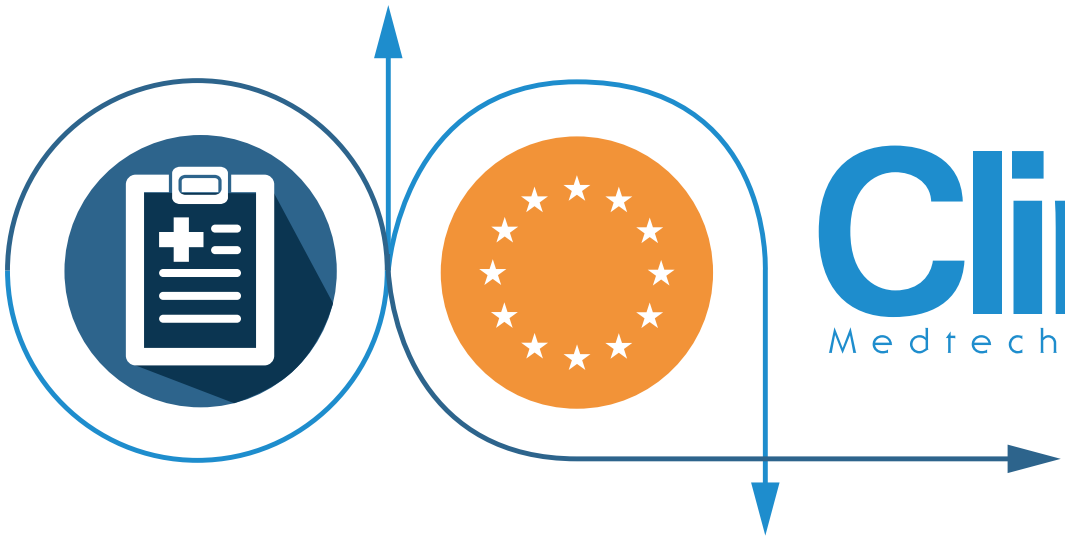

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Overworked Notified Bodies Turn Clients Away And Demand Own 5-Yr Transition

By Amanda Maxwell, 2 November 2015

EUROPE'S NOTIFIED BODIES that are designated to test medical devices and IVDs are running out of capacity to accept new clients or conduct new assessments.

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Clinica has learnt that at least one notified body in the UK has claimed recently that it could not even give price quotes for new work due to existing work overload, which it attributed to "recent successes".

But the recent flood of additional requirements that are now expected of notified bodies and the time it takes to develop or acquire the additional skills needed in today's tighter regulatory environment are taking their toll.

It seems that there are not enough auditors with sufficient time nor skills to meet the needs of the medtech industry.

While notified bodies are reluctant to speak out individually about this situation for fear of the impact it may have on future business, the European association of notified bodies, TEAM-NB, is now stepping in.

TEAM-NB has just issued a position paper explaining not only how the workload of notified bodies has increased over the last few years, but why it is going to keep increasing and what needs to be done now to prevent a crisis.

Among its suggested urgent measures to address the growing notified body shortages, TEAM NB is calling on legislators to ensure the new medtech regulations allow sufficient time for notified bodies to be designated, or re-designated, and then to carry out the necessary audits/dossier reviews of manufacturers and their products.

The association believes that the legislators need to give the notified bodies the full transition period – and ideally as much as five years - before the requirements relating to notified bodies come into force, because of their limited resources and the huge workload.

TEAM-NB has told *Clinica* it has concerns about essential life-saving products being delayed access to the market if the notified bodies are not given this period of grace before they have to take on yet more additional requirements.

The notified bodies association is also calling on the European institutions to assess the feasibility of an EU-funding scheme for the training and qualification of auditors in the field of medical devices, not only for notified bodies but for national authorities too.

So why are such measures necessary?

This work overload and the threat to the system operating smoothly have long been predicted as the regulatory load has increased - over the last two years especially. But it is only recently that the real signs of strain have started to break through in practice.

There had already been an increase in conformity assessment procedures concerning additional requirements introduced by the Medical Device Amending Directive 2007/42/EC, including for clinical data and risk analysis.

But the flood of new requirements introduced in September 2013 through the European Commission's Plan of Immediate Actions are largely the reason for the increased workload. These

new requirements were the result of the Implementing Regulation on the designation and supervision of notified bodies and the Recommendation on notified body audits, both introduced in the context of the existing medical devices legislation.

These Commission documents have resulted in the following additional work for notified bodies:

- further training and qualification requirements for staff;
- hosting extensive joint audits which may total up to 60 auditor man days per year; and
- conducting unannounced visits in a minimum frequency (one per cycle) on top of regular assessment cycles. This generally represents a minimum of a third more audits each year.

In addition, the joint assessments by member states and commission experts of notified bodies uncovered weaknesses in many notified bodies which led, in some cases, to scope restrictions, the inability to take on new clients and even some de-designations.

Some notified bodies have even voluntarily stopped their activities and the reductions in availability led to an increase in work for the remaining notified bodies.

TEAM-NB's Reaction

TEAM-NB notes that most notified bodies have started hiring new auditors, but this is a considerable way to go.

"There is a lack of available qualified people on the market," it says. Indeed, in the case of the UK notified body that had ceased quoting, it is taking measures by upskilling existing auditors and recruiting, but warns this will take time.

It requires "a training period of six to nine months before the new auditors are able to take over some audits", TEAM-NB said. For dossier reviewers it can be much longer – about a year to be fully operational and up to three years to be able to do all reviews with a broad scope, TEAM-NB explained to *Clinica*.

Already, demands for better application reviews, and checks upfront of available resources for quality systems audits, dossier reviewers and clinician reviewers etc mean that:

- the quotation process itself is longer than before (2 to 3 months instead of a week up to 1 month); and
- the timeline from contract signature, either for a new client or for a scope extension with an existing client, to audit planning is now around 6 months although it was usually around 3 months in the past; the same delays may occur at the start of dossier reviews.

Gets Worse Before It Gets Better

But if it is tough now for notified bodies to manage all their growing responsibilities now, it is going to become much more onerous.

TEAM-NB says the trends show clearly an increase in applications from new manufacturers and/or for new products, including applications for innovative products such as nanomaterials, mobile health applications, robot, and genetics testing. These innovative medical devices usually demand time-consuming reviews, it notes.

And of course the new Regulations for medical device and IVD are in the pipeline and expected to be adopted within the next two to six months.

All notified bodies will need to be assessed - and re-notified - against the new regulatory requirements in the Medical Devices and IVD Regulations before they can audit manufacturers against them. This is a huge undertaking for the whole sector and the arguably the biggest upheaval that notified bodies will have encountered since the EU-wide medtech regulations have been introduced.

It is probably unlikely, TEAM-NB notes, that notifying authorities will be able to assess the 40 to 50 applications forecast ahead of the new Regulations becoming mandatory for manufacturers. This means there is a risk that some notified bodies will not be in a position to audit – or re-audit – their clients.

The question of planning of notifying audits by designating authorities and the publication of the notifications also has to be addressed. If publication occurs as soon as an individual notified body is designated, that will lead to unfair competition and an additional burden for the first notified bodies to be notified. TEAM-NB believes, along with a risk of transfer requests.

Moreover, when it comes to the new IVD Regulation, this is likely to see a major increase in workload for notified bodies – under the current IVD Directive 80% or more of IVD manufacturers do not need to involve a notified body, in future 80% or more will need to.

What Should Companies Do?

Because of the current lack of capacity among notified bodies, TEAM-NB told *Clinica* that it would recommend that medtech manufacturers call a number of notified bodies prior to formal application and ask if they have capacity in a certain scope/clinical area.

The association suggests trying to find two or three notified bodies with an adequate scope and enough resources before making the formal application in case hurdles are encountered.