TIC Council Recommendations to Improve MDR/IVDR transition process

September 2021

TIC Council appreciates the European Commission's (EC) efforts to implement the new Medical Devices Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746) which have already entered into force and are applicable from May 2021 and May 2022 respectively.

These two new EU Regulations aim to improve patient safety by strengthening qualification requirements for medical infrastructures, devices, products, as well as by tightening market surveillance requirements. In line with TIC sector's mission to support the design of policies that improve health and safety while promoting innovation and facilitating trade, the objectives of these new Regulations are fully supported by TIC Council.

However, TIC Council would like to express its concerns regarding the effectiveness and speed of implementation and application of the texts. There are a series of challenges that TIC Council members (Notified Bodies - NBs) and manufacturers face that could lead to unprecedented consequences. Challenges faced by NBs include:

- Delay of important MDCG (EC's Medical Device Coordination Group) guidance and documents, which are essential for clarity and consistency of NBs processes;
- Frequent changing processes, due to National Authority demands for changes (especially in Quality Management System), or due to MDCG guidance that revise previously accepted and implemented NB processes;
- Restrictions and lack of harmonization among member states on the use of remote/hybrid audits, as these are only permitted in case of a risk of shortage for medical devices and application varies considerably among Member States;
- Manufacturers' uneven and limited understanding and awareness of the content and consequences of the new regulations, leading to late and faulty applications/submissions;
- Slow and inefficient designation process;
- High number of expiring AIMDD/MDD/IVDD certificates that need to be renewed with MDR/IVDR certificates will induce a peak in the workload of NBs in 2024[1].

[1] https://www.team-nb.org/wp-content/uploads/2020/12/Team-NB-PositionPaper-ExpiringCertificates-20201215.pdf

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These challenges, among others, leads to longer certification processes, higher costs and slower time to market. And most importantly, if not addressed, they will have a major impact on device availability and consequently on patient safety, security, and health.

To address these challenges and ensure the continuous availability of safe and performant medical devices/IVDs on the European market, TIC Council recommends:

- **Ensure harmonisation and acceptance of remote/hybrid audits** under the Regulations. Remote audits have proven to be effective and suitable according to data from Team-NB survey[2] and would support the MDR/IVDR transition;

- **Improve speed and transparency of the designation of Notified Bodies** to avoid bottlenecks. NBs should be able to easily track status of applications as well as receive timely and clear communication about potential delays of their applications;

- **Encourage manufacturers to continue to make progress with Regulation submissions in** order to minimize workload peaks in the coming years;

- **Ensure MDCG guidance are clear and published in timely fashion**.

The TIC sector welcomes the opportunity for further discussions with the Commission in support of an aligned and coordinated effort during these challenging times to ensure the continued delivery of life-saving medical devices in the European market.

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[2] https://www.team-nb.org/wp-content/uploads/2020/11/Team-NB-PositionPaper-RemoteAudits-20201118.pdf and https://www.team-nb.org/wp-content/uploads/2021/06/CIRCABC-Remote-Audit-Analysis-May-2021.pdf

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About TIC Council

TIC Council is the global trade federation representing the independent third-party Testing, Inspection and Certification (TIC) industry which brings together more than 90-member companies and organizations from around the world to speak with one voice. Its members provide services across a wide range of sectors: consumer products, medical devices, petroleum, mining and metals, food, and agriculture among others. Through provision of these services, TIC Council members assure that not only regulatory requirements are met, but also that reliability, economic value, and sustainability are enhanced. TIC Council's members are present in more than 160 countries and employ more than 300,000 people across the globe.

The Value of TIC Report

To learn more about TIC Council and its member's activities, the landmark report on the Value of the TIC sector, developed jointly by the international law firm Steptoe and the London-based consultancy Europe Economics is now available to read. This report illustrates, by using data and case studies, how the TIC sector benefits a variety of stakeholders and industries around the world. You can find the study here, and we welcome you to share it with anyone who might be interested.

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