TIC Industry Global Position on Medical Device Conformity Assessment Policies

Conformity assessment frameworks that leverage the independent third-party testing, inspection and certification (TIC) industry allows governments to rely on the private sector to ensure the supply of life-saving medical devices that meet safety, quality, cybersecurity and privacy requirements.

In particular, health emergencies such as the COVID-19 pandemic have demonstrated the value of robust and effective public-private partnerships for medical device safety and verification. Established accreditation frameworks involving independent third-party conformity assessment bodies (CABs) provided the capacity and specialization to support governments and better prevent devices from being placed on the market without the proper verification. The COVID-19 response involved a considerable work effort from regulators, manufacturers and the TIC industry to support the market entry of adapted devices for the diagnosis, prevention, and monitoring of the disease.

In this context, and to ensure that patients benefit from the timely approval of medical technologies, TIC Council provides the following recommendations to policymakers:

1. **Leverage private-sector conformity assessment to fulfil policy objectives**: CABs have the ability to scale services, technical expertise, and offer innovative technologies to provide services in a cost-effective manner. These allow governments to save resources and focus their role on oversight and supervision of a market-based approach. Some examples are included below:

    a. European Union market access for medical devices (higher risk classes) is enabled through independent third parties called Notified Bodies. This system allows an economic driven buildup of technical resources. In addition, competition between the Notified Bodies enhance both service quality and efficiencies.

    b. In the U.S., the FDA is seeking to increase third-party involvement to foster improved time to market and approval process efficiency such as in the 510(k) third-party review program[1] as well as the new ASCA program[2].

    c. In 2008, the U.S. Occupational Safety and Health Administration (OSHA) estimated that it costs about US$1 million annually to operate the Nationally Recognized Testing Laboratory (NRTL) program. If OSHA were to stop relying on accredited independent third-parties, the Agency would need to spend approximately US$360 million annually ($430 million in today's dollars) to maintain the program[3].

2. **Implement Good Regulatory Practice (GRP) and regulatory convergence:** GRP fosters an open, transparent, predictable and accountable regulatory environment and provides the foundation for regulatory convergence between different jurisdictions, reducing costs and time to market. Further, GRP and regulatory convergence facilitate mechanisms through which CABs can deliver single certification services that meet the requirements

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[1] https://www.fda.gov/medical-devices/premarket-submissions/510k-third-party-review-program
[2] https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca
[3] https://www.regulations.gov/document?D=OSHA-2008-0032-0099

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of multiple jurisdictions, as has been demonstrated through the Medical Device Single Audit Program (MDSAP). Where possible:

    a. Engage regulators from across the globe towards regulatory convergence multilaterally within the International Medical Device Regulators Forum (IMDRF) Working Groups and via bilateral dialogues.

    b. Use international standards as a basis for national technical regulations consistent with WHO guidance and WTO requirements in lieu of creating country-unique requirements.

    c. To the benefit of secure global supply chains engage in harmonized organizational and technical criteria related to cybersecurity and privacy requirements

    d. Leverage existing international conformity assessment mechanisms such as the IECEE CB scheme.

3. **Develop effective conformity assessment policies**:

    a. **Provide market access through National Treatment** for both manufacturers and CABs: global device manufacturers frequently rely on qualified third-party CABs to help facilitate global market access. This helps to improve time to market and control compliance costs. Unfortunately, the regulatory structure of many countries requires conformity assessment and compliance functions to be carried out domestically, and in many cases only by government CABs. This makes the approval process cumbersome, slow, and more costly than necessary to ensure technical safety.

    b. **Focus proper oversight**: Regulators must develop and set clear accreditation parameters so that accreditation activities and practices are sufficiently rigorous and the technical competence ensure consistent outcomes. Additionally, clear acceptance criteria for third parties should be developed to ensure that regulators have confidence in the compliance judgement of accredited third-party CABs. Regulators may choose to accredit CABs directly or rely on independent accreditation bodies.

    c. **Consider policies to access the benefits that come with third-party participation** including a large (global) expert pool of TIC players and the marketplace for related services (e.g. trainings). Measures like governmental direct price control will jeopardize proper competence building and subsequently device safety. If involvement of CABs is not commercially attractive, the necessary expertise will not be available, leading to extended time to market, lack of product availability and eventually endangering patient safety in those markets.

The TIC industry is committed to continue working closely with policymakers across the globe to craft effective conformity assessment polices that leverage private sector resources and expertise and advances the timely access to innovative and life-saving medical technologies and patient safety.

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