Johner Institute

Textile medical devices

With Maike Andersson, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

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

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In this podcast, we have already talked a lot about the upcoming MDR, about the changes that come with it, from classification to machine learning.

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But there is one class of medical devices that we have so far completely left out, the material medical devices.

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And we want to change that with today's podcast.

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And I invited my colleague, Maike Andersen, to join in.

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Dear Maike, can you briefly introduce yourself and perhaps also report on what you have already done in the context of these material medical devices?

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Hello Christian, it's nice to have me here today.

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I am Maike Andersson, I am a graduate biologist with a focus on plant secondary substances.

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And before I came to the Jona Institute, I worked for many years as a medical writer for a service provider for the pharmaceutical and medical device industry, where I took on many projects in the field of pharmaceuticals, then specialized in substance-based medical devices in 2015 and have since written a lot of clinical evaluations for these products.

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Afterwards, I worked for a service and consulting company that also acts as a legal manufacturer for substance-based medical devices, and thus stand against the background of the M.D.R., so to speak, at the interface between the increased requirements for the clinical data listed in the clinical evaluation on the one hand and the concerns and questions of the manufacturers who are unsure how they can meet them, on the other hand.

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Yes, you have already mentioned a lot of keywords, namely the keyword of this requirement of clinical data.

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But before we get that far, let's pick up another keyword from you.

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On the one hand, you spoke of material medical devices, you spoke of medicines.

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Can you briefly explain to us and our higher ones, what are actually material medical devices and how do they differ from pharmaceuticals?

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Material medical devices consist of substances or a combination of substances and these products are similar to medicines in their presentation and dosage form.

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Typical material medical products are, for example, seawater nasal sprays, mucous membrane moisturizing lozenges, hydrogels for sealing wounds or scars, osmotically effective laxatives or oral agents for neutralization

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of stomach acid and the key to distinguishing between drugs and substantive medical devices is their mechanism of action.

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While medicinal products have a pharmacological, immunological or metabolic mechanism of action, which is usually based on specific receptor binding, material medical devices achieve their intended main effect via a

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chemical or physical mechanism of action.

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It is perhaps also interesting to know that before the MDD came into force, i.e. before 1993, all substantive medical devices were approved as medicinal products and are therefore still on the market as medicinal products in some cases today, even though they have a chemical or physical mechanism of action.

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Could you perhaps very briefly describe such a mechanism for a product, i.e. that one can imagine this chemical-physical one even better?

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The mucous membrane sealing effect is quite typical.

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We often have them, for example, with nasal sprays, throat sprays or even lozenges for coughs and hoarseness.

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There, the material combination

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which is contained in the product, a protective layer that lies on the mucous membrane and thus physically protects this mucous membrane from drying out, for example.

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You have already given us a second keyword in your introduction, namely the requirements for these substance-based medical devices.

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Could you give us an overview of what

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requirements specific to such material medical devices.

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And maybe in this context, I hope it won't be too much, which will happen in the transition from the M.

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D.

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D.

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to M.

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D.

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in this regard.

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In contrast to many other medical devices, material medical devices usually have clinical functions and achieve their effect in direct contact with the human body.

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And

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And for this reason, the safety and performance of these products cannot be proven, or at least not fully, on the basis of preclinical data or performance data.

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This means that I necessarily need clinical data here and this is precisely where the claims with the M.D.R.

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for example, by significantly tightening the requirements for proving equivalence when using literature data.

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Another change is the introduction of the new Rule 21, which results in a higher classification of substance-based medical devices that previously fell into class 1 under the MDD, and these products must now undergo a conformity assessment procedure with the involvement of a notified body for the first time with the MDR.

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Another new requirement set by the MDR

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of material medical devices that are absorbed by the body or distributed locally in the body, the documentation of their kinetics, i.e. their absorption, distribution, metabolism and excretion, is similar to what is required for human medicinal products.

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So I think there were 3 things that I understood.

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So the first thing was the higher requirements for clinical data

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and once again I found your statement quite remarkable that because these products only work in interaction with the body, we are not as easy to test preclinically as, for example, software would be now.

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Yes, you can try out a lot of things without it happening directly on the patient.

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In other words, more requirements for clinical data.

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Then the second thing you said was this rule, which ultimately leads to a higher classification and thus to the inclusion of a notified body.

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And the third thing was,

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actually, if I understood correctly, again the clinical data, but this time with a very special focus, namely kinetics, you mentioned it, i.e. how these substances are absorbed by the body, how they are metabolized and so on.

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If you could perhaps give us a very brief thought, what exactly does a manufacturer have to show with this data, so

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that they are metabolized or that they are not doing so.

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So I would need a bit of background, so to speak, as someone who is not so familiar with this area.

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Substance medical devices that do not contain an additional drug component are usually not absorbed by the body at all and are therefore not metabolized and excreted accordingly.

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This is the rule for most substance-based medical devices

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and this is now to be documented by the M.

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R.

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and this could be done, for example, by documenting these points accordingly in the biocompatibility assessment.

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Ah, O.

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K., that helps me.

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Yes, now you've actually been

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what you actually have to do regarding this requirement.

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But I think that's worth a separate point now.

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So, what would be your concrete recommendations on what manufacturers should do now?

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So now not only to meet the requirement per se, but also to deal with these changes, which are now with the M.

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have found their way into the market in order to continue to sell their existing material products after the

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end of the transition periods, manufacturers should definitely use the time now.

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You should first sift through the existing clinical data, then identify the missing data using a gap analysis and generate that data now.

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While clinical trials are usually mandatory for Class 3 products and new developments,

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were used for long-term existing products with a low risk profile under the M.D.D.

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often do not carry out such clinical trials of their own and in order to generate the missing data here, the manufacturers should always provide a P.M.C.F.

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study should be started when it has been determined that the existing clinical data are used to demonstrate safety, performance and

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clinical benefit is not sufficient.

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And here is perhaps a little tip from me, often preclinical or in vitro data can also be used to close existing gaps, especially when it comes to non-clinical performance functions or special claims, for example.

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A clear strategy is therefore required here so that the gaps can be filled in time with manageable effort.

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can be closed.

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Mhm, I'll summarize again so that you can check whether I, as a layman, have understood correctly.

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So, you said the first thing you should do is do this gap analysis to find out what's actually missing and then you actually brought us some good news.

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You probably said that that's why large clinical trials are not necessarily always necessary now.

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There are 2 ways out in a way that you recommended.

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One is via post-market sustainable follow-up studies to close these gaps or, if necessary, via in-vitro data.

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Did I summarize that correctly?

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Exactly, a combination is also possible, of course.

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Ah, OK, absolutely.

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Now you've said, actually what you should do.

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I may now ask the counter-question again: What are the mistakes that manufacturers should avoid at all costs and perhaps put special emphasis on the mistakes that you may also see made more often?

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Typical errors often lie in the formulation and in the equivalence assessment.

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Often, for example, the formulation contains substances that have a medicinal effect in the present quantity and according to the advertised intended purpose, although these substances were added, for example, as flavourings or preservatives and thus a medicinal effect was not intended at all.

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However, the consequence is that the product is classified in class 3 and thus clinical trials are required for this product.

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Here, manufacturers should therefore once again check their recipe, the mechanism of action and the intended purpose very carefully.

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That means you want to do a little thing somewhere to make it smell better and afterwards you finally have medication built in.

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Yes, it is quite typical, for example, when peppermint oil is added.

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Peppermint oil has a medicinal effect, there is a specific receptor to which the menthol binds and if something like that is now added as a flavor, then you just have to see,

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It's just important to look at what is the intended purpose, what is there a threshold value for the pharmacological effect.

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These are points where you have to take a close look at the recipe again and correct the corresponding points accordingly, perhaps even change the recipe or check the mechanism of action, for example towards the threshold value.

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Great, I think that's very, very helpful.

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You also told our readers

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Article written on the topic of material medical devices.

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You can find it on our website and in the show notes you will also find the link.

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Maike, I suspect you are also available to all manufacturers if you have any questions.

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I suspect that one of the most common questions will possibly be, are my clinical data sufficient here and then they may turn to you.

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With pleasure.

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Yes, you, then I thank you for being there and

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introduced us to a world that we have not yet discussed here in this context.

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The material medical devices.

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Thank you for joining us, Maike.

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Thank you.