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Stalemate Over Virtual Audits In EU As Commission Tells TEAM-NB To Back Off

by Amanda Maxwell

Notified bodies' efforts to enhance a harmonized approach to remote audits have failed, raising questions about whether there is any avenue left to get vital devices certified by the 26 May EU MDR deadline.

The European Commission has told the EU notified body association, TEAM-NB, that it is not within the association's remit to develop a position paper providing guidance and interpretation on the commission's notice on virtual audits.

So the association has had to fully withdraw the draft position paper which attempted to lay out a cautious way forward. It had been proposing virtual audits, decided on a case-by-case basis where justification could be made.

Medtech Insight notes that this is arguably the first time that the commission has told a medtech organization to withdraw, rather than amend, a proposed position paper which was intended to help bring clarity and harmonization in interpreting a document whose legal impact is far from clear.

How The Virtual Audit Situation Threatens Product Availability

The commission notice fails to provide a legal way forward on how and when virtual audits can be carried out during initial MDR audits. While physical audits are being made difficult, and in many cases impossible, by the current COVID-19 pandemic, this means that many products cannot be audited.

Without the go-ahead to be able to conduct audits virtually, notified bodies' ability to fulfil their role in auditing medical devices under the MDR is being impacted.

Today, TEAM-NB has an opportunity to make its case to the Medical Device Coordination Group (MDCG), which helps the commission with Medical Devices Regulation /IVD Regulation implementation issues. It only

has a 5-10 minute slot; but it hopes that its concerns will prompt further review of this topic.

Commission Damaging Years Of Work?

The commission stance effectively blocks the way forward for the harmonization of virtual audit conditions among notified bodies.

Moreover, it places many testing bodies in a situation where they feel they cannot fulfil their critical auditing role; they fear they will not be able to certify key products in compliance by the MDRby 26 May, given that the COVID-19 pandemic is still hampering initial audits being carried out in person.

It means that products that cannot benefit from the grace period up until 26 May 2024 and that have not already received an initial audit are unlikely to receive a conformity assessment certificate before the 26 May 2021 deadline for the MDR and will need to be withdrawn from the market as of 26 May 2021.

The commission notice also threatens IVD manufacturers' ability to be compliant in time for the 26 May 2022 IVDR deadline.

Products that are particularly under threat of having to be withdrawn from the market (or not making it onto the market in the case of innovative products) are those that cannot benefit from the MDR's three-year grace period (see box) and include custom-made, class III devices, software devices and devices where there have been significant changes to the design or intended purposes.

There is frustration in the medtech sector that this situation is going to cause delays in certificates being issued under the MDR and the IVDR, as those attending the Qunique panel session on virtual audits heard during the second week of February. (Also see "*Commission 'Must Act' Over Uncertain Virtual Audit Situation As Threat Looms Over MDR Certificates*" - Medtech Insight, 17 Feb, 2021.)

Member States Nervous

The notice leaves responsibility in interpreting the document with individual member states and their notified bodies.

Director of TEAM-NB, Francoise Schlemmer, told *Medtech Insight* that the content of the notice has made some member state authorities so concerned of the legal consequences of allowing their notified bodies to carry our virtual audits that many are deciding against permitting such audits under the MDR.

Further clarification and direction is urgently needed, *Medtech Insight* notes, but it is difficult to see where it will come from.

Fragmented Response

As things stand, and unless the commission updates its notice to provide more clarity and direction, there is the likelihood that different member states and different notified bodies will choose different solutions for MDR products.

This would fundamentally undermine confidence in the embryonic EU MDR medtech regulatory system; moreover, the lack of clarity appears to be work counter to all the goals that the new Regulation aims to put in place in terms of harmonization and transparency.

It also means unfair competitive advantage for some manufacturers.

TEAM-NB Efforts Frustrated

TEAM-NB has tried to take a series of pragmatic steps to help ensure that its members are able to audit products which will otherwise become unmarketable from 26 May.

Not only has it drafted a position paper aiming to ensure a uniform and practical way forward with remote audits, it has carried out a survey to assess how successful virtual auditing have been among its members. This survey demonstrated that as many non-conformities are found during virtual audits as in-person audits. TEAM-NB believes it provides adequate justification for its members to carry out virtual audits based on careful case-by-case analysis

Another measure TEAM-NB has taken is to provide urgent training to its members on how to optimally perform virtual audits.

For notified bodies, the ultimate frustration is not being able to do the job they feel equipped to do, at the same time as knowing how this will hold products back from the market and also lead to potentially unmanageable bottlenecks between now and May 2024 , the end of the grace period, where the whole sector, plus patients, are likely to suffer.

Products Stuck In The Pipeline

While this nebulous situation persists, some manufacturers have found their products stuck in the middle of the EU MDR conformity assessment process. While they had taken all the steps necessary to normally achieve conformity assessment by a notified body in time for their products to be CE marked by 26 May, the social distancing and travel restrictions rules have worked against them getting an audit. And for many of these, Schlemmer told *Medtech Insight*, it will already be too late to finalize the process even if they were to receive a fully recognized audit shortly.

What Is The Solution?

If TEAM-NB is not permitted to provide a way forward, where can the medtech industry go next?

While panelists at the Qunique panel session agreed that the best way forward now would seem to be a revision of the MDR and IVDR to permit virtual audits, there has been no indication from the commission that it is considering such a move, and its notice would seem to be suggest that it would be unwilling to do this on what it would judge as safety grounds.