

A close-up photograph of a moth hanging from its pupa. The moth's wings are white with prominent black stripes and a bright yellow patch on the forewing. The pupa is translucent and hangs from a piece of brown bark. The background is a soft, out-of-focus green.

How the new EU Medical Device Regulation will disrupt and transform the industry





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How the new EU Medical Device Regulation will disrupt and transform the industry



Sweeping reform of the rules that govern the medical device sector in Europe represents one of the most disruptive changes to affect the industry in recent times. When the European Medical Device Regulation (EU MDR) replaces the current set of directives, companies will have three years to comply with a broad swathe of new rules for almost every kind of product in the medical device spectrum.

Under the new rules, medtech companies will have to:

- ▶ Provide substantially more clinical evidence to get products to market, or even to keep some products on the market
- ▶ Conduct deep portfolio audits to determine the new rules' impact on margins
- ▶ Relabel products and make data ready to be made publicly available

In total, they can expect a significantly more costly path to compliance in the world's second-biggest medtech market. The costs associated with compliance may force some companies to take drastic steps, such as offloading product lines or even putting themselves up for sale. The aftermath of the shake-up will be a stronger, more accountable medtech industry that may look substantially different from today's.

Many medtech companies have begun to look at how they should address compliance, and realized that the extent of the changes requires a company-wide approach. These companies have grasped that the EU MDR represents not just a compliance challenge, but an opportunity to add value to the business at the same time.

The events that triggered the need for regulatory reform

Medtech is one of the most trusted components of the health care ecosystem. A global poll of patient groups by PatientView, a consultancy, found that device companies had a better reputation than all other health sectors – even retail pharmacists – with biotech and pharma companies some way behind. Medtech companies are largely seen as providing useful, quality, innovative products. But the sector's reputation was tarnished by a series of recent events, prompting an urgent need for regulatory reform.

August 2010:

DePuy announced a voluntary recall of its ASR metal-on-metal hip replacement system after a study showed that the five-year failure rate for the product was about 13%.

July 2011:

The U.S. Food and Drug Administration (FDA) warned of serious complications associated with surgical mesh for transvaginal repair after nearly 4,000 adverse events.

June 2012:

Poly Implant Prothèse (PIP), a French company, was revealed to have knowingly sold breast implants made with industrial-grade silicone, rather than medical-grade. About 300,000 women were affected.

July 2012:

Whistleblowers claimed that the FDA had approved medical devices that posed severe health risks.

Changes to the existing rules, which date back to the 1990s and have barely been updated since, are long overdue. Incremental changes began to be discussed by European policymakers as far back as 2008. But it was a series of events from 2010 (see box) that emphasized, to both policymakers and the industry, the need for regulatory reform to confirm that patient safety concerns were adequately addressed. In 2014, "regulation" began to be used to refer to the updated medical device legislation, rather than the softer "directive" – this served as a wake-up call for the sector. By mid-2015, the broad details of the new legislation were being widely discussed, and the current and near final iteration of the text has been determined and agreed by the so-called "trilogue" of the EU Commission, Parliament and Council.

That long run-up to legislative change offered ample time for medtech companies to begin to explore the right path to compliance. But how far have they gone down that path? Auditoriums at recent medtech conferences in the US and Europe where the EU MDR has been discussed have been packed, suggesting that for many companies the real compliance work has not begun. Yet the implications of the EU MDR for the sector, globally, are big – the European medical technology market is significant and important for the industry, at around 31%, and is estimated to be about €100 billion (US\$108 billion), according to the World Health Organization's Eurostat database and calculations by Eucomed, an industry association.

What is the holdup? The challenge for medtech companies here can perhaps be summed up as, "We don't know how the final text of the regulation will be interpreted, and we don't know when the players in the industry will be ready for its implementation – so what should we be preparing?"

For many companies, the real compliance work is yet to begin, but the implications for the sector, globally, are big.

What will the EU MDR look like?

Since the earliest days of reform discussions, policymakers have focussed on several weaknesses in the current directives:

- ▶ Existing rules have failed to keep pace with technical and scientific progress.
- ▶ Patients and care providers do not have access to sufficient evidence about devices' safety and clinical performance.
- ▶ It is not always possible to track devices back to their original suppliers.
- ▶ Different EU countries interpret and implement the directives in different ways.

With these issues in mind, medtech companies should have been able to predict that the new rules would clearly focus on patient safety, by stipulating greater transparency and traceability and better clinical evidence to support claims of a product's safety and efficacy.

Within medtech companies, these issues, unsurprisingly, land in the regulatory team's inbox. But as more detail emerged about the composition of the new EU MDR, it became apparent that the full impact of the changes would extend beyond regulatory. The proposed legislation will be broader in scope than the reforms first proposed in 2012, and includes the following proposals:

- ▶ A requirement for clinical trial data to be provided before a CE mark is granted for implantable and high-risk devices
- ▶ Pre-market and post-market approval processes for high-risk, implantable devices
- ▶ Data transparency – including publication of clinical trial data and safety summaries
- ▶ Defined content and structure for technical files to support registration
- ▶ Tightening of vigilance reporting timelines from the current 30 days to 15 days
- ▶ A unique device identification (UDI) system, possibly similar to that implemented in the US
- ▶ The establishment of the Eudamed medical device database, through which regulators, providers and the public can access technical data, clinical trial results and adverse event reports
- ▶ Expanded "directions for use" content associated with products
- ▶ A possible ban on some restricted substances in the manufacture of products, and a requirement to track certain chemicals and restricted substances throughout the supply chain
- ▶ More power to notified bodies, including the establishment of "super" notified bodies which will be responsible for high-risk, implantable devices
- ▶ A requirement that companies retain at least one person responsible for regulatory compliance





- ▶ Economic operators in the medtech supply chain will need to comply with new reprocessing, up-classification, post-market surveillance and reporting rules

These are transformational shifts for medtech companies, from several points of view: accessing the EU market, complying with regulations, restructuring operations and planning future business.

Bear in mind that for at least a decade, Europe was the first port of call for most medtech products entering the market: after obtaining a CE mark in Europe, suppliers could test their products there *in vivo*, building the dossier of clinical evidence they would need in order to secure FDA approval down the track.

As and when the new legislation is passed, that familiar path to market will almost certainly need to be reviewed. It seems

highly likely that, at least while companies are in the process of becoming compliant, Europe may look like a less attractive “first market” destination. Market authorization timelines will become protracted, curtailing patients’ access to technology innovations. And the costs of operating in Europe will increase, too. From a regulatory point of view, one bonus of the EU MDR is that it will iron out inconsistent determinations over devices by individual Member States. Likewise, plans to introduce a centralized “expert-led” scrutiny process will also be a significant change – possibly a positive one, assuming it does not lead to bottlenecks.

Meanwhile, a shake-up of the notified body network will lead to consolidation and the rise of “super” notified bodies with broader capacity and deeper expertise. This will lead to more competition between notified bodies for companies’ business – some will flounder under the volume of products to review, while others will restructure for success and gain more market share. It will be important for medtech companies to pay attention to the health and capacity of their notified bodies to prevent bottlenecks in getting products to market.

From an operational point of view, companies are anticipating a significantly more costly path to compliance. While the final requirements still have a number of uncertainties, there is no doubt that the EU MDR will mandate significantly more clinical evidence from manufacturers of higher risk products if they are to be allowed on the market, including, to some extent, products already on the market. Market access will require companies to conduct deep portfolio audits to determine impact on margins, assess UDI readiness, relabel products and make data ready to be made publicly available. It all adds up to a complex change program – a paradigm shift, even, after which nothing will look quite the same. Meanwhile, companies must maintain business as usual and ready themselves for a “new normal” to sustain compliance: “like trying to change a car’s tires while it is being driven on the highway,” as Erik Vollebregt of Axon Lawyers in Amsterdam told *Regulatory Focus* in 2015. There is a scale issue here, too – smaller firms will find it more difficult than larger ones to manage all these issues at once. Some will simply not be able to afford the cost of remediation, particularly when it comes to generating clinical evidence, and may therefore look to exit the market or put themselves up for sale. One effect of the EU MDR may be an M&A spree for larger firms looking to augment their portfolios or expand into new areas.

What does compliance cost?

It is difficult to estimate, in an industry as diverse as medtech, what will be the total cost of compliance with the EU MDR. For some companies, only a small part of their portfolios will be affected by the changes; but for others, the compliance process may be applicable to nearly all product lines. One rough estimate is that the total cost of compliance, industry-wide, will be between 3.5% and 5% of revenues.

In 2013, the industry group Eucomed surveyed its members to assess the financial impact of the EU MDR, as it was then proposed, over a five-year period. Based on that survey, the estimated costs to the industry were calculated as follows:

€7.5b

(US\$8.1 billion): cost to industry of compliance with a UDI system, improvements in labelling and clinical performance data

€17.5b

(US\$18.9 billion): cost to industry if a centralized pre-market authorization system is implemented

€17.5m

(US\$18.9 million): cost to a small-to-medium-sized enterprise (SME) to bring a new Class III product to market under a pre-market authorization system

But despite these costs, respondents generally agreed that the proposed UDI, labelling, clinical performance data and administrative changes would be welcome improvements to the existing legislation.

Compliance with legislation is generally viewed as a driver of complexity and costs for businesses, whose regulatory teams are tasked with ensuring that their companies are compliant with legislation and minimizing the risks associated with it. But it is apparent that tackling the list above goes beyond the remit of even the most dedicated regulatory team. Providing data on product lines may require conducting new clinical trials. Some implantable products may need to have their safety and efficacy validated clinically, or be at risk of being removed from the market, although the “proven technologies” principle – otherwise known as “grandfathering” – is one of the key points of the EU MDR determined by the trilogue (If grandfathering is accepted, it will certainly come with the requirement that each case is backed by some kind of supporting evidence). Nonetheless, the EU MDR’s three-year compliance period should be enough time for companies to back up the claims they make for products. The legislation is expected to be less stringent for less complex products, such as sutures.

However, the additional clinical evidence requirements likely to be stipulated by the EU MDR will mean that products in development may take longer to get to market – which is likely to have a significant impact on revenues and the raising and allocation of capital. Suppliers, too, will need to be audited to make sure they are also compliant. Companies will need to refer to their bills of material and track down the whole chain of each product’s component to the suppliers of that component, and even possibly to those suppliers’ suppliers. Some suppliers to medtech companies have already realized that compliance with the EU MDR will differentiate them from competitors, and are acting accordingly. If some products require new materials in order to comply, production processes may need to be redesigned.

Additionally, relationships with notified bodies may need to be reset. Under the EU MDR proposals, consultation with notified bodies will continue to increase and requirements on the notified bodies will intensify. Many in the industry fear bottlenecks will occur at the certification stage. As one leading external affairs and regulatory policy executive advised to delegates at the 2015 MedTech Europe conference, companies should be looking to conduct an audit of their notified bodies to develop a relatively seamless path to market.

A whole-of-business approach

Even with a three-year window, regulatory teams will not be able to complete all this work in isolation. It is evident that compliance with the EU MDR requires an approach that takes in all aspects of the business. For the regulatory teams into whose laps this has fallen, this represents a separate challenge: how to engage senior leadership to understand the importance of the task ahead and commit resources to tackle it.

“Regulatory teams know what’s coming, and how much of the portfolio will be impacted,” says EY Advisory Partner Lucien de Busscher. “What we are asked by regulatory people is advice on how to bridge the gap to the C-suite. The first questions the C-suite asks about the EU MDR are, ‘Will it go away?’ and ‘If it won’t, what is the impact if we’re not compliant?’ The third question is, ‘What will it cost us?’ And the fourth question is, ‘Where does it hit our portfolio hardest?’”

Regulatory teams that successfully convinced the C-suite of the need for firmwide action on the EU MDR have learned that the

crucial element in the conversation is to look beyond compliance and link it to their firm’s leadership agenda: emphasize the EU MDR’s impact on top-line revenue and profitability, M&A opportunities, or operations, and present best-case and worst-case scenarios. The questions on EU MDR to which medtech CEOs and CFOs will most want answers are:

- ▶ What percentage of our revenue is at risk?
- ▶ What is the total cost of compliance? (And what is the cost of compliance by product line, function and interdependence, e.g., supply chain?)
- ▶ Will we have to rationalize our product lines?
- ▶ Have we conducted due diligence around EU MDR preparedness with our partners, alliances, notified bodies and M&A prospects?

Adopting the new regulations will impact different parts of the business in different ways along three distinct phases of the process:

	Pre-final text	Final text (day zero)	Transition (3-5 years)
Leadership	<ul style="list-style-type: none"> ▶ C-suite understands transformational impact and prioritizes as strategic objective 	<ul style="list-style-type: none"> ▶ Business response defined and leadership supports transition 	<ul style="list-style-type: none"> ▶ Strategic issue escalation ▶ Business continuity
Business	<ul style="list-style-type: none"> ▶ EU MDR is on all business units’ agenda ▶ Gap assessment completed (MDD vs. EU MDR) 	<ul style="list-style-type: none"> ▶ Enabler projects to support journey to compliance 	<ul style="list-style-type: none"> ▶ Implementation execution ▶ Cross-functional complexity management
Financial	<ul style="list-style-type: none"> ▶ Revenue impact and costs identified ▶ Year one transition budget finalized 	<ul style="list-style-type: none"> ▶ Allocation of year one budget ▶ Resource allocation to support transition 	<ul style="list-style-type: none"> ▶ Budget management ▶ Financial reporting
Governance	<ul style="list-style-type: none"> ▶ Enterprise-wide steering committee ▶ Regulatory leads and has planning remit ▶ Communications strategy agreed 	<ul style="list-style-type: none"> ▶ Remit for validated implementation plan 	<ul style="list-style-type: none"> ▶ Implementation management

One of the first tasks for the team leading a firm's EU MDR readiness program, even before all the differences between the existing directives and the new legislation are understood, will be to design and perform a gap analysis. This itself could prove to be a complicated and time-consuming process and needs to encompass business functions right across the enterprise, as in the example below.

Business structure	How many of our business units/ franchises/product families will need to be assessed?
Technical files	How complex is the technical file structure? How many design centers do we use, and do they use a consistent format internally?
Notified bodies	How many notified bodies certify our products?
Process and data systems	Are the IT systems, data repositories and processes consistent between franchises?
Manufacturing and distribution network	How is our supply network (authorized representatives, distributors, importers) structured?
Restricted substances	Are our technical files structured by product family? If so, do they share components and materials?
Clinical trials	How many Class III and implantables do we have in our portfolio? For how many of our products – on the market and in development – will we need to generate evidence?
QMS	How many quality management systems do we have in operation?

It is the companies with Class III and implantable products in their portfolios which have the biggest compliance task ahead. The EU MDR's central tenet – that clinical information on these products is provided and made publicly available – will add cost and complexity to the European registration process. This will clearly be a challenge for companies that are not used to doing clinical trials – they will have to establish not just an in-house clinical organization, but a complete clinical network.



The US UDI precedent

One lesson for companies seeking to become compliant with the EU MDR may be in the way companies responded to the introduction of unique device identifier (UDI) legislation in the US. Minnie Baylor-Henry, Medical Devices Practice Lead at YourEncore and former Worldwide VP of Regulatory Affairs for Medical Devices at Johnson & Johnson (as well as a former FDA official), recalls that the UDI legislation, like EU MDR, was also debated for many years before coming into effect in 2014. "Medtech management teams grew skeptical that it would be enacted," Ms Baylor-Henry says. "When the UDI was finally implemented, teams may not have appropriately budgeted to ensure compliance. However, as will be the case with EU MDR, teams of diverse stakeholders – encompassing, for example, regulatory, supply chain, quality, IT and safety divisions – were formed to oversee compliance. This was long discussed, but many companies grew weary of the anticipation."

Beyond compliance

It is fair to say that few companies are now unaware that regulatory change is imminent. If any companies can be described as laggards in addressing the compliance process, it is largely because they are small companies, operating in only a few markets, with a handful of products and with limited resources to start the process. They will wait until the final draft is complete before assessing the implications of EU MDR for their companies.

Many medtech companies – particularly those with broad product portfolios and revenues over US\$5 billion – have at least already begun to look at how they should address EU MDR compliance. In those companies, a common thread is an awareness at the senior leadership level that an extensive strategy will need to be implemented to assess portfolios and create an organizational structure that can deal with the changes.

That kind of focus has given the early adopters a unique perspective. Understanding that the impact of EU MDR on their operations and bottom line will be substantial, they regard the process not as simply a compliance exercise, but an opportunity to add value to the business at the same time. They have already begun to analyze gaps in their business models, in terms of regulatory risk hotspots and parts of their portfolio where regulatory compliance will eat into margins. And they have started to build implementation road maps that they will execute before the legislation comes into effect, including creating cross-functional teams.

Where companies seek to leverage the opportunities inherent in compliance with new legislation, the outcomes for the business can be fruitful.

Preparing for MDR: opportunities for manufacturers

Brand enhancement.

Compliance with the EU MDR, with its focus on public safety, will enhance companies' standing as trusted partners in health care.

Competitive positioning.

It is likely that different companies will adopt different strategies in response to the new legislation, based on their capacity to undertake the potentially extensive changes. This may present market expansion opportunities and/or acquisition targets for the business.

Portfolio rationalization.

While portfolio audits are part of life at medtech companies – in principle, at least – compliance with EU MDR will require a deeper dive. The opportunity to critically examine the product portfolio to assess the EU MDR's impact on margins, or the need for product redesign, new manufacturing processes or new supplier agreements, offers opportunities for portfolio optimization and/or divestments and acquisitions.

Market opportunities.

In response to the points above, commercial teams are likely to find revenue potential and the opportunity to revise marketing and sales.

A safer world

Compliance with new regulations may seem onerous, costly and distracting. But as they go into the process, companies ought to remind themselves of the ultimate goal. Will the new EU MDR make the world a safer place for the end users of medtech products? That, after all, is the driving force behind the reforms. John Brennan, Eucomed's Director of Regulations and Industrial Policy, thinks so. "We, the medtech industry, welcomed these changes [to the legislation]," he says. "The industry was facing a trust issue. Questions were being asked of the regulatory system, and if the system cannot answer those questions, then that reflects badly – not only on the system, but on the reputation of the industry."

Investment in transparent clinical processes, traceability and the ability to prevent or at least cushion the effects of adverse events involving medtech can only boost the industry's standing among those who most value it. Of course, someone will ultimately need to shoulder the operating and compliance costs initially borne by medtech companies as they ready themselves for the impact of the EU MDR. These costs will not be borne by regulators or policymakers. The industry will need to demonstrate its commitment to the end users by absorbing much of the cost of compliance over the next several years. But it also needs to understand that compliance brings benefits beyond improving its public image. For example, some companies have, for many years, been able to bring products to market without having to provide much in the way of clinical data to prove their efficacy and safety; the new legislation levels the playing field.



And intensive scrutiny of their business practices and processes can leave companies considerably better equipped for the future. "Transformation can be a fantastic opportunity to break down silos within companies and between products and processes, and to better take advantage of interesting acquisitions on the horizon," says EY's Lucien de Busscher. "It's an ideal opportunity for diversified companies to build a baseline across divisions."

The merits of the EU MDR will be debated for some time. One question will be whether the authors of the legislation intend that it will be in place for as long as the current directives. But in view of the rapid rate of change within the medtech sector, the EU MDR in its draft form does not appear to contain enough flexibility to account for some current trends, such as devices custom-made for individual patients via 3D printing, apps

associated with products, or patients "health hacking" their own devices. A 2015 report published by BSI, a UK-based notified body, argues that the proposed EU MDR focuses too much on regulation of "traditional" medtech, and "software-related issues such as compatibility, interfacing standards and security are not addressed in any detail."

But all that aside, from the day the EU MDR passes into law, companies will have three years to thoroughly understand the legislation and its impact on their portfolios, to comply with the law and to position themselves to take best advantage of a new era in medtech regulation.



Planning for an ideal scenario



Minnie Baylor-Henry

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Former Worldwide VP, Regulatory Affairs (Medical Devices),
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The new EU MDR promises to disrupt medtech in several ways. For years, launching new devices in Europe was believed to be the most efficient strategy for entering the marketplace. Given the uncertainties around the new legislation, it's not clear whether that will still be the case under the updated EU MDR. This is an important consideration, because as a company enters its strategic planning process, there will be greater uncertainty about whether its product will be registered in certain markets and by what date. While there has always been a certain amount of ambiguity in this process, the impending European regulation makes it even more difficult. Added to the complexity is the fact that smaller markets around the world often look to the US or Europe as a reliable benchmark for product entry into other markets. The uncertainty in Europe around the EU MDR may result in many unanticipated consequences, including delayed launches in other parts of the world.

Many companies may see this as an opportunity for portfolio rationalization. This idea flows naturally from the perception that one burdensome element of the new regulations will likely be an increased need for clinical data. Therefore, as companies examine their product lines, they will identify products that may require a considerable investment in new clinical data if they



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are to be compliant with the EU MDR. The outcome, in many cases, may be to divest the asset, particularly if the products are associated with smaller margins or don't have much future growth potential. Despite the clinical requirements not being clear, portfolio review is a prudent approach for companies to take in order to position themselves effectively and efficiently react to regulations when their final form is determined. At the end of the day, consumers, patients and physicians all want devices that are safe, reliable and effective, and that improve outcomes and get reimbursed.

In an ideal scenario, the enactment of the EU MDR could have numerous positive results. For instance, the public is consumed with stories about substandard devices, such as the PIP breast implant scandal, which have led to skepticism about the quality of medtech products. If the new regulation restores consumer and health care professional confidence in the quality of our products, it will be a good thing.

So why the concern? One challenge in tackling the changes required for compliance with the EU MDR is that companies have been hearing about the new regulations for so long that preparing for the new requirements may be viewed as a low priority. Back in 2012, when organizations first heard that the European Medical Devices Directive would undergo a huge shift, there was a great deal of anxiety about what this would entail. However, when the directive was reframed as a regulation in 2013, it signaled that the initiative may be an even bigger regulatory shift than many originally thought. Perhaps that should have sparked a sense of urgency within companies. But, with the implementation many years in the future, other issues took precedence, including UDI implementation in the US, the International Medical Device Regulators Forum, medical device provisions in China and many others. As companies began

to experience fatigue about where the impending European legislation would fit within the panoply of new requirements, it has been challenging for regulatory affairs, quality and commercial teams to motivate senior leaders in disparate parts of the medtech organization to stay focused on the enormity of this issue. This challenge is even greater when the potential ramifications of the regulation are still largely unknown.

Some may argue that large companies will have the resources to make sure they are in compliance with the new regulations. In some instances, they are building special teams capable of predicting the final regulations and are beginning to adapt their business processes to reflect these forecasts. For smaller companies with fewer resources, the EU MDR becomes more burdensome. Smaller companies might choose to wait and focus instead on getting products to the market – although the uncertainty could mean that looking to Europe as the first market for launch may not be feasible.

With so much uncertainty in the marketplace, medtechs can best prepare for the coming changes by performing a gap analysis that benchmarks a company's current capabilities against what is known will be included in the coming legislation, in hopes of identifying any deficiencies – such as insufficient clinical data associated with higher-risk products. Performing a gap analysis takes time and is not something companies should hold off doing. It is prudent to understand what the baseline looks like today in order to begin to plan the resources and tasks necessary for compliance in the future.

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A fundamental impact on innovation



John Brennan

Director, Regulations and Industrial Policy, Eucomed

We live in a Europe that cherishes health and wants to invest in health, which makes it a good place for being in the medtech business and a good place to innovate.

From a reputational point of view, the new European Medical Device Regulation is an important step. It will lead to an EU registration database and transparency about issues associated with products. It will lead to clarity about what is needed in terms of clinical development. It will lead to clarity on adverse events – when they occur and how they are controlled, tracked and investigated. It will lead to unique device identification, which will aid track-and-trace for health systems. And, importantly, it will lead to transparency of notified bodies – who they are, what competencies they have and how they do their checks. The legislation gives authorities more power to make sure that the system is working as it should. The current legislation says that all information that flows between the notified bodies and the manufacturer and the authorities is confidential. That was normal in the 1990s, but a lot of that information would never be considered confidential today.

We, the medtech industry, welcomed these changes. The legislation needed to be refreshed and updated. The legislation was also facing a trust issue, particularly after the PIP breast implant scandal. Questions were being asked of the regulatory system, and if the system cannot answer those questions, then that reflects badly – not only on the system, but on the reputation of the industry.



While there are many positives, industry strongly maintains that the draft texts published so far still require improvement to fulfill the global objective of a new Regulation designed to offer a high level of protection to patients while fostering innovation in the EU. For example, industry is strongly against the foreseen so-called “scrutiny mechanism” – a duplicative look by a panel of experts on the clinical review by the notified body – as it is redundant with other improvements and only serves to delay access to needed innovation for patients.

Likewise, the texts defining what constitutes clinical data and how data from clinically equivalent devices can be used are unscientific and risk making innovation in Europe less attractive – especially at a time when the US FDA is actively making its system more ‘European-like’ and innovation friendly with a stated vision of patients in the US having “access to high-quality, safe and effective medical devices of public health importance first in the world.”

There will be big impacts at both ends of the medtech spectrum. Small, entrepreneurial businesses, particularly those making an implantable or Class III product, are going to have to make sure that they get their clinical pathways correct, and hopefully in



the future be able to avail themselves of early scientific advice in terms of getting their clinical risk management plan right and thereby securing the right investment to get their product to market. And larger companies will have to re-examine their portfolios, look at their clinical evaluation files and assess whether they need to be reshaped or reviewed to make sure they meet the new requirements for clinical evaluation files in the new regulations.

It's clear that there will be a fundamental impact on the innovation pipeline. The work required to get a CE mark will change: companies will need to put heavier emphasis on solid clinical dossiers for Class III and implantable products. It will require extra time and investment to put those dossiers together to make sure products meet the new requirements – and the same will be true for iterations of existing products. Notified bodies will be more competent, so there will be pressure on companies to invest more time and effort to make their dossiers user-friendly and approachable for reviewers – intuitively simple and easy to follow and verify under the new, more intense review they're going to get. The assessment process itself is, in all likelihood, going to take longer – not as long as in the

US, but certainly longer than it is today. Businesses will need to factor the additional time into all their future developments and planning decisions. We understand, for example, that the scrutiny mechanism could add up to 60 days. The biggest concern about that is that patients will have to wait longer for access to products.

What we have heard from the big consultancies is that the best-in-class companies are getting ready for the impact of the changes, many are sitting on the fence and wondering when to start getting ready, and some are in denial, thinking it will go away. The level of readiness can't be linked with a company's size or geographic location; it's more that businesses which have decided to be close to the discussion are further ahead than businesses which have not. Those which have not may be surprised and find themselves behind their competitors by not having adequately provisioned resources to deal with some aspects of the final regulation.

The review process has taken so long that it has been difficult for many companies to maintain their focus. It is highly relevant to their business, but it has gone on far beyond the horizon for many C-suites. Businesses want clarity and predictability. And the continuous prolongation of the end date for the European legislative process coupled with the secrecy of the process is more than frustrating to companies that want to get on with the job of helping patients and doctors have better outcomes.

There is also the secondary legislation that will follow from the primary regulation – which will also trigger changes to harmonized standards and EU guidelines. This will involve consultation with stakeholders including Eucomed and is a large “second phase” of work. At Eucomed, we intend to help the industry by developing a solid training package offering best practice guidelines on the new regulation – which can be implemented by SMEs as well as global players – to bring together industry's views for input into the EU legislation's second phase.

I am hopeful that in considering the legislation, the policymakers have also considered its impact on growth, jobs and investment in the medtech sector. We need to get the safety and patient safety aspects of the regulation correct. You can do that with a system that's inefficient, bureaucratic and unattractive to investors – which is a negative for advancement in patient outcomes. Or you can do it with a system which is less bureaucratic, more transparent and more approachable for business – which is a positive for advancement in patient outcomes.

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How EY's Global Life Sciences Sector can help your business

Life sciences companies – from emerging start-ups to multinational enterprises – face new challenges in a rapidly changing health care ecosystem. Payers and regulators are increasing scrutiny and accelerating the transition to value and outcomes. Big data and patient-empowering technologies are driving new approaches and enabling transparency and consumerism. Players from other sectors are entering health care, making collaborations increasingly complex. These trends challenge every aspect of the life sciences business model, from R&D to marketing. Our Global Life Sciences Sector brings together a worldwide network – more than 7,000 sector-focused assurance, tax, transaction and advisory professionals – to anticipate trends, identify their implications and develop points of view on responding to critical issues. We can help you navigate your way forward and achieve success in the new ecosystem.

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