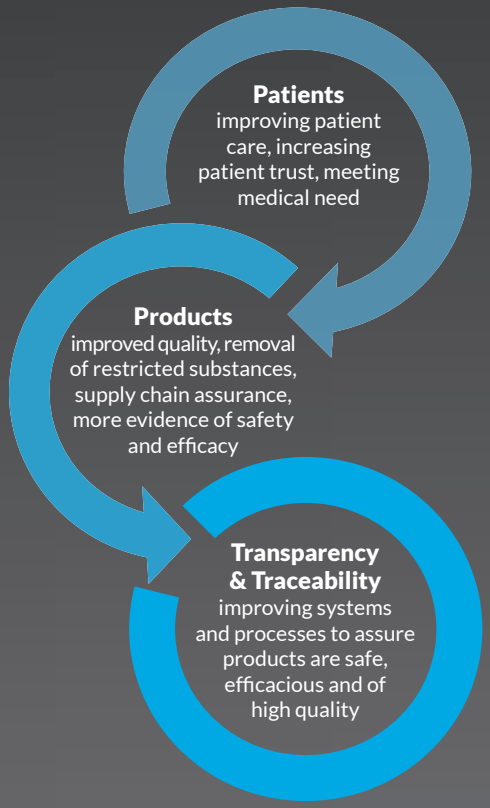

Likely EU MDR Change	Regulatory Implications	Business Implications	Functions Impacted
Patients			
EU will now require clinical investigation rather than equivalence for novel Class III and implantable devices New scientific review panel that will introduce independent level of scrutiny for novel* Class III implantables	No grandfathering of products leading to re-registrations: existing products may be in jeopardy Investigational Device Exemption (IDE) like studies	Increased time to market and costs to generate clinical data Strategy plan surrounding portfolio of products (in-flight, current, legacy)	R&D Clinical Medical
Products			
Class I/II: New CER requirement Class III: More frequent CER update Class IIb impantables Design Dossier Expanded requirements (patient implant cards, SSP-summary of safety and performance)	Dramatic increase in amount of content creation, review and approval	Increased requirement for lifecycle management Increased responsibility for accuracy and patient understanding of content	R&D Regulatory Clinical
Transparency & Traceability			
Increased collection of adverse event data safety surveillance and reporting by patients, HCPs Trend reporting to authorities, annual PSURs for devices, proactive Post Marketing Surveillance plans UDI, European Database (Eudamed)	Increased amount of collected data requiring analysis Increased frequency on requirement of Post Market Clinical Follow-up Studies (PMCF) Multiple requirements surrounding UDI, DOC, Implant Cards	Resources, Timing, and Cost will be affected due to a 50% reduction in time for responses Rigor will become similar in nature to Pharmaceutical standards Performance will be public	QA Medical safety Regulatory Supply chain

*novel designation excludes iteration of currently CE marked products

Why YourEncore?

1

Strategic Leadership

YourEncore has a world-class Strategic Advisory Board of industry leaders to provide oversight and counsel to clients and engagement teams.

2

Proprietary Frameworks

Don't know all the details about EU MDR changes? You don't need to. Our proprietary tools provide the approach needed to deliver a comprehensive expert analysis, and get started quickly.

3

Experience & Technical Know-How

The EU MDR team has already completed multiple EU MDR assessments using teams of highly experienced regulatory professionals. With YourEncore, you get best practices and proven expertise.

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