The need for ‘virtual audits’ under the Medical Device and In Vitro Diagnostic Regulations in the context of a pandemic, such as COVID-19

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POSITION PAPER

Call for Action

The medical technology industry urges the European Commission and Member States to publish guidance clarifying that in place of 'on-site' audits, Notified Bodies may conduct audits under the new Medical Devices and In Vitro Diagnostic Medical Devices Regulations in a 'virtual' mode by using all available technological solutions and following a risk-based approach. The scope of these 'virtual' audits should not only be limited to COVID-19 related products.

The measure of allowing 'virtual audits' should apply for as long as deemed necessary by the EU to address the COVID-19 pandemic related bottlenecks or duplication of work for manufacturers and Notified Bodies when going through the process of CE marking devices.

Looking ahead and in anticipation of potential further pandemics, the medical technology industry would strongly encourage allowing 'virtual audits' when necessary and consider them as a tool to overcome challenges linked to the CE marking procedure when on-site audits cannot be performed.

The Issue at Stake

The medical technology industry welcomes the postponement of the Date of Application of the Medical Devices Regulation 2017/745 (MDR) by one year. This additional time allows for the new regulatory system to be fully operational and for all impacted stakeholders to remain focused on supporting healthcare systems combat the COVID-19 outbreak.

Industry fully commits to the European Commission's call for all actors to "ensure that this additional year is used appropriately and consciously"[1]. One critical element for device manufacturers to do so is to swiftly proceed with Notified Body audits as a step to obtain CE marking under the MDR or IVDR.

Nevertheless, the COVID-19 related travel restrictions and quarantine orders around the world, make it neither possible nor safe for Notified Body audits to happen on-site in the foreseeable future. To address this unprecedented situation the Medical Devices Coordination Group (MDCG) has issued MDCG guidance 2020-4[2] as a temporary extraordinary measure allowing – among other measures – audits under the existing Directives[3] to be conducted in a virtual mode for surveillance and re-certification audits and audits triggered by changes.

Outside of COVID-19 products, there is however, no similar extraordinary guidance that would apply to audits that are supposed to happen under the frame of the two new Regulations. This leads to situations where manufacturers who aim to transition to the new Regulations as early as possible, are currently held back by Notified Bodies' assumption that audits under the MDR/IVDR must be conducted at the manufacturer's premises, i.e. on-site. Other challenging situations arise when manufacturers already

received certification in accordance with the Regulations and are not able to extend the covered product portfolio by scope extension audits, leaving them caught in the middle of (AI)MDD/IVDD and MDR/IVDR certification.

This matter is of high concern, both in general and specifically regarding the risk it poses to the availability of device innovations needed to help Europe fight the COVID-19 outbreak.

Several Notified Bodies are meanwhile set-up to certify *new* devices under the two Regulations, and no longer under the three prior Directives[3]. Unless 'virtual' audits are permitted under the Regulations, there is a high potential that innovative products needed in the EU (e.g., to shield COVID-19 intensive care units from saturation) would not be available on time. These innovations include digital solutions and devices for minimally-invasive surgery, which can help moving surgeries to outpatient and ensure capacity in intensive care.

Many devices, such as pacemakers, implantable defibrillators and neuromodulation devices now include technologies that allow for remote monitoring of the patient using cellular and Bluetooth technology via secure applications available via a mobile phone or tablet. This leads to better outcomes and early warning of potential issues that require review. The technology to remotely manage patients can limit the need for patients to have follow up visits in the direct presence of a physician thereby minimising the risks posed to the healthcare provider and patient from a pandemic.

Ensuring such technology to be assessed and approved under the two Regulations allowing remote exchange of information and patient management between doctors and patients, would significantly free up critical hospital capacity during a pandemic.

In addition, while Member States are prioritising technologies and access to devices to treat COVID-19 patients, there is an obligation to treat patient with serious underlying existing health conditions. For example, those such as oncology patients, patients with diabetes and those with heart conditions that if left untreated could lead to significant adverse health consequences. Access to state-of-the-art technology and devices approved under the MDR would be of benefit and meets the EU goals of ensuring a high quality of life and protection for EU citizens.

Manufacturers who are ready to be audited under the MDR and IVDR would need to go back to working under the Directives if virtual audits are not made possible.

Current Practice and Challenges

The current challenge for audits to be conducted 'on-site' whilst COVID-19 restrictive measures are still in place is two-fold:

- Many medical device design and manufacturing sites have site-specific restrictions on access to facilities for third parties, such as Notified Body auditors, to protect the safety of workers and the continuity of product supply.
- Country and company travel restrictions severely hamper the ability for auditors and internal company experts from other areas of the world to travel and ensure a proper representation at the audit.

Manufacturers who are planning to undergo the conformity assessment under the new regulatory framework have to suspend the certification process and might have to go back to operating under the medical device Directives to conduct audits virtually and compliantly placing their devices on the EU market. Alternatively, manufacturers would be forced to either seek derogations from the conformity assessment requirements (where eligible), or otherwise potentially even stop supplying certain devices to healthcare systems and patients.

The option to abstain from the certification under the new Regulations and 'to go back' to a certification under the three Directives to address the current COVID-19 limitations with respect to audits would come with substantial inefficiencies. For instance, for the medical devices' sector it would mean:

- The AIMDD/MDD route implies duplication of work and a general increase of workload because the structure and content of the technical documentation differ significantly between the MDR and the AIMDD/MDD.

- In addition, manufacturers would face challenges bringing themselves into compliance to MDR and this later than originally planned, thereby risking the creation of unnecessary bottlenecks and capacity issues at Notified Body level. Allowing MDR virtual assessments would allow to help flattening the peaks of workload faced by Notified Bodies.

- Several MDR-designated Notified Bodies are not set-up to redirect substantial capacity towards continued AIMDD/MDD certification work and are explicitly limiting this route to very exceptional cases.

- Even in those cases where Notified Bodies perform virtual auditing and certification under the Directives, e.g., for devices which are "*clinically necessary during the period of COVID-19 restrictions*" as per the MDCG 2020-4 guidance, an additional on-site verification audit will be required, which requires both the Notified Body and the manufacturer to allocate additional resources. Today already a backlog situation is building up for the time after the end of the pandemic.

For the IVD sector, there is a need to schedule on-site audits by the end of 2020/early 2021, to certify products against the IVDR by that Regulation's 26 May 2022 deadline at the latest.

Some manufacturers – who already scheduled audits – may face significant delays due to restrictions that prevent auditors from travelling to their premises. Manufacturers who now want to plan audits are similarly facing delays in moving ahead with their transition to the IVDR due to the COVID-19 lockdowns.

Proposed Solutions

Considering the above, industry suggests allowing audits under the MDR/IVDR to happen virtually, by using all available technological solutions and a risk-based approach.

Recommended conditions for these virtual audits include:

Initial MDR/IVDR QMS certification audits

- Virtual initial QMS certification audits should be allowed and undertaken under the Regulations for a new technology or a significant change to an existing device, which may be considered critical or useful to healthcare systems, when an on-site audit is not possible due to a pandemic crisis (like the COVID-19 outbreak). The following should be considered:

    - The previous QMS audit under the Directives led to no major findings that could present a barrier to MDR/IVDR certification, or
    - The manufacturer's site is certified under ISO 13485; and/or under the Medical Device Single Audit Program (MDSAP) – these audits have already been successfully done remotely.

- Alternative approach: Conduct a virtual QMS audit while the COVID-19 (or similar) crisis is ongoing, then (in the case of a positive audit outcome) issue a certificate, and schedule an on-site audit, within a defined time period, but after the crisis has been declared to be over.

Surveillance audits

Considerations for manufactures that have already completed their initial MDR/IVDR audit:

- Apply the same logic as in MDCG 2020-4
- Conduct surveillance audits in 2020 virtually
- Sample technical documentation via virtual audit

The possibility to use temporary alternative extraordinary measures such as virtual audits using available technological solutions would be an efficient solution to respond to the existing challenges.

Information and Communication Technology (ICT) solutions such as Google glasses, webcams, use of teleconferences should be fully leveraged, as they allow site manufacturer representatives to walk auditors through the manufacturing lines (IAF MD 4:2018)[4]. In cases where the Notified Body has already visited the manufacturer's premises in the past (whether for audits under the Directives or for MDSAP or ISO assessments), an additional physical inspection of the site may be considered not necessary and unwarranted in light of the risks of infection to both the auditors and to the manufacturing site's staff.

Virtual audits would help manufacturers transition device certifications as swiftly as possible to the new Regulations whilst acknowledging and operating under the restricted format due to the COVID-19 induced circumstances.

Virtual audits would aid manufacturers in their efforts to providing sustaining and breakthrough technologies, devices, and solutions to their patients while demonstrating compliance to the new Medical Device/IVDR Regulations.

With proper guidelines and a clear risk-based approach, virtual auditing can happen in a way that maintains patient safety and device performance, allowing for safe, efficient and innovative devices to reach in a sufficient quantity the user and patient to support uninterrupted treatment and support.

Legal Background and References

MDR Annex IX Section 2.3 Annex VII section 4.5 and Annex XI Section 6.3 and the IVDR require that, before issuing an EU certificate, the auditors conduct a Quality Management System (QMS) audit at the premises of the manufacturer.

[1] 25 March 2020 communication from DG SANTE Unit B6 to the stakeholders of the Medical Devices Coordination Group (MDCG).
[2] MDCG 2020-4 Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions
[3] Directive 90/385/EEC, the AIMDD; Directive 93/42/EEC, the MDD; Directive 98/79/EC, the IVDD
[4] IAF MD 4:2018 IAF mandatory document for the use of information and communication technology (ICT) for auditing/assessment purposes

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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