Johner Institute

# 7 days left until the MDR – what's changing at the national level

With Prof. Dr. Christian Johner

## Transcript

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Medical Device Insights, a podcast by the Jona Institute for medical device manufacturers, authorities and notified bodies.

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On 25.

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May the MDR will come into force and thus some laws and regulations will either be changed or even completely repealed.

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In this podcast episode, I would like to give you a brief overview of which laws and which regulations are affected.

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The M.D.R.

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is an E.U. regulation and not one of the E.U. guidelines we had before.

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Well, we knew the Medical Devices Directive, the M.D.D., then the Directive for Active Implantable Medical Devices, the A.I.M.D., and the Directive for In Vitro Diagnostic Medical Devices.

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But these were guidelines.

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In other words, the task of the nation states was to transpose this directive into national law.

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And this has been done in Germany or Austria, for example, more Medical Devices Act, in Switzerland with the Therapeutic Products Act.

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However, these were independent laws that were complete, even if they referred back to the EU directives.

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The EU regulations are different.

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Now these regulations themselves have already

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legal nature.

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In other words, the laws that are still being created are only there to close certain regulatory gaps or to set specific requirements for the individual nation states.

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And that's exactly what the M.P.P.G., the Medical Devices Implementation Act in Germany, does.

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It regulates, for example, what the criminal provisions are or the fines.

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It regulates which

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authorities.

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It also specifies a few other things, such as the medical device advisor.

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This is a German invention.

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There are responsible requirements for clinical trials and it also stipulates, for example, that accompanying materials must usually be written in German, in German.

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However, there are exceptions for professional users, where English is also possible.

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So, this M.P.D.G., this Medical Device Implementation Act, yes, these are actually more like text fragments that regulate what is written on the E.U.

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level in the Medical Devices Directive of the M.D.R.

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has not yet been regulated.

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The fact that this M.P.D.G.

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, i.e. this Medical Devices Implementation Act, which in turn is described in another law.

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Namely, this is the Medical Devices E.U. Adaptation Act or M.P.E.U. for short.

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Adaptation Act.

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That's how it's abbreviated.

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The Medical Devices EU Adaptation Act now regulates that the Medical Devices Act will be replaced by the Medical Devices Implementation Act.

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However, this is not one hundred percent true, because for the In Vitro Diagnostica, the IVD, the MPG remains valid for another year, i.e. until 25.

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May 2022.

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But after that, the MPG will finally be obsolete and, as I said, that's it for the

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other medical devices.

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However, this EU Medical Devices Adaptation Act, as it is called, also regulates a number of things at the level of the regulations.

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For example, it says that there is no longer a medical device clinical trial regulation.

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Because as far as these clinical trials are concerned, it is now no longer regulated at national level, but at EU level.

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And most of the requirements are in the MDR and a few additions can also be found in the Medical Devices Implementation Act.

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But a specific regulation is no longer needed.

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The DIMDI Regulation and the Medical Devices Regulation, i.e. the national MPV, have also been abolished.

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And the Medical Devices Safety Plan Ordinance, the MPSV, has now been replaced by a so-called medical device share.

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User Reporting and Information Ordinance becomes a super long name, is abbreviated to M.P.A.M.I.V.

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and this M.P.A.M.I.V.

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now regulates what was previously regulated in a comparable way in medical devices in the Medical Devices Safety Plan Ordinance, namely who must report in what form and in what periods.

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However, most of these requirements are already in the M.D.R.

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so that these

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national regulation is no longer allowed to regulate so much.

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So here, of course, the specific authorities are mentioned again and she also says, but she also says, if this regulation still affects and that goes a little beyond what was written in the M.D.R.

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is in it.

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This User Notification and Information Ordinance is also addressed to the authorities, i.e. by B.F.A.

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to state authorities, of course to the manufacturers.

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I think that's clear.

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but also to the operators, it goes to forensic scientists and pathologists, she addresses patients.

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This means that the scope contained in this User Notification and Information Ordinance is somewhat broader.

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For the manufacturers, however, it does mean a few small changes and that's why, for example, the IT systems would have to be adapted, the processes would have to be adapted, for example in such a way that:

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that there is no longer a safety officer, but a responsible person, i.e. the person Responsible for Regulatory Compliance.

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So, that was the change at the level of the Medical Devices Safety Plan Ordinance and then we have the Operator Ordinance, which essentially remains in place.

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But there are a few small changes.

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I'll briefly summarize what we've had so far.

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Due to the transition from the EU Directive to the EU regulations, especially in the direction of the MDR,

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Will the MPG for normal medical devices now be repealed and replaced by the MPDG?

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However, what is in the MPDG is no longer as complete as what was in the MPG, because most of it is already regulated at EU level.

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The Operator Ordinance remains essentially the same.

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The Safety Plan Ordinance will be replaced by the Medical Devices User Notification and Information Ordinance.

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The Medical Devices Clinical Testing Ordinance M.P.K.P.V., the DIMDI Ordinance and the Medical Devices Ordinance will be deleted without replacement.

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A few more ordinances have been issued or are being planned, for example on fees.

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But I don't think that's so important now in the context of this podcast.

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For you as a manufacturer,

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if you click on the M.D.R.

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are prepared, then these legal requirements, which have now also just been decided, i.e. the last version of the Medical Device Adaptation Act dates from 7.

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May.

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It only went through the Federal Council, but you are well prepared, so to speak, if you adapt to the other requirements of the M.D.R.

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have already held.

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Maybe just a few important things where we see again and again that things are forgotten.

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Think about your

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Person Responsible for Regulatory Compliance.

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Think of the topic of the U.D.I., even if we have transitional periods.

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Above all, however, think about the requirements we have in the area of post-market surveillance.

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In other words, that your systems are really up and running and that you also have product-specific post-market surveillance plans and not just a general S.O.P.

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So, those are a few things that we would highly recommend to you so that the

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Transition to the M.D.R.

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runs smoothly.

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I have also linked the articles to you.

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This means that if you were to read on, you will find an article on the Medical Devices Implementation Act here in the show notes.

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You will also find an article on medical device users and information regulations and where else you can get help, from the approval of your products to the postmark for Wellens.

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You know that.

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Yes, that was today's podcast.

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Thank you for listening

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then see you next week.