RAPS WEBINAR TRANSCRIPT:

Dr Royth von Hahn's Presentation on EU MDR Extension

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Presentation

Here you can see a brief overview of what I am doing at TUV. We are globally responsible for the medical and health service business, and we have been dealing with the MDR for quite a long time now, preparing for that transition. Today, I will give you a brief overview of mainly three items. One is with respect to this additional year from the perspective from a notified body. How to use this time, and what steps you should take to really make use of this additional year of MDD for the transition into the MDR. Then I will turn to two other major aspects where we already can see that the preparation of the industry is not yet adequate to meet the needs. One is the post market activities you are supposed to do, and the next one is the economic operators.

Transition Planning from MDD to MDR Depending on Product Portfolio

Now, I'll start with the transition planning from MDD to MDR. This is really something where you need to look at your product portfolio and do an evaluation of your priorities. We have this new date of application in place. So, you have some time for additional changes on the existing certificates and you may also have time to renew some of your certificates. But you need to keep in mind that the timeframe is limited. So, it is unlikely, especially in the high-risk classes, that you will be able to complete a conformity assessment under MDD for a completely new product. The other aspect Sophie mentioned already, and that is the capacity of the notified bodies being limited, especially with those who are already designated for the MDR. So, they are trying to focus all their resources on the MDR transition. In case you have projects you still want to pursue under MDD, make sure you line those up, and you make a clear roadmap together with your notified body, so that they can line up their resources to be prepared

for submissions. Also, keep in mind that the final review stages at the notified bodies take a couple of weeks. So, the latest submission dates for new MDD related files, change notifications, renewals, or some transfers, will be sometime this year depending on your notified body. But there will be a deadline for applying under MDD that is earlier than the date of application, of course. Then also make sure you align your own resources to these timelines, because usually there are some questions that go back and forth that you have to answer, and you have to have your people in place to respond quickly to really conclude the conformity assessment.

Structure of the MDR

Then I would like to go briefly over to the post market surveillance and vigilance requirements under the MDR. This is specifically important because this chapter and this part of the MDR does not only apply if you are certified under MDR already. Even if you continue to use the grace period for your existing and ongoing MDD certificates, you are supposed to execute the post market surveillance, according to the MDR. So regardless, if you have formally transferred to the MDR or not be, please be aware. Maintaining the MDD certification after the date of application is also something that is happening under the MDR, the deed ends and does not exist beyond the date of application. So that specific chapter is applicable also for the MDD certificates.

Major Elements of Post Market Surveillance (PMS)

Now, if we look at the major elements of the post market surveillance (PMS), here you see a brief overview of what you're supposed to do with the post market clinical follow-up. The reports, the plans, the periodic safety update reports, are a whole bunch of things you are supposed to do under MDR postmarking surveillance.

Periodic Safety Update Report (PSUR)

Looking a little bit into the structure here, one central element is the periodic safety update report. That is something where you need to look at the conclusion of the benefit risk determination, and how that would be modified or changed with the information you are gathering from the market. That's where the main findings of the PMCF report have to end up. Then you also have to consider things like the sales volume of the devices and the estimate of the population using the devices involved in usage frequency. That's to make a link to the risk management where you have certain probabilities to find, and for checking that the assumptions you've taken in your risk management are actually valid.

Article 83, 84: PMS and Annex II + III, XIV, B: PBCF

On the other hand, here you see how these different activities are embedded in each other. This is for the planning stage where you have the clinical evaluation plan, and within that, you have the PMS plan. And as a part of that, you have the post market clinical follow-up plan. All these things need to be laid out in your system. These processes have to be established in your quality system so that you have a systematic approach on how this planning is done, and later, can execute it.

Annex XIV, Part B: PMCF - Report

Once you come to the reporting part, here we have the post market clinical follow up report, so that it meets to match whatever you have planned before.

It is part of the clinical evaluation report that is regularly updated. And all of that is part of the technical documentation, including the risk management and some copies of the instructions for use. So, all these documents and processes are linked to each other and it is important that you implement that structure in this way. In the end, that means with the PMCF report and the clinical evaluation report, you have to update the technical documentation.

Processes, Plans (P), Reports (R), Summary (S)

Here you see an overview for how the plans of the different aspects refer, or relate, to the reports or the summaries given. You can see again that the summary of the safety and clinical performance is the central part where you aggregate all the information on the post market surveillance process. And again, make sure that this is in place even for existing MDD certificates of products.

Economic Operators

So now the second aspect I want to highlight here are the economic operators. Before we go into the different roles here, it's important to understand that these terminologies are used for the European market, which is 'placing on the market' and 'making available.'

Placing on the market - Placing on the market is the first transfer of the device from a manufacturing stage into the European Union.

Making available - is really the distribution to the end user of the device, whoever that is.

Economic Operator Activities & Obligations

Now looking at the economic operator activities and the obligation, we started with a **manufacturer** - if the manufacturer is on European territory, more precisely, the territory of the European Union, then the manufacturer places those devices on the market by themselves.

But if not, they will have to have an authorized representative for doing that. And if the devices are shipped from outside the European Union into the European Union, that is done by a so-called **importer.** So, in that case, the **importer** takes on the role of placing the devices on the market. There is another role that can be the same entity, but does not have to be, and that is the **distributor**. The distributor, according to our definition, makes the devices available on the market. With these roles, there are different obligations they are following and different things to consider here. So here, you see the overview of what the economic operators from the authorised representative, the importer, and the distributor are supposed to do, and for what parts of the device information they are responsible for.

Now, what is really important and a significant change to the previous set up under MDD, where you had this European representative in a slightly different matter, is that there are legal responsibilities on each of these economic operators. The distributor is obliged to verify the CE marking and the declaration of conformity (DoC), the instructions for use, and the UDI. The importer needs to verify it again, this is the CE marking, the DoC, labeling, and the UDI, and these are legal requirements.

Authorised Representative - Also, the **authorised representative** is legally responsible for the product on the market in Europe. So that is important also for your business relationship with these economic operators.

Person Responsible for Regulatory Compliance

One of the things we also have to consider here, is that **Authorized representative** is supposed to have a person in place that is responsible for regulatory compliance. The way the different tasks are split between the **manufacturer** itself, and the European representative, you can see here. The basic check of the device, and the conformity before the release of the device, is on the manufacturer, as well as the technical documentation and issuing the declaration of conformity. But the European representative is supposed to carry out the post market surveillance, the vigilance reporting, and the device statements for international performance studies. Additionally, it's important to mention that the technical documentation has to be available with the EU representative at any time. That's also a change to the previous set up under MDD, where the E.U. representatives would just have to make access to the technical documentation available. Here, the technical documentation needs to be available with the European representative, so, that also means your European representative will have access to the technical documentation in full.

Conclusion

In conclusion, regarding your planning of the remaining year, coordinate resource planning with your notified body, and prioritize your projects strategically because the resources will be limited. Prepare postmarket activities for the complete product portfolio, MDD and MDR, because the respective MDR requirements also apply for maintained MDD certificates. Establish the PMS in your systems and your documentation. Make sure that all the updates and reporting is in place for all the post market activities. Take a close look at the setup of your economic operators and their legal obligations. Make sure that the economic operators you have in place are ready and prepared to take on the roles and responsibilities they have under MDR. And then lastly, ensure each of the European economic operators is clear about their obligations and duties, including legal responsibility. And with that, I would conclude my brief overview of what to consider in this additional year before the date of application of MDR.

Thank you very much!

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The New EU MDR Challenges

Celegence has a wealth of knowledge to help you navigate through the complex regulatory challenges that the new EU MDR bring.

We can assist you throughout the entire process to ensure that you and your business are compliant with all of the EU MDR requirements.

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