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EU Notified Bodies Prepare For En Masse Redesignation

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Executive Summary

Members of the TEAM-NB association, which account for about half of the anticipated future force of EU medtech notified bodies, are taking a coordinated approach to applying for redesignations against the new EU Medical Device and IVD Regulations. Will they succeed?

The EU notified body association, TEAM-NB, is working to support its 22 members to jointly submit their applications to the European Commission for redesignation under the forthcoming Medical Device and IVD Regulations.

The association is asking the European Commission and national competent authorities to review these applications concurrently and declare the successful new designations simultaneously to the degree that is possible.

TEAM-NB believes that by standardizing the approach among its members, it will help simplify the joint audits of the notified bodies conducted by the European Commission and competent authorities for redesignation purposes.

There has been much concern expressed by notified bodies, and their device-manufacturer clients, about the competitive advantage that could be gained by being among the first to be redesignated under the new EU rules. TEAM-NB hopes its coordinated approach will help even the playing field and that the Commission will accept the strategy.

Of course, the association is acting only on behalf of its members. There are likely to be another 20-40 testing and certification bodies that will apply for redesignation under the new regulations that are not members of TEAM-NB.

There are currently just under 40 notified bodies practicing under the current medical device directives that are not TEAM-NB members, but estimates suggest that perhaps as few as 20 of those organizations will have the resources and will to apply under the tougher new regulations.

Pros And Cons Of Being First, And Last

There have been reports of some of the non-TEAM-NB members waiting for the adoption of the new regulations (expected in the coming months) to assess whether they want to push forward in operating as a medtech notified body under enhanced rules.

But experts say this approach will put these organizations into a difficult position, where both the notified body and the device manufacturer that hired it will be adversely impacted by being at the back of the queue for redesignation. For device-makers that need to have their products redesignated within a relatively short timeframe to remain on the market, this could be a difficult issue, not least because other notified bodies are unlikely to have the capacity to take them on at the 11th hour.

The TEAM-NB approach is likely to be welcomed by the European Commission and competent authorities, *Medtech Insight* notes, because the Commission will be measuring performance within what is likely to be a well-structured framework during the early phase of redesignation audits. By addressing the TEAM-NB designations concurrently, it could provide a baseline off of which to more easily measure the performance of notified bodies that are not members of TEAM-NB and, thus, who do not claim compliance with that organization's Code of Conduct and may work in a less standardized way.

Making Redesignation As Straightforward As Possible

The job of the regulators will be made easier by all TEAM-NB members addressing the requirements in a similar way, Francoise Schlemmer, director of the association, explained to *Medtech Insight*.

The association has been doing a great deal of preparation in the last few months. In particular, it has set up working groups to, among other actions, draft a handbook outlining a standardized approach to prepare for redesignation and associated audits; prepare guidance; and review the new regulations, particularly the chapters and annexes focused on notified bodies.

The groups are also performing a gap analysis comparing the requirements of the MDR and IVDR against 2013 European Commission recommendation on audits and assessments by notified bodies and the 2013 European Commission implementing regulation on the designation and supervision of notified bodies. The goal is to ascertain what extras notified bodies need to install in their quality management systems to be successfully designated against the new regulations.

The TEAM-NB working groups have completed the first phase of their efforts and plan to meet shortly in Munich, Germany, to discuss phase two of this work. Key focus areas for the second phase will be supporting notified body members in making the necessary quality system changes and fulfilling the necessary submission criteria. The working groups will work to provide members with checklists, guidances and flowcharts.

Members of TEAM-NB are already generally in good standing with the European Commission because each one has to comply with the TEAM-NB Code of Conduct. The association claims that the requirements of the code go beyond the current EU Medical Devices Directive (MDD) and *In Vitro* Diagnostics Directive (IVDD), and are a big step toward complying with the new MDR/IVDR.

Being Realistic

Notified bodies will need to be ready to submit their applications for redesignation six months after the new regulations take effect, which is expected in May or June.

This is a tough goal. Being realistic, Schlemmer says that if 16-18 are ready by that time, this would be considered a big success. It is likely that some notified bodies – up to 40% or those that apply – might be found to have major non-conformities against the new regulations, which would take time to address. Ultimately, Schlemmer said, if 10 of its members are designated against the new MDR/IVDR during the first wave, Team-NB will see it as a success.

The MDR and IVDR state that notified bodies can submit their applications starting six months after the regulations take effect. After that, the competent authorities and the Commission have 18 months to review the submissions, to carry out the joint audits and to make their designating decisions.

In practice, it remains to be seen whether all the structures are in place to make this possible.

Where TEAM-NB Notified Bodies Are Seeking Redesignation

THERE ARE 22 NOTIFIED-BODY MEMBERS OF TEAM-NB, AND ALL CURRENTLY PLAN TO CONTINUE OPERATING UNDER THE NEW EU REGULATIONS. THIS TABLE BREAKS DOWN HOW MANY OF THE ORGANIZATIONS PLAN TO OPERATE IN KEY COUNTRIES. ALL NOTIFIED BODIES APPLYING UNDER THE IVDR ARE NOTIFIED BODIES THAT ARE ALSO APPLYING UNDER THE MDR. IN THE CONTEXT OF THE BREXIT DISCUSSIONS, IT IS WORTH NOTING THAT UK AND IRISH NOTIFIED BODIES ACCOUNT FOR FIVE ORGANIZATIONS THAT HAVE APPLIED TO BE DESIGNATED UNDER THE MDR AND FOUR OF THE 11 UNDER THE IVDR.

Country	MDR	IVDR*
Germany	7	3

UK	4	3
Netherlands	2	1
Denmark	1	1
Turkey	2	0
France	1	1
Ireland	1	1
Czech Republic	1	1
Sweden	1	0
Slovenia	1	0
Norway	1	0
TOTAL	**22**	**11**

A full list of TEAM-NB members is available on the TEAM-NB website.

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