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Expert Panel: How Manufacturers Are Paying For Notified Body Struggles

by Amanda Maxwell

The increasingly challenging environment that EU notified bodies find themselves operating in is translating into some real headaches for device and diagnostics manufacturers. Here, three top EU medtech regulatory experts spell out the challenges.

Bassil Akra, Gert Boss and Erik Vollebregt

It is no secret that EU notified bodies have been working in an increasingly supervised environment, a trend that has accelerated in the last four to five years. These organizations have been hit with the most far-reaching EU regulatory changes within the context of the Medical Device Directives and related guidance documents. Now, they are having to prepare for even more stringent requirements and scrutiny to become designated under the new Medical Device and IVD Regulations.

This is inevitably leading to consequences for device manufacturers, as Erik Vollebregt, partner

at Axon Lawyers, indicated in his recent blog post, "*The Notified Body Conundrum*." But is the picture as bleak as Vollebregt paints?

Medtech Insight spoke with Vollebregt, along with two other respected EU regulatory experts: Gert Bos, executive director and partner at Qserve consultancy, and the former president of the EU notified body association TEAM-NB; and Bassil Akra, VP of global focus teams (cardiovascular, orthopedic and clinical) at German notified body TÜV-SÜD Product Service.

> ***"While I have seen letters to clients from notified bodies dropping a specific code, I have not seen that many. Such decisions tend to be down to losing staff," Qserve's Gert Bos says.***

In the discussion, we sought insights into the questions that Vollebregt raises, and more about how the authorities tightening control over notified bodies is resulting in some very challenging situations for device-makers. One thing that comes out from our discussion is, the lack of transparency about who has applied for designation under the MDR and IVDR is making informed decision-making more difficult for device and IVD companies.

The European Commission, *Medtech Insight* understands, will not publicly identify the names of applicants, and there are no signs yet that the national designating authorities will either.

Read the details of the conversation below.

Q ***Medtech Insight*: Vollebregt mentioned recently in his blog post how notified bodies are struggling to cope, especially with limited experts. He specifically referenced how losing staff can result in notified bodies suddenly informing some device companies that they can no longer support them because they must drop a specific code of their designation. How frequent an occurrence is this? And how long do companies have to find a new notified body to cover that specific code when it happens? Until their valid certificate runs out? Or does the certificate become immediately invalidated in this situation?**

A Gert Bos: While I have seen letters to clients from notified bodies dropping a specific

code, I have not seen that many. Such decisions tend to be down to losing staff – in most cases, the notified body concerned will probably only have a few clients under the code that they are dropping. If they had many, they would not rely on a single person and have sufficient back-up. Indeed, historically, the majority of countries have demanded at least two people per code, e.g., one internal and one external so they would have back-up in most cases.
But for the manufacturers involved, it truly is a nightmare to get a letter from the notified body stating they invoke the paragraph from the contract in the 90-day notice period.

Changing notified body in 90 days only is a huge challenge anyway, but if your previous notified body dropped the code it is simply undoable; the new notified body will not trust the work done by the previous notified body, and will scrutinize dossiers and quality systems.

There have been a few cases where CE-marking certificates have been prolonged under threat of a court case to allow the manufacturer a longer transition period to be certified by a new notified body, as manufacturers are defending their own future.

"I've seen at least one company having been orphaned and not being able to be recertified by a new notified body in time, which turned out disastrous for the company involved," Axon's Erik Vollebregt says.

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Bassil Akra: We have had a series of requests from manufacturers asking if we can take over following a notified body dropping a code or ceasing activities. This is tending to happen in specific geographic regions and among particular notified bodies.

It puts manufacturers in a vulnerable position, as Bos said, because even where they still have a CE-marking certificate that is theoretically still in date and still valid, any potential new notified body is going to be very cautious about accepting oversight for a device where the previous notified body was struggling, especially if that notified body had been instructed to reduce its scope by the designating authorities, or had been found to have major nonconformities. Nor can the company apply from the beginning again as if the device has never been on the market.

Moreover, a certificate can only remain valid in such cases if the notified boy's competent authority grants a "grace period."

Erik Vollebregt: I don't know absolute numbers because I only know what clients and others tell me. I do know that I see and hear about it more and more, and expect this to happen more. In theory, certificates that were granted in a situation where the notified body's expertise is not under discussion remain valid until the termination date of notified body mandate. But this depends on feedback from the competent authority.

Q **Also, the blog mentions that notified bodies are applying for a more limited scope under the MDR or the IVDR than currently. How serious is this problem? Are we talking about most of them, half of them, or just 5% to 10% of them?**

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Bos: It is hard to say. The 10 largest notified bodies have indicated that they are applying for a similar scope under MDR compared to their MDD scope, and IVDR applications tend to be wider than their IVD scope.

But notified bodies have also been selectively dropping codes before a joint audit would force them. With the new scrutiny under MDR/IVDR, one could easily see that some would drop another few codes.

Akra: To my knowledge, none of the notified bodies are intending to reduce their scope. Of course, it is worth pointing out that the cost of offering a service for high-risk devices is too much for most of the smaller notified bodies. But then again, it

seems that some of the newcomers are intending to apply for a broad scope.

Vollebregt: I don't have market-wide figures of course, but I see instances of this about to happen with clients, and this will create big problems for companies. We will only know for sure when the notified bodies that do apply on Nov. 26 are transparent about the scope they applied for.

Q **Vollebregt mentioned that there is the possibility for companies who find themselves in limbo in this situation to have a 12-month stay of execution while they find a new notified body because of the temporary competent authority supervision clause that has been agreed to by some competent authorities. However, only the French, Swiss and Dutch agencies have made public statements on this topic. Given the demands on companies in terms of demonstrating evidence of the safety of their devices in this situation, plus the fact that they cannot make changes to their device, plus given that the situation is not clear across Europe and devices are generally sold throughout the EU, is this really a viable option? What would you advise companies that are based in Slovenia or Sweden, for instance?**

A Vollebregt: It's only a viable option if all parties involved handle these scenarios as a matter of urgency, which – in my experience – doesn't always happen. I've seen at least one company having been orphaned and not being able to be recertified by a new notified body in time, which turned out disastrous for the company involved. That's what you get if there are no deadlines, or overly tight deadlines, that the notified bodies observe.
The "grace period" agreed procedure proposed by the Competent Authorities for Medical Devices (CAMD) group allows for a subsequent 12 months in the orphanage of the competent authority (or proportionately less if the original certificate would expire under 12 months). Also, development of the device is locked during these 12 months – a company cannot change anything that would normally require notified body evaluation, such as the change of crucial supplier. This means that, additionally, the company involved is captive to any crucial suppliers and critical subcontractors during that period. Not a nice place to be.

> Bos: In my experience, I have seen Swissmedic previously shepherd some manufacturers whose notified body dropped out during a nine-months interval. This has now been increased to a more formalized 12-month program.
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> Some other countries try to protect their industry as well, but there is no EU-wide process, so some manufacturers find themselves in a worse position than others in this kind of scenario.
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> Akra: So far, we have seen authorities in France, Switzerland and the UK offering a grace period. But even where there is no official "grace period," the local competent authority should be in contact with the manufacturer and offering advice. Where it does not, the manufacturer, as long as its certificate is still otherwise valid, should approach the local authority and ask for a grace period letter, or equivalent.

"Manufacturers cannot sue the notified bodies as, more often than not, it was a designating authority decision that resulted in the narrowing of their scope," TÜV-SÜD's Bassil Akra says.

Q **The blog post mentions that manufacturers who find themselves suddenly dumped by their notified body – for whatever reason – should focus first on ensuring their documentation and clinical data are good and finding a new notified body. Or, even better, they should anticipate where the notified body may not make it under the MDR/IVDR and transfer at the earliest possible opportunity before most other notified bodies are swamped with work.**

Q **But where manufacturers are dumped, is it plausible for them to try and sue the notified bodies involved? If we envisage a situation where there is some type of group action by several manufacturers against notified bodies that have been forced to drop certain designation codes due to staffing, do firms risk overwhelming notified bodies and forcing even more out of this sector**

just at a time when firms need them most? And, arguably, isn't the root cause the way in which the new regulations are being rolled out, and therefore the Commission and other EU institutions that adopted them?

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Akra: Trying to sue a notified body would not be the best way to solve issues. Manufacturers cannot sue the notified bodies as, more often than not, it was a designating authority decision that resulted in the narrowing of their scope – often triggered by joint assessments involving combined efforts of designating authorities and the European Commission following new or more stringent criteria.

It is also important to realize that some notified bodies are simply too small to increase their resources and competence level to meet the new regulations in a short period of time. Also, from a financial strategy point of view, notified bodies may decide that the various costs (such as, but not limited to, structure, knowledge, resources and clinical expertise) linked to working with high-risk medical devices are just too steep.

These are not factors that companies could sue notified bodies for. Manufacturers would do better to spend their resources on preparing compliant technical documentation and finding the best notified body to address their strategic needs.

Vollebregt: What I am saying in my blog is that, as a company, you have to create a situation where if you are dumped the quality of your dossiers is such that you have the best chances to be recertified quickly by another notified body – which means that you have to make sure everything is state-of-the-art.

Notified bodies often dump clients in scenarios where, as an additional complication, the clinical evidence is often not up to standard – and that could be because the notified body has been OK with that for years. But that doesn’t mean that another notified body is going to accept the sub-state-of-the-art evidence.

Rather than neglect the quality of their clinical data, manufacturers should work on improving it, as to improve their chances in a switch scenario.

In that scenario, you are not going to win a case either against the previous or new notified body claiming that they must certify your device.

Class actions against abandoning codes are not going to work, because it's the discretion of notified bodies whether to drop codes.

You can only hope to successfully claim damages if the notified body acted negligently in the way they handled things.

Also, I think the root cause is in the way that the authority supervision of notified bodies has been substandard for a long time. Now that the bar has been raised, this has become painfully obvious.

I agree that the process could have been managed better, and especially that member states could exercise a lot more control on how notified bodies act when they drop their codes. Unfortunately, the newly foreseen handover procedure in the MDR and IVDR applies only for certificates granted under those regulations.

Bos: I would agree that in any transfer at this moment, the new notified body will either do a quick check or a thorough check. And key aspects in such review would be consistency in claims, seriousness of risk management, and a balanced approach to support clinical claims in line with the clinical evidence guidance document MEDDEV 2.7.1 rev 4, as well as compliance demonstrated in the clinical evidence plan (CEP) and Clinical Evaluation Report.

So, if a manufacturer is weak in these areas, a rapid upgrade before applying might make the overall process faster, as the new notified body might otherwise lose trust in the company on first reading the available documentation.

Preventive transfers are happening a lot at this moment – where companies change notified bodies because they fear the notified body may not continue in a given area or be redesignated. But, for larger companies, they tend to spread their risk and have their feet in multiple notified bodies for eventual rapid transfers.

> In case of urgency, one of course can sue a notified body and hope a settlement can be reached. But it will not be easy for a judge to force the continuation of a certificate if the notified body claims the clinical data is insufficient and the safety of the device is not supported by reliable evidence.
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> There have been a few cases where certificates have been prolonged to allow a longer transition period into a new notified body, as manufacturers are defending their own future.
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> But a class action of any kind might undermine the entire system, as more notified bodies might drop out, or finding their legal and liability insurance will be hard to continue.

Turning to notified bodies and IVDs, in another *blog post* on the "mass extinction in the EU IVD market," Vollebregt suggested that some notified bodies that currently review IVDs will not apply under the IVDR and that there will just be five IVD notified bodies. However, there have been reports that 12 TEAM-NB members are applying for designation under the IVD Regulation, and of course there are a further 12 notified bodies currently designated for IVDs under the IVD Directive that could potentially apply that are not members of TEAM-NB. What is the likely reality?

A Vollebregt: The point is that 12 Team-NB members *intend* to apply at some point, because that's what the TEAM-NB document says – not that they are actually doing it. We don't know anything about the intention of the others that are not Team-NB members. And we certainly don't know what the chances are of any of them actually being designated. I heard the suggestion that there would be just five IVD notified bodies at the RAPS Regulatory Convergence in Washington, DC, in September of next year.

Bos: You are right that more than five notified bodies have indicated they will apply for IVDR designation. Even beyond TEAM-NB membership, rumor has it that there is likely to be at least one totally new applicant. The trouble starts with the low volume of current staff, linked with their scope and technical background. IVD notified bodies all are small, and historically they have tried to acquire staff knowledgeable on the current List A and B IVDs that need notified body review.

> With the new IVDR, the scope of products needing notified body review is hugely enlarged, meaning they not only need to hire more staff, but also people with different skills. It is likely to be a challenging process for many of them to emerge from the designation process with a considerable scope. On the other hand, for those that succeed it is highly likely to be worth their investments given the anticipated huge increase in volume of applications for those notified bodies.
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> Akra: Unfortunately, there is a lack of transparency in this area. But I, too, have heard that there are some newcomers who have put in applications; it seems they are based in Ireland, Bulgaria and Croatia. At TÜV-Süd, we plan to publish details of applications under both the MDR and the IVDR, and we will be encouraging TEAM-NB to encourage all its other members to do the same. While there may be some among the 12 TEAM-NB notified bodies that are intending to apply under the IVD Regulation whose applications were not made on Nov. 26, we can expect these will follow in the not-too-distant future.

From the editors of Clinica