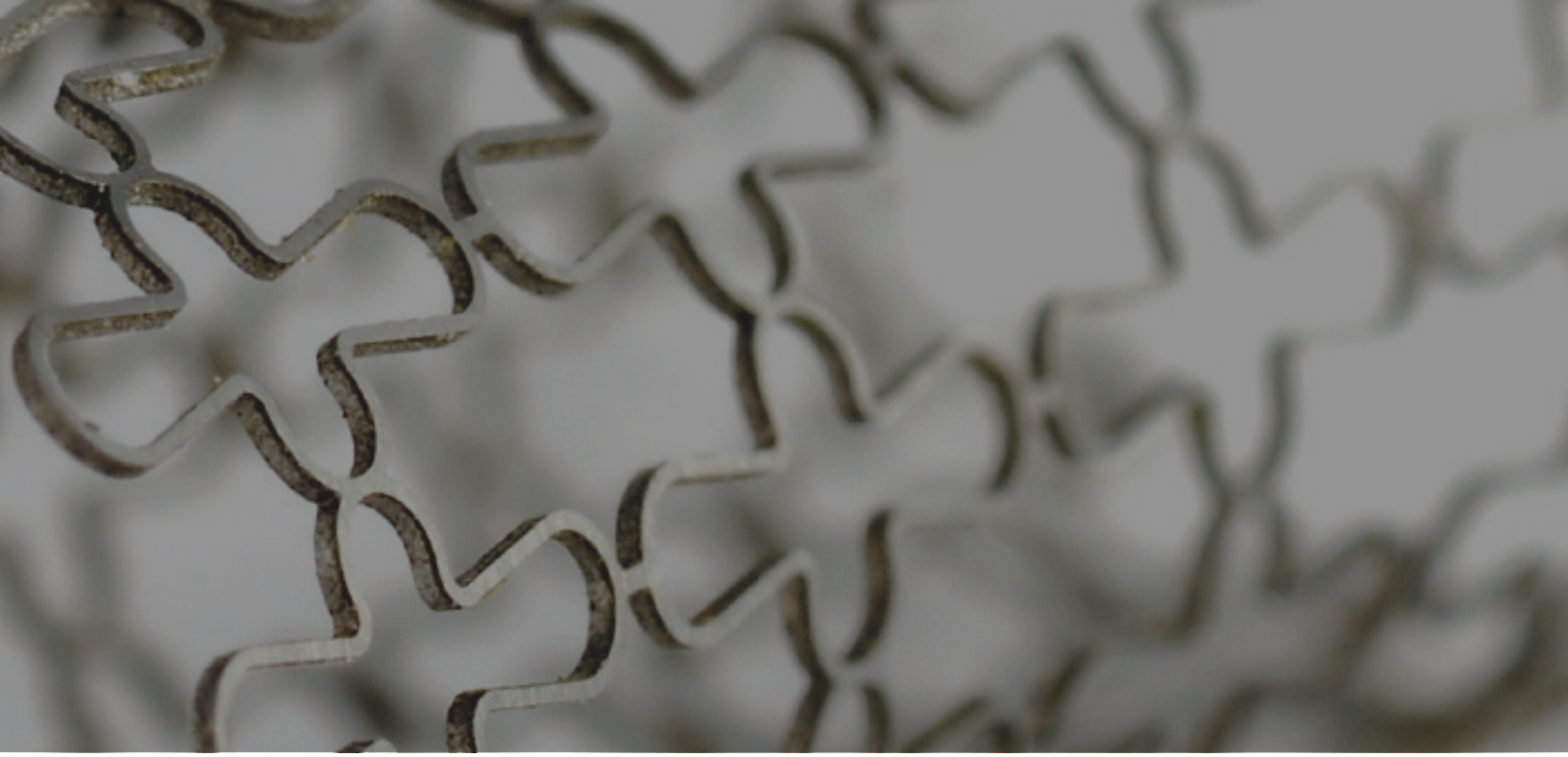

Executive Briefing: EU Medical Device Regulation

5 Ways EU MDR Will Impact Your Business

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EU Medical Device Regulation Overview:
The European Union has agreed on a new Medical Device Regulation meant to improve patient safety and data transparency. The regulation is extensive and impactful – it touches many functions within the company and companies that fail to comply will not be allowed to sell products into the EU. With the legislation expected to publish in 2017, companies will have three years to bring medical devices into compliance and, under a separate new regulation for IVD's, five years for these products..

5 Ways EU MDR Will Impact Your Business

With the EU finally reaching agreement on its new Medical Device Regulation (MDR), the compliance clock is ticking. Although many functions are impacted, regulatory leaders will most likely be responsible for driving corporate compliance. If you're just starting the process, here are five ways MDR will impact your business.

1. Impact on Device Approvals in the EU

- **Increase in Data Requirements**

Herein lies one of the greatest impacts of the Regulation: the need for product specific clinical data, depending on the Risk Classification of the device. Clinical evaluations under the current Directives allowed for comparison to prior devices, or equivalence to be the basis for safety and performance. Under the new Regulation, this will no longer be the case, and clinical data specific to the device will be needed, particularly for Class III and Class IIb implantable devices. Clearly this changes the time to approval, as well as the cost, requiring a full re-determination of the timelines and budgets within your pipeline.

Another consideration is the decision to launch a new device first in Europe. With the increase in clinical data requirements and increase in time for review of a dossier, this may no longer be the most optimal scenario in the launch plan. There is, of course, global launch implications as well, as countries which depend on the CE Mark and associated documents will be delayed in their registration efforts.

- **Increased Time to Approval**

Depending on the Risk Classification of your device and the necessary Clinical data, reports for this will be submitted to third parties outside of the Notified Body under the "scrutiny" process. The resultant discussions will occur between these parties and your Notified Body, not directly with the manufacturer. Although timelines are defined within the Regulations, experience will tell how long these reviews will actually take and what a new estimate for approval should be for launch planning purpose.

- **Increased depth of review**

You can count on a more in depth review by your Notified Body, based on the expanded requirements for what a dossier or Technical File must contain, as well as their assessment criteria within the various Annexes specific to the Notified Bodies. As noted above, the process termed "scrutiny" will certainly be a much more extensive review of clinical data and reports.

2. Cost of Compliance

It is likely that manufacturers have underestimated costs to achieve compliance. Understanding the existing gaps within your portfolios is an important first step before estimates surrounding the work to bring them into compliance can be made. Some considerations include:

• Will your current Notified Body be re-certified? The requirements on Notified Bodies are also greatly increased, as well as the level of continual scrutiny they will receive. It is estimated that many of the smaller Notified Bodies will not survive the changes. You should be in discussion with your Notified Body(s) to have a sense of their continued availability, as well as their capability in working with you to achieve compliance. While not desired, you may need to consider changing Notified Bodies.

• There is very limited opportunity for "grandfathering" under the Regulation. While it may be applicable to some products, these will still need considerable evidence to support their compliance without new data. Developing a strategy and rationale for these to present to your Notified Body is key.

• It is likely that some products may not be available on the market while sufficient clinical evidence is gathered to achieve compliance. While internal resources are applied to this, a business may find the need to bring in external resources to complete the work of rebuilding Technical Files, following Annex I and Annex II, and gathering the associated underlying data and reports to complete these efforts. A full assessment of your Technical Files is a key first step to predicting these costs.

• All Clinical Evaluation Reports will likely need to be revised to comply with the new requirements, particularly under Annex XIII. An assessment of these must be done to determine if new clinical data will be needed to provide sufficient evidence of safety and performance. Clearly, if new clinical data is needed, costs are significant.

3. Overall Time to Comply

Once the Regulation publishes in the European Journal, which is expected to occur within Q4 of 2016, manufacturers will have a three year transition period to bring their products procedures, processes and files into compliance. However, Notified Bodies must also be re-certified, which has been estimated to take 6 months. Until they are re-certified, they cannot take any official action on assessments or dossier reviews under the Regulation. Effectively time is reduced to 2.5 years, assuming your current Notified Body receives their certification in that 6 months.

About the Author
Patrice Napoda is a former Director of International Regulatory Affairs for Johnson & Johnson's Ethicon franchise, current YourEncore expert, and frequent speaker on EU MDR readiness. For the past two years, Patrice has helped Fortune 500 medical device companies assess their compliance risk and prepare for the final EU Medical Device Regulation.

4. Cross Organizational Impact

Although your organization may view this as a Regulatory action, in truth, it has a very high degree of cross functional impact and will require a team across the organization to fully implement the changes. A few examples follow:

• If part of your portfolio includes devices which are implants, how will the newly required Patient Implant Information (now required to be a card) be implemented?

• There are extensive changes in label requirements, either increased specificity of information or new information, such as the European UDI. How are these going to be rolled into your graphics, implemented within operations and managed across the globe?

• If your device contains restricted substances, how will these be addressed and mitigated? If a potential replacement must be done, this will require some degree of re-design, necessitating a full project team and new preclinical and possibly clinical testing

• There are multiple impacts to your Quality Management System, likely driving the need for new procedures as well as changes to existing procedures. How will these be managed and implemented?

• The new Annex I and Annex II greatly expands requirements for Technical Files, either with increased specificity or new elements to be included. A review of these may trigger the need for new or expanded pre-clinical testing. How will this be managed?

• The Eudamed database will be more specifically established, requiring significant data feeds from both the manufacturer and the Notified Body. This will contain publicly available information on clinical safety and performance, thereby achieving one of the goals of increased transparency, as well as post-market performance data. Support from your IT functions as well as Supply Chain and Quality will be required in order to comply.

• The new regulation establishes much greater focus on Post-Market Surveillance (PMS) as an integral part of the Total Product Lifecycle Management. A PMS plan is required for each device, to be included as a component of the Technical File. In fact, the newly created Annex IIa lays out the details of the PMS program which must be contained within the Technical File and continually updated. Each device must either have a post-market clinical follow-up (PMCF) study implemented, with data feeding into the overall surveillance, or a justification for not having a related PMCF. The impact on the function managing your current PMS work is significant.

• The newly required Person Responsible for Regulatory Compliance will need to be defined, which does not necessarily require a new headcount, but the responsibilities for this role need to be assigned within the organization.

5. Potential Portfolio Impact

As the full impact of changes required to bring a product into compliance is understood, it may exceed the value of the product itself. This presents an opportunity for portfolio rationalization, possibly divestiture, or expediting the next generation of this product within your development pipeline. The reverse situation may also present itself if other companies decide to divest, there may be acquisitions or mergers to be identified. Within the due diligence process for these candidates an extensive review of their compliance to the EU MDR should be done to fully evaluate any investment required on the part of the purchaser.

Summary

Achieving compliance to this new Regulation is a daunting task. For those of you who have worked for a while in the Regulatory function, it has been described as a once in a career opportunity. In order to mobilize the organization, discussions with your executive management must look beyond compliance and tie the results to the overall leadership agenda, presenting most and least optimal cases. Do not wait, the time is upon you now. We here at Your Encore are ready to help in a variety of ways, please reach out to us as needed.

The Fast Track to EU MDR Readiness:
YourEncore and EY have collaborated to develop a suite of tools and teams to help companies rapidly achieve EU MDR compliance. Whether you need help to understand the final regulations, assess your risk, or implement your compliance plan, YourEncore can help.

To learn more, contact Mary Ellen Schipp (maryellen.schipp@yourencore.com).