Johner Institute

EUDAMED Transition Periods

With Prof. Dr. Boris Handorn, Prof. Dr. Christian Johner

Audio File: 2026-01-HANDORN-EUDAMED.MP3

Transcript

00:00:00 Speaker 1

So for the time being, there is a six-month transition period for the start of validity of these modules.

00:00:07 Speaker 1

That means it depends, on the day after publication in the Official Gazette.

00:00:14 Speaker 2

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

00:00:26 Speaker 3

Today's guest, you probably already know, is Professor Handorn, whom I have now invited again and for a rather current occasion.

00:00:35 Speaker 3

You may have noticed that the EU has now activated parts of EUDAMED or the last parts of EUDAMED, and these are of course things that manufacturers must comply with and know.

00:00:47 Speaker 3

And there are now some questions that arise.

00:00:49 Speaker 3

So questions arise, when does this apply?

00:00:52 Speaker 3

Do we have transitional periods?

00:00:54 Speaker 3

What exactly do I have to do now?

00:00:56 Speaker 3

And it is precisely these questions that I would like to clarify with Mr. Handern today.

00:00:59 Speaker 3

Mr. Handern, I came across you through your article Eutermed.

00:01:04 Speaker 3

That means you've already really dealt with it.

00:01:07 Speaker 3

What were the activities that brought you to this and how did you do it in the context of your law firm, how did you come across it and deal with it?

00:01:17 Speaker 1

Yes, greetings, thank you very much for the invitation.

00:01:20 Speaker 1

We have actually been involved with Eutermed since the MDR came into existence.

00:01:24 Speaker 1

or even before, because it should have been activated in May 2020 after the May 2021 postponement.

00:01:33 Speaker 1

This means that from a legal point of view, we are dealing with the implementation of Eudamed, with the Eudamed deadlines.

00:01:42 Speaker 1

Of course with U.D.I.

00:01:44 Speaker 1

is always a big related topic.

00:01:48 Speaker 1

And of course now with the question of how economic actors can

00:01:52 Speaker 1

Use soidamide, how do you have to use it and by the way, soidamide is actually very, very helpful for us, for example, in competition law proceedings, always just to look at what kind of market player it is and what kind of products it has in the market and has it done everything right.

00:02:09 Speaker 3

Ah, you also come over a second page, because you know them in

00:02:14 Speaker 3

for liability issues, where you can also ask for them, also in the context of medical devices, of course, is the focus that we also have here in the podcast.

00:02:22 Speaker 3

But now we have just learned, so Eudabit is relevant in your legal practice for various reasons and one of the reasons was also to be able to observe the market.

00:02:33 Speaker 3

That's a very exciting thought.

00:02:35 Speaker 3

Perhaps let us take a step back.

00:02:38 Speaker 3

Could you tell us from your point of view why the E.U.

00:02:42 Speaker 3

has this topic been taken up by Eutermed at all?

00:02:45 Speaker 3

Also, was will die E.

00:02:46 Speaker 3

U.

00:02:47 Speaker 3

what are the goals?

00:02:49 Speaker 3

I think that would perhaps also help us a little bit to find motivation to meet this requirement.

00:02:54 Speaker 1

Yes, indeed, the Eutermed already existed before the M.

00:02:57 Speaker 1

D.

00:02:57 Speaker 1

R.

00:02:59 Speaker 1

This European database sometimes dates back to the 2000s and it is now to be deliberately expanded again under the M.

00:03:10 Speaker 1

D.

00:03:10 Speaker 1

R.

00:03:10 Speaker 1

So, above all, it‘s about

00:03:12 Speaker 1

transparency in the market.

00:03:15 Speaker 1

Also in the direction of the public, in the direction of patients, in the direction of health professions.

00:03:23 Speaker 1

In this context, it is also a question of standardising the flow of information between the various economic operators, between notified bodies and the authorities.

00:03:35 Speaker 1

Multiple reports should be avoided, but if you

00:03:40 Speaker 1

big label on top, in the end it is increasing transparency.

00:03:44 Speaker 3

Mhm, and what you just described, efficiency, so precisely because you said that we can avoid double reports and we have had this topic quite often, that manufacturers in X.

00:03:57 Speaker 3

countries then have to report and register again and they were not coordinated with each other and I think that there is reason enough for them to say, O.

00:04:06 Speaker 3

K., let's deal with it,

00:04:08 Speaker 3

apart from the legal obligation, of course.

00:04:12 Speaker 1

And perhaps a very important point, to name it, sometimes quite practically, the verification obligations that an importer or a dealer has to comply with according to the M.

00:04:21 Speaker 1

D.

00:04:21 Speaker 1

R.

00:04:21 Speaker 1

They are supposed to be made easier via Eudamed, that you go into the database and see, are these products available, are the information entered correctly, in order to be able to fulfill my duties myself?

00:04:36 Speaker 3

Mhm.

00:04:36 Speaker 3

So not only does safety support in a certain way, it not only serves the manufacturers, but also the patients.

00:04:45 Speaker 3

Of course, that was also one of these topics.

00:04:47 Speaker 1

Definitely up to recalls.

00:04:51 Speaker 3

Okay, so hopefully we have gathered enough courage and motivation to take on this topic.

00:04:58 Speaker 3

Now I had already mentioned at the beginning, there was now a new release and it's now about deadlines.

00:05:04 Speaker 3

what did the E.

00:05:06 Speaker 3

U.

00:05:06 Speaker 3

given to us exactly now, since a few weeks ago, what is actually new now?

00:05:11 Speaker 1

Yes, so you are referring to the Commission's decision, which was published in the Official Journal on 27.11.2025.

00:05:26 Speaker 1

And very specifically, it's about this gradual rollout, as it's always called,

00:05:33 Speaker 1

that of the individual Eutermed modules.

00:05:35 Speaker 1

You may have to keep in mind that the Eutermed should have been fully functional with all modules with the start of validity of the M.

00:05:44 Speaker 1

D.

00:05:44 Speaker 1

R., i.e. in May 2021.

00:05:48 Speaker 1

This has been delayed again and again, especially as a roadblocker, the module for clinical trials, which is planned, which is not yet activated, yes.

00:06:03 Speaker 1

So with the third amendment in 2024 they said, well, we now allow a yes a a gradual entry into force and gradual start of validity of EulerMed modules.

00:06:19 Speaker 1

For this, the M.D.R.

00:06:20 Speaker 1

and that's exactly what this decision is based on.

00:06:26 Speaker 1

Yes, so what does the decision say in concrete terms?

00:06:30 Speaker 1

It actually represents the

00:06:32 Speaker 1

Functionality of fixed EuDA-MED modules and this determination of functionality is a prerequisite for applicability.

00:06:43 Speaker 1

Sounds logical so far.

00:06:45 Speaker 1

So we are talking about the actor module, i.e. the registration of economic operators, then the product registration and U.D.I. modules, which have been merged, then the module for notified bodies and certificates

00:07:00 Speaker 1

and the market surveillance module referred to in Article 100 of the M.

00:07:04 Speaker 1

D.

00:07:04 Speaker 1

R.

00:07:04 Speaker 1

That means that what doesn't yet exist, what hasn't been activated and isn't yet functional, that the module for clinical trials, it's not really foreseeable when that will come.

00:07:14 Speaker 1

And the module for vigilance, which will also be important for economic actors later on.

00:07:23 Speaker 1

But these are exactly these 4 separate modules that are now available for

00:07:29 Speaker 1

declared functional and from now on the transitional periods will also tick.

00:07:34 Speaker 1

Now we can also say, when do I have to apply what.

00:07:37 Speaker 3

We should talk about them in a moment.

00:07:39 Speaker 3

You also deliberately mentioned the date when it was published, because it plays a direct role in it.

00:07:45 Speaker 3

It seems a bit like a classic I.

00:07:48 Speaker 3

T.

00:07:48 Speaker 3

Project, you don't get finished and then you sell it, then let's introduce it piece by piece.

00:07:54 Speaker 3

Seems to have happened the same now.

00:07:57 Speaker 3

We had already created EUTAMEDIA in the 2017 version and now we have the year 2025 and we are now talking about it really going into partial operation from 2026, nine years later.

00:08:13 Speaker 3

But we don't want to mock failed projects here, because we know enough of them, but we want to see what the manufacturers have to do now.

00:08:21 Speaker 3

So to put it positively, they have now been spared, but part of the sparing

00:08:27 Speaker 3

seems to be ending now and that is exactly what we are talking about now, the transition periods.

00:08:32 Speaker 3

So by when do they have to have done something now?

00:08:36 Speaker 1

Mhm, exactly, so there is a six-month transition period for the start of validity of these modules.

00:08:47 Speaker 1

In other words, it depends on the day after the publication of this decision in the Official Journal

00:08:54 Speaker 1

and the day after, that would be 28.11.2025 and from that day we now calculate another 6 months into the future.

00:09:03 Speaker 1

In other words, all these modules will be valid on 28.5.2026.

00:09:13 Speaker 1

If you stay with it again, what actually has to be done now, what do you have to have on your screen, broken back to these individual modules.

00:09:23 Speaker 1

the essential thing for the manufacturers and all economic actors in the implementation is ultimately the arming of the U.

00:09:30 Speaker 1

D.

00:09:30 Speaker 1

I.

00:09:31 Speaker 1

database and product registration.

00:09:34 Speaker 1

Yes, that's where you have to work practically now, because you have to have one more thing in mind when it comes to this actor module.

00:09:42 Speaker 1

So before you ask yourself, yes, we have been registering in this module for years, which is also completely correct due to national regulations.

00:09:53 Speaker 1

So there was once this famous announcement of the BMG on 26.5.2021, where in Germany it was bindingly said that we have validated this module, already in 2021, that works.

00:10:06 Speaker 1

Therefore, economic operators based in Germany, please use this mandatory.

00:10:12 Speaker 1

Therefore, in practice, it is of course already the case as an economic operator, i.e. manufacturer, importer, authorised representative,

00:10:24 Speaker 1

are registered in this module.

00:10:27 Speaker 1

Now, on top of that, there is the binding nature of the whole thing under European law.

00:10:31 Speaker 1

So, the other two modules, Notified Certificate of Employment, now does not affect the ones that

00:10:40 Speaker 1

economic operators directly, and this market surveillance module under Article 100 also concerns communication between public authorities.

00:10:47 Speaker 1

In short, the activities of economic actors are now essentially focused on the implementation of the U.D.I.

00:10:55 Speaker 1

Product Database.

00:10:57 Speaker 3

That's very, very important.

00:10:58 Speaker 3

So that then takes

00:10:59 Speaker 3

I don't say pressure off, but that puts it into perspective.

00:11:01 Speaker 3

So we don't have to worry about 4 modules right away, because they just said that the first one was at least already mandatory for the Germans anyway.

00:11:08 Speaker 3

This means that you have to have done it or you are already not in compliance with the law and the other two do not apply, so that it is now very specifically about this one module.

00:11:18 Speaker 3

But now we always have the question, OK, from then on it's all about now.

00:11:22 Speaker 3

So it is understandable if I now bring a new product onto the market,

00:11:26 Speaker 3

then put it on the market for the first time.

00:11:28 Speaker 3

Sure, I have to stick to it.

00:11:30 Speaker 3

But now we have scenarios that we have to take care of products that we may have been selling regularly for a while.

00:11:39 Speaker 3

At what point do these modules, i.e. for which we have already declared conformity, which we have perhaps been bringing to the market regularly for quite a while now, have to take into account what transitional periods do we have to consider?

00:11:51 Speaker 1

Yes, that's very important.

00:11:53 Speaker 1

This is because a

00:11:56 Speaker 1

a further transitional period, namely another 6 months from the date of application, i.e. a total of 12 months from the publication of this decision in the Official Gazette.

00:12:08 Speaker 1

Specifically, these, let's say, existing products, I'll say something about it in a moment, what they are specifically, these existing products, they have another time to organize the upload for another half a year.

00:12:24 Speaker 1

And it must have happened by 27.11.2026.

00:12:30 Speaker 1

That is, on 28.

00:12:32 Speaker 1

November 2026, all products must be included.

00:12:37 Speaker 1

Now we come back to this distinction, what is actually an existing product in this context?

00:12:45 Speaker 1

This is about products that were already available before the 28th century.

00:12:51 Speaker 1

fifth in 2026.

00:12:55 Speaker 1

And that doesn't mean the specific product, that's actually always the point of reference when using the term to put on the market, that's unfortunately conceptual here, I know that's a bit different, that's what the product series ultimately means.

00:13:09 Speaker 1

And very, very important is the U.D.I.D.I.

00:13:12 Speaker 1

in this context.

00:13:13 Speaker 1

This means that if I have already purchased a product with a certain U.D.I.D.I.

00:13:18 Speaker 1

placed on the market, especially

00:13:21 Speaker 1

before 28.5.2026 and I want to continue to market this product after 28.11.2026.

00:13:31 Speaker 1

Then I have this additional six-month window to take care of the upload of such existing products.

00:13:42 Speaker 1

Very important, new products, i.e. with a new U.D.I.D.I., which will be available from

00:13:49 Speaker 1

28.5.

00:13:51 Speaker 1

placed on the market.

00:13:52 Speaker 1

They must then be uploaded immediately, i.e. put on the market before they are put on the market.

00:13:57 Speaker 1

And this also applies to those existing products that change in such a way that I offer you a new U.D.I.D.I.

00:14:04 Speaker 1

.

00:14:05 Speaker 1

So there, too, product management and say the coordination of the yes of market access is quite important, that I think about it,

00:14:17 Speaker 1

when do I change my products or not?

00:14:20 Speaker 1

So, what impact does this have on the deadlines for OidaMate upload?

00:14:26 Speaker 3

I summarize very briefly, so you have now distinguished, on the one hand products that I have under a certain U.

00:14:34 Speaker 3

D.

00:14:34 Speaker 3

I.

00:14:35 Speaker 3

for the first time.

00:14:37 Speaker 3

So suppose I've always built a defibrillator, I want to sell it now, haven't done it yet and plan to do it now, then I have to

00:14:47 Speaker 3

have registered this by May, which no, May 2026.

00:14:55 Speaker 1

Well, if I put it on the market before May 2026, then I will still benefit from the transition period.

00:15:02 Speaker 3

That is, then I would still have time until the end of November 26, if I do it then, i.e. the first, the first instance of this defibrillator, I have to do it immediately.

00:15:12 Speaker 3

Then we really only have a third case, I

00:15:15 Speaker 3

I have already put all my defibrillators on the market and do not intend to sell any more.

00:15:22 Speaker 3

Would I have to act then?

00:15:25 Speaker 1

No.

00:15:26 Speaker 3

O.

00:15:27 Speaker 3

K., so that makes it clear.

00:15:29 Speaker 3

So that, the big question is actually only, or can we limit it to, when will this first marketing take place and the key point is this May 26.

00:15:40 Speaker 3

Now you have already hinted at it,

00:15:44 Speaker 3

what should be done for this, so now apart from that, of course, to fulfill the regulatory obligations.

00:15:49 Speaker 3

You have now talked about product management.

00:15:52 Speaker 3

So, what would be such concrete activities that you would recommend to manufacturers to prepare for this, to create clarity so as not to run the risk of non-conformity here?

00:16:05 Speaker 1

Yes, what you actually see now, species, you have to take care of the question, how do I get my whole product portfolio

00:16:14 Speaker 1

into the database.

00:16:16 Speaker 1

Of course, this is very individual, depending on the manufacturer, depending on the class, depending on the scope of the portfolio.

00:16:24 Speaker 1

So basically you have to think about it, do I still get this via a manual entry into the product database tra-ded.

00:16:33 Speaker 1

This may be the case with a few U.D.I.D.I.s

00:16:38 Speaker 1

be the path you can take.

00:16:39 Speaker 1

As soon as this has a certain extent, you have to think about corresponding I.

00:16:44 Speaker 1

T.

00:16:45 Speaker 1

Solutions.

00:16:45 Speaker 1

So let it be an X.

00:16:48 Speaker 1

M.

00:16:48 Speaker 1

L.

00:16:48 Speaker 1

Bulk upload of data, which must then be prepared accordingly.

00:16:54 Speaker 1

This also has a lead time that you have to take into account.

00:16:58 Speaker 1

There are also transitional periods for this, but they should also be tackled at an early stage.

00:17:05 Speaker 1

or even a machine-to-machine upload.

00:17:08 Speaker 1

Yes, but even there you need corresponding I.

00:17:11 Speaker 1

T.

00:17:11 Speaker 1

Expertise, either in-house or through external service providers.

00:17:16 Speaker 1

But these are exactly the issues that companies are facing now.

00:17:23 Speaker 1

And maybe that's where you get your U.D.I.D.I.

00:17:29 Speaker 1

built.

00:17:29 Speaker 1

Yes, because that's what the whole thing depends on.

00:17:32 Speaker 1

and maybe you realize now that you have a lot of U.D.I.

00:17:35 Speaker 1

D.I.s, which then leads to the fact that I have a higher upload effort.

00:17:39 Speaker 1

No, so everything is always very much related to the U.D.I.

00:17:42 Speaker 1

system.

00:17:43 Speaker 3

Mhm, so regulatory strategy should also include this aspect, which often does not happen.

00:17:50 Speaker 3

Maybe one step ahead, you were now in between the technical possibilities or requirements that must be met.

00:17:57 Speaker 3

Of course, it requires clarity about the product portfolio in the first place.

00:18:01 Speaker 3

So that doesn't just mean which products with which UDIs do I have, but also, if necessary, what is planned?

00:18:07 Speaker 3

Which products do I perhaps no longer want to put on the market because of this deadline?

00:18:12 Speaker 3

Which ones do I want to continue to put on the market?

00:18:15 Speaker 3

Are we planning any variants or updates of these products that would affect UDI DI again?

00:18:22 Speaker 3

So this clarity about the product portfolio and the associated UDI DIs is the basis on which it is all based.

00:18:29 Speaker 3

and once we have this clarity, then what you have just described will come, namely to create the technical prerequisites to be able to enter all the reports or data in the first place.

00:18:39 Speaker 3

And what you also said, yes, in the end these technical solutions also require I.

00:18:45 Speaker 3

T.

00:18:46 Speaker 3

Projects and the should and this is where the circle of our conversation closes, this I.

00:18:50 Speaker 3

T.

00:18:50 Speaker 3

Projects should be something

00:18:52 Speaker 3

Move forward faster than what happened today.

00:18:56 Speaker 3

Now, of course, you could say that this is totally unfair.

00:18:58 Speaker 3

We only have half a year.

00:19:00 Speaker 3

The EU has taken almost a decade.

00:19:02 Speaker 3

But of course you have to say that this release doesn't come as a complete surprise and many of these specifications have been known for a long time.

00:19:11 Speaker 3

Nevertheless, those who hoped to be able to go the usual EU way, simply waiting until another transitional period was postponed, may this time

00:19:21 Speaker 3

be disappointed.

00:19:23 Speaker 3

That means it's time to act.

00:19:26 Speaker 3

How can, how can, can your team support this work?

00:19:34 Speaker 1

We are well positioned to support precisely this marketing strategy on the basis of the various deadlines.

00:19:46 Speaker 1

because if you get into the legal requirements of the M.

00:19:49 Speaker 1

D.

00:19:49 Speaker 1

R.

00:19:49 Speaker 1

look, we already had the topic, which date applies exactly and what does it apply for.

00:19:56 Speaker 1

In the end, very complex legal questions can arise and we are very happy to support clients on a regular basis.

00:20:06 Speaker 1

These questions are coming now.

00:20:07 Speaker 3

Excellent, so we will link your product law firm there, which means that we will contact them for all these very legal issues.

00:20:16 Speaker 3

If it is about practical topics, you can also contact us.

00:20:19 Speaker 3

But I would say that we have created a good overview.

00:20:23 Speaker 3

We have shed light on what the goal of the udder bit was.

00:20:26 Speaker 3

We had a look at what the EU has just published in this context.

00:20:32 Speaker 3

This then also resulted in the transition periods.

00:20:35 Speaker 3

We had looked at this with examples of when which transitional period applies.

00:20:40 Speaker 3

We have recognized that it is high time to get clarity about the product portfolio, about the UDI, also the planning and to get the necessary IT projects off the ground or, better yet, actually complete them, because otherwise it will be extremely tight.

00:20:54 Speaker 3

And you know that Professor Hunter and his team are just as ready as I and my team are.

00:21:00 Speaker 3

Yes, there is only one more thing left for me to say a thousand thanks for this refreshing interview.

00:21:05 Speaker 1

Thank you very much.