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UNLOCKING LEGALITIES: Challenges And Surprises In The EU Reg Reform

by Amanda Maxwell

The texts of the new EU Regulations have now been published in their likely final versions, save for the tweaking expected during the European Commission's legal review. *Clinica* asked Erik Vollebregt, partner at Axon Lawyers and a well-known expert in this field, what the most significant challenges will be now for the whole of the medtech sector, and where the biggest surprises lie

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Looking to the future now in the light of what we know about the new EU medtech regulations, the whole sector is going to have to gear itself for some big changes, Erik Vollebregt of Axon Lawyers told *Clinica*. Impressions may be preliminary as the lengthy texts have only been available just over a week, but it is clear that the sector will have to adjust to a mountain of new rules.

Under the reformed regulatory framework, notified bodies will need to reinvent themselves, member states competent authorities will have to become even more competent, and new committees in Brussels have to be staffed, he said. And the European Commission needs to start cranking out delegated and implementing acts to enable the regulations to function in the first place.

Manufacturers are going to have a particularly tough time ahead: not only will they have to start strategizing and implementing their transition plans to comply with the new Medical Device and

IVD Regulations, they will also have to work on the transition to the now revised General Data Protection Regulation (which has already entered into force), Vollebregt explained.

Companies will have to make sure that all of their devices currently on the market have been shepherded into the new system in time, and from the end of this year decide whether to go for the first certification of a new device under the current rules or certify under the new rules.

There's a great deal for manufacturers to do simultaneously. It is critical they do not underestimate what is ahead.

Clinica delved deeper into Vollebregt's views and reactions to the new regulatory landscape that lies ahead.

Clinica: So what, in your view, is the most challenging aspect related to the new Regulations?

Erik Vollebregt: The biggest challenge, the one that will impact all actors in the medtech sector, is moving all the devices on the market into the new system under the MDR and IVDR, during a transitional period in which the medical device database, Eudamed, still has to come online and the notified bodies will be re-accredited (likely resulting in fewer notified bodies designated for medtech products) – consequently these notified bodies will not be issuing new certificates during that process.

Clinica: How should manufacturers start to prepare for compliance?

EV: They should have started by doing gap assessments already. But the gap assessments alone – where manufacturers compare the requirements they need to meet under the future regulations with the requirements under the current medical device directives - will take so much time that even companies just starting with that today may already find themselves challenged to be ready in time.

It will almost be tantamount to companies having to CE mark their whole portfolio for the first time in a new system that they have yet to understand and of which only the basics are known at this moment. For now, I see very few companies that are freeing up the necessary resources for that.

Clinica: And what about SMEs – how will they manage to adapt?

EV: This is going to be particularly difficult for SMEs. The Regulations specifically state that they were designed to take SMEs into account, but if you look at the administrative and regulatory burden that they result in, I can't see that SMEs have ever been a concern during the drafting nor during the political negotiations. If you look at all the additional requirements for interaction

with the Eudamed database, for example, this is going to cost companies a lot of time and resources and be particularly onerous for SMEs.

Clinica: And while we have the texts of the Regulations – 355 pages for the MDR and 306 for the IVDR - there is more to come, isn't there?

EV: You are right. The MDR and IVDR are by no means finished yet. Delegated and implementing acts as well as Common Specifications will need to be put in place for essential parts of the regulations to even function. These will include rules around the functioning of Eudamed and requirements for non-medical devices (Annex XV) and reprocessing. Companies will need to keep a close watch on these developments.

Clinica: Will industry be involved in the drafting of these additional requirements?

EV: Although the Commission will consult with industry, it is likely that these consultations will be rapid and only with the parties the Commission usually consults with when talking to industry. In other words, anybody not tied into the large EU trade associations will have to keep their ear very close to the ground to know what is going on and act fast if they wish to have any influence.

Authorized Representative Liability

Clinica: What other issues are among those likely to cause the biggest challenges?

EV: Liability issues concerning the authorized representatives and manufacturers and the issues concerning the reprocessing of single use devices. The liability responsibilities for the authorized representatives are particularly challenging, with their joint and several liability with the manufacturer for defective medical devices. It is also at odds with European law.

Clinica: You have explained that this approach to liability is unique under the MDR and IVDR compared to other New Approach (CE) legislation Can you explain more?

EV: In my view, the approach taken in the MDR and IVDR is counter to the authorized representative function as intended in the EU's Goods Package. The underlying regulatory philosophy does not intend the authorized representative to be a target for enforcement by authorities or to be product-liable in case of a defective device.

Clinica: What is it in the texts, exactly, that is causing confusion?

EV: The medtech texts are very confusing on this point, because the texts say that the authorized representative is "legally liable for defective devices" and that this liability of the authorised

representative is “the same” as the manufacturer’s. The manufacturer’s liability is described as follows: “Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.” This means that this liability comes on top of the already existing provisions of the Product Liability Directive.

Why is it so confusing? Because the Product Liability Directive exonerates parties like the authorized representative because they were never involved in production or modification of the device after placing on the market. So now we have the Regulations say that the authorized representative is liable for defective devices *like the manufacturer*. But this is not possible under the Product Liability Directive, which explicitly excludes authorised representative liability in this scenario and this directive is not amended by the MDR or IVDR.

Clinica: And you believe there is an issue with the words “legally liable”?

EV: From a legal perspective this is a non sequitur. There is a possibility that member states will interpret this as legal basis for enforcement by competent authority against the authorised representative (as some member states are now doing, unlawfully in my view). But then would that only be possible in case of defective devices and not in case of other non-compliance? As I said, very confusing and not good law-making.

Clinica: What implications are there for manufacturers in terms of liability?

EV: Manufacturers will have to plan to deal with the process where the competent authorities have to facilitate that the manufacturer provides information to a party that claims to have suffered damage from a defective device. We will have to see how this will be applied in practice.

Reprocessing Of Single-Use Device

Clinica: And what about the other very challenging issue of the reprocessing of single use devices, where the Commission struggled to agree with the Council and Parliament over future rules?

EV: It’s good that there is language in the MDR clarifying that the reprocessor qualifies as a producer for the purpose of product liability.

It would also have been quite evident under the Product Liability Directive that the manufacturer was not liable. But it saves the manufacturer potentially having to prove that the defect caused by reprocessing was not present when the device was first placed on the market. This can be assumed now.

Clinica: What about the labelling and packaging of reprocessed devices?

EV: There is nothing explaining how reprocessed devices are labeled and packaged with a view to not negatively affecting the trademark of the OEM and avoiding confusion.

Reprocessors will have an incentive to make the device pack looks as much as the original. But in each case the distinctive character of the trademark of the manufacturer of the reprocessed device is at risk. For example, is a reprocessor allowed to copy the original pack exactly but put himself on the pack as manufacturer (as required) by just changing the name behind the little factory symbol, with the packaging still looking completely like the original? That will create a lot of confusion in practice and it will be difficult for end users to keep OEM and reprocessed devices separate.

Advertising, CA Information Requests, QP

Clinica: Thank you for explaining what the most significant challenges are in the respective texts. What, do you think, are the biggest surprises of all which exist in both the new MDR and IVDR texts?

EV: There are particular surprises in the areas of: advertising; competent authorities requesting information from manufacturers on behalf of patients; the person responsible for regulatory compliance; and the making public of clinical performance data. And there's also the transitional regime that has a surprising twist, which merits a separate publication I think.

Clinica: So what surprises do we have in the area of advertising?

EV: We will now finally have EU harmonized rules for claims and advertising of medical devices. However, I think they are quite superfluous because they mirror exactly what is already in the Unfair Commercial Practices Directive (2005/29/EC) and can be read into the provisions on misleading advertising in the Misleading and Comparative Advertising Directive. Now we'll have the same rules in different statutes which is not conducive to coherence of EU law. Coherence with other EU law has not been a big concern of the institutional actors, in my view.

Clinica: Why is industry concerned about competent authorities requesting information from manufacturers on behalf of patients in liability matters?

EV: This is a matter of concern for industry because of the obvious risks of widely divergent application of this by member states and fishing expeditions by competitors. There are corrections on data protection and protection of intellectual property rights but it really remains to be seen how national competent authorities will implement this. The range of people that can ask for such information is very broad: the potentially injured patient or user; the patient's or user's successor in title; the patient's or user's health insurance company; or other third parties affected by the damage caused to the patient or user. The competent authority does not have to

ask for information where disclosure of the information referred to is "ordinarily dealt with in the context of legal proceedings". But words like "ordinarily" set off all my lawyer alarms, because it means both yes and no.

Clinica: The concept of the Qualified Person similar to the role in the pharma sector has disappeared. So how will responsibility for regulatory compliance work in practice?

EV: It is interesting that the role of person responsible for regulatory compliance can now be split into multiple persons, provided that their areas of responsibility are properly documented. It will be important for manufacturers to keep a close eye on this documentation internally and to tie it into their QMS obligations as well. Not getting this right would be flagged up by your notified body.

Clinical Data Confidentiality

Clinica: Manufacturers are going to have to reveal what would otherwise be confidential information about clinical data. Can you explain more?

EV: The MDR and IVDR introduces an obligation to publish the clinical investigation report or performance study report respectively and a summary into Eudamed within a year, which will become public upon CE marking, and immediately in case of halt or termination of the study. This means that competitors will have rapid access to the information too. (If the device is not CE marked within a year after entry into Eudamed of the report and summary, then the report and summary become automatically publicly available in Eudamed.).

Clinica: Are there going to be guidelines in this area?

EV: Yes, Also interesting in this respect is that the Commission may issue guidelines for the formatting and sharing of raw clinical or performance data, for cases where the sponsor decides to share raw data on a voluntary basis. Those guidelines may take as a basis and adapt, where possible, existing guidelines for sharing of raw data in the field of clinical or performance studies.

Software Classification Rule, Clinical Evaluation Consultation

Clinica: What about surprises in the MDR alone, when compared to the Council's general approach?

EV: One of the big surprises for me in the MDR is the new software classification rule (rule 10a). It will result in all clinical decision support software and monitoring software that is currently mostly in class I being bumped up to class IIa or higher. This will affect a significant number of

software devices currently on the market. The most worrying thing is that all these devices will need to be recertified by notified bodies under the MDR, while notified bodies have almost no experts on software.

It's also strange that clinical decision support software has no similar rule under the IVDR, because clinical decision support in the form of expert systems is playing a more and more important role in that field.

Clinica: What else has taken you by surprise?

EV: The MDR mandatory clinical evaluation consultation procedure – as this is essentially repackaging of the scrutiny procedure and which impacts implantable class III devices and - Class IIb active devices intended to administer and/or remove a medicinal product. What used to be the scrutiny procedure has been changed to a sort of emergency brake that the authorities can pull if they're not happy with the CE marked end result.

The final scope of devices subject to the scrutiny procedure (implantable devices classified as class III, and for Class IIb active devices intended to administer and/or remove a medicinal product) is also a surprise. The scope of devices subject to scrutiny looked to be much wider in earlier versions of the texts. And of course we have seen the proposed scope diverge immensely between the Commission, Parliament and Council so in the end it is also not so surprising that we ended up somewhere unexpected.

IVD Regulation Surprises

Clinica: What have been the biggest surprises in the IVDR?

EV: The surprises in the IVDR relate to: genetic testing; mandatory consultancy for performance evaluation report; the transitional regime; the down-classification of certain IVDs; and a gap in rules for software.

Clinica: We have heard that the European Parliament accepted a big compromise when it came to genetic testing. Can you please explain this?

EV: The Parliament had had an ardent wish to regulate informed consent procedures with respect to genetic testing in great detail. I have argued on behalf of companies providing genetic testing services that this was not within EU competence and member states have picked up on this unconstitutional encroachment on their competence to regulate national practice of medicine too. The compromise now is that there is a requirement for member states to prove information related to genetic testing to patients and access to counselling, except "where a diagnosis of a medical condition and/or a disease which the individual being tested is already

known to have is confirmed by a genetic test or in cases where a companion diagnostic is used".

Clinica: What about the need for a performance evaluation report?

EV: This mandatory consultancy procedure for performance evaluation report this is a repackaging of the scrutiny procedure offering an emergency brake when CE marking has been granted, exactly like happens under the MDR. The IVDR provides that where no Common Specifications are available for a device in Class D and it is the first certification for that type of device, the notified body shall consult the expert panel on medical devices on the performance evaluation report of the manufacturer.

Clinica: Which are the products that are being down-classified in the IVDR?

EV: The IVDR down-classifies certain self-testing devices from class C to B, namely for the detection of pregnancy, for fertility testing and for determining cholesterol level, and devices for the detection of glucose, erythrocytes, leucocytes and bacteria in urine.

Clinica: What does the absence of a classification rule for software imply?

EV: There is no classification rule for software in the IVDR to mirror Rule 10a under the MDR. The clinical decision support functionality that rule 10a MDR up-classifies is also an important item in the IVD space, because more and more expert systems become available. So I'm not really sure what it implies. It looks more like an oversight to me, but I may be overlooking something.

Clinica: Thank you, Erik, for giving your views at this early stage. It is clear that all players in the sector have an enormous task ahead of them and that the interpretation of these new rules is going to be a very demanding and lengthy task.