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# MDR And IVDR Fail Risk-Benefit Assessment, EU Reg Expert Says

by Amanda Maxwell

"I fail to see any merit in this piece of dismally bad legislation. It is absolutely in no one's interest," says consultant and regulatory expert Jaap Laufer, who predicts disastrous impact on many companies and the end of notified bodies as we know them.

The EU failed to do its homework properly and the result is two new Regulations, the Medical Devices and IVD Regulations (MDR and IVDR), that are going to cripple notified bodies and manufacturers. That is the personal view of consultant veteran medtech regulatory expert Dr. Jaap Laufer.

EU institutions are going to have difficulty defending the impact of these texts as patients see products disappear and prices rise, Laufer said in an interview with *Medtech Insight*.

Laufer stressed that these opinions are his own and do not necessarily reflect the opinion of consultancy Emergo, where he works as medical director. But they make for thought-provoking reading and are a reminder, as we approach the end of 2017, an eventful, but equally frustrating, year for EU medtech, of the broad context in which medtech stakeholders are currently struggling.

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**Q** ***Medtech* Insight: How much of an idea do we really have about the impact the new MDR and IVDR are going to have on the medtech industry and on other stakeholders?**

**A** Jaap Laufer: Unfortunately, the negative impacts of the new regulations far outweigh the benefits. The supposed benefits are a better level playing field for notified bodies - but that could have been easily achieved and, in fact, is being achieved, by multinational audit teams, or Joint Audit Teams (JATs).
The onerous incremental requirements for manufacturers, the ill-defined support structures, such as the nebulous MDCG [Medical Device Coordination Group], the accelerating demise of notified bodies with devastating impact on both established, well-functioning manufacturers and startups, and the stifling of innovation are amongst the deeply disturbing effects this poorly written and ill-considered regulation is starting already to have on the supply of medical devices. It is not inconceivable that a very substantial number of European manufacturers will disappear within 5-7 years.

The main reason why all of this is happening lies in the fact that the original "Impact Assessment" by the EU Commission was performed in 2012, well before the deeply impacting 800 Roth-Behrendt amendments. The European Parliament and the Council of Minsters never demanded a re-evaluation of the new draft regulation, and approved it without any understanding what the changes meant.

As a leading notified body speaker recently mentioned, the impact may be compared to a man falling from the 12$^{th}$ floor to his death, while shouting at every floor that he is still doing fine.

**Q** **Given the challenges presented by the regulations, where in your view, are the weakest links?**

**A** Laufer: Hard to know where to start! The short-term challenges we are seeing include the rapid disappearance of adequate notified body resources to deal simultaneously with the normal review and monitoring tasks, the acceptance of new products and

new manufacturers (delays are already occurring as we speak), and the transition to the new regulations. On top of that, it is doubtful that the Commission will be able to implement the necessary infrastructure, such as a properly functioning Eudamed, the Medical Device Coordination Group - and the appeal mechanisms corollary to it, many of the “Common Specifications” necessary for the review of innovative products and, last but not least, the educated and well-trained manpower to perform all these tasks.
Legacy products, those that have been on the market for decades without problems, will be the first to disappear as manufacturers cannot invest substantial amounts for these mostly very moderately priced devices. I can see essential surgeries and other interventions being cancelled because of this problem that the Council could resolve by simply issuing an emergency Regulation overriding the Medical Devices Regulation, for this explicit purpose. In addition, competent authorities should step in where notified bodies are overwhelmed to prevent irreparable damage to the device flow for patients.

Longer term we will see a lot of manufacturers going out of business, as well as additional notified bodies- the business will become unviable. It is hard to predict how many, but some experts say it may be up to 30% of manufacturers. Large manufacturers will survive, but hesitate to bring medium-risk products to Europe, when the hurdles have grown so unacceptably high.

This is in sharp contrast to the US, where the introduction by the FDA of the aspect of “medical need” (unmet or otherwise) is starting to affect a facilitation of new products, just as the pressures increase in Europe. Many well-established companies in Europe will disappear without a chance of ever coming back with their knowledge lost forever.

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*patients."*

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**Q Do you think that adequate transitional time has been given for the implementation of the new Regulations?**

**A** Laufer: No, I think the transitional time is insufficient, nor is has the time been adequately structured to optimize its use. I already mentioned Eudamed, the MDCG and the Technical Specifications, but there is also the need for the EU Commission to produce the 100 or so implementing acts in about three years, where their track record has been a paltry five since 2010. Not to mention many interpretative opinions, which cannot not be produced without the active input of the same industry that is now being under increasing duress.

Last, but not least, November 27 saw a gunshot application run by less than 30mostly Team NB members to get re-accredited and re-notified under the new MDR and IVDR. The applications will have to be processed, and then a schedule will have to be published for audits by the multinational Joint Audit Teams, the international accreditation groups who do the work on the ground. Not only are there preciously few auditors who can do this elevated scrutiny, but the track record of the JAT has been up to about 7 applications per year. This would mean many notified bodies would be accredited too late to achieve accreditation by the time the MDR and IVDR fully apply, and consequently a disastrous number of manufacturers will be “orphaned”, as they won't be able to be recertified within the transitional time.

**Q It is generally accepted that notified bodies are finding it very difficult to serve their customers on time with recertification and surveillance audits – can this be improved or is it likely to get worse? At what point, after it getting worse, might it then be likely to improve again?**

**A** Laufer: The problems for notified bodies are multiple and increasing by the month. I am afraid that we will soon see a crisis, where notified bodies will not only have to put a moratorium on new customers, but we are seeing already that some have to tell their existing ones that they will be unable to fulfill their duties on time. The results for small companies are catastrophic; and for established ones very damaging. One of the early signs of dysfunction of a notified body is its inability to conduct Unannounced Audits as currently demanded by the JAT.
I do not see any improvement under the current system any time in the foreseeable future, but rather a general demise of the system as we know it as more notified bodies depart or shrink their scopes. In my opinion, the notified body system for medical devices is bound to disappear under a successor piece of legislation that will establish an “EMDA”, a European Medical Devices Agency that will absorb the major notified bodies, as we know them, into national agencies that are subsidiaries to the EMDA.

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**Q** **What are the consequences of these notified body delays for manufacturers and the public?**

**A** Laufer: We will see a decrease of the number of devices and as a consequence, less choice for physicians to treat their patients as necessary. Some products, notably legacy products, will be killed by their manufacturers fairly soon; others will disappear suddenly, leaving no alternatives and creating a new “unmet medical need." Innovation will be stifled and may wither altogether. Finally, the enormous increase in regulatory burden for many products – although not for all - will conspire with the narrowing of choice to trigger steep price increases.

> In short, I fail to see any merit in this piece of dismally bad legislation. It is absolutely in no one's interest.

**Q** **What are your advising your clients in this situation?**

**A** Laufer: The advice we give to our clients depends entirely on their particular situation. We generally recommend that they be very diligent in monitoring the timeliness of the surveillance audits; whether the notified body is conducting an unannounced audit every cycle as they should; and what the lead times for new products or design change approvals is (where applicable, of course). Emergo has on its website numerous white papers and several blogs which may be of use to manufacturers.

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**Q** **Do you think anything could be one better to improve this situation?**

**A** Laufer: Absolutely! The best thing that could happen is a rescission of the regulation in its present form and a redraft, during which the good old Medical Devices Directive (MDD) and In Vitro Diagnostics Directive (IVDD) would stay active.
In parallel, the quality of notified bodies as well as the level playing field for them should be drastically enforced, especially with regard to the need for clinical evidence. The latter is still not the case and, in my opinion, will not be either under the MDR nor IVDR. This may be because the notified bodies are run by engineers, even though they increasingly employ a medical doctor and because the MDCG will not have the expertise to review dossiers in a scientific and timely fashion.

**Q** **When it comes to regulatory experts that are needed by all stakeholders – manufacturers, e.g., person responsible for regulatory compliance, notified**

**bodies, ARs, regulators, the Commission, expert panels etc. - it seems there are not enough. But where are the gaps most concerning and what do you advise your clients in this respect?**

**A** Laufer:: The glaring shortage of experts in almost all fields – from data handling to scientific reviewers in almost every field is evident. Here, we are all guilty of not heeding the warning signals that we could see coming. The answer is to establish in Europe a series of faculties in Regulatory and Clinical Affairs at universities. Unfortunately, that will take many years to accomplish, so we may have to import expertise from other countries like India in the meantime.
With regards to our clients, we would advise to critically assess whether the current clinical evidence for their products in the wider sense is adequate or needs improvement, and whether post-market systems are functional, or need to be increased in effectiveness. In the short term, we may offer our support which, by necessity, has to be tailored to their specific needs. One word of caution: It is better to be alert early on than wait until it may be very difficult, if not impossible, to remedy a situation.

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**Q** **MI: You have said that the crisis is accelerating and is becoming deleterious to smaller companies, to any innovative or novel product, especially in the lower-risk classes, to legacy products without sufficient clinical corroboration and companies becoming orphaned by notified bodies while their certificates are about to expire. But what will the overall likely impact of this situation be? How possible is it to find ways around these problems, and how likely is it that the worst-case scenario will come to bear and there will be some sort of crisis? If so, how will it manifest itself, do you think?**

**A** Laufer: I think most of the answers have been given already above. I strongly believe that we will see a "sudden" series of product unavailability around the year 2020. At the same time, notified bodies will start disappearing because some will no longer see their business model as viable. There will be companies lining up for CROs to help them generate data with studies, which they should have started years ago, and European companies and products will be forced to withdraw from the market. How the crisis will pan out and be resolved is anybody's guess; but it will be an unpleasant surprise to many patients and I do not see how the European Parliament, the Council and "Brussels" in general can explain this situation in a rationally satisfactory way.

**Q** **Finally, Brexit complicates everything. Given the total lack of certainty over the future for medical device regulations in the UK, and the future for UK notified bodies and authorized representatives, what are you currently advising your clients to do?**

**A** Laufer: Given the uncertainty of how soft or hard Brexit will be, I find it terribly risky to provide any advice to clients in this respect. We have seen that BSI has taken certain precautionary measures; that the EMA is moving to Amsterdam; but there are other institutions that have not moved or taken action at all. So the only recommendation is that British manufacturers should ensure they can access the EU market in an optimal way.

*From the editors of Clinica*