



The Future of **STANDARDIZATION** in the Context of the **European Medical Device Legal Framework and Regulatory Globalization**

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European Medical Device Framework – Where do we go from here?

The European legislation governing medical devices is constantly evolving. After the relatively recent changes in 2010 that followed the implementation of amending directive 2007/47, the Commission is in the midst of preparing for a new overhaul of the framework.

With the introduction of the Medical Device Directives (medical devices, in vitro diagnostic devices, and active implantable medical devices) in 1993, Europe aimed to achieve better access to safe devices and eliminate obstacles to the free movement of products in the Member States of the European Union. Manufacturers are to follow the appropriate conformity assessment route and demonstrate compliance to the essential requirements (Annex I) relevant to the devices they are placing on the market. The Directives are clear but very general at the same time, and compliance specifics are very much deferred to other tools such as Standards and Guidance documents (the so-called MEDDEVs). This new approach to European legislation was introduced more than 25 years ago. Since then, we have witnessed great industrial growth and competitiveness in Europe, thanks largely to this flexible but solid approach.

All regulatory models have the same fundamental goals of safety. The EU model of implementing those objectives, however, differs significantly from the FDA approach and most other regulatory settings in the world.

In Europe, a large part of the responsibility is placed on the manufacturer. In the case of Class I devices, manufacturers can follow a conformity assessment route leading to CE marking without any intervention of a third-party verifier. In most cases though, notified bodies (NB) play a crucial role in verifying the quality management system and the technical files. Documentation is focused on quality assurance, safety performance, and, to a lesser extent, on demonstrating clinical efficacy. Although the need for clinical evaluation has been more emphasized in the most recent version of the Directive (Annex X), there remains a need for better guidance.

Besides the approval procedure itself and the focus on clinical performance, another main difference between FDA and EU regulations comes in the perception of risk and how to manage it. The FDA reviews specific data about complaints and uses a quantitative method of risk assessment. The EU regulatory system's risk assessment

process employs a more qualitative method, based on the entire set of available data. Licensed officers carry out the FDA's risk assessment, while the EU holds companies responsible for it.

The decentralized European model has resulted in a situation where, in particular for higher-risk devices (Class IIb and III), manufacturers can generally enter the market more quickly. This approach is an economic driver and offers industry an advantage that the European legislator is not inclined to abandon.

Since its inception, the European framework has been compared, analyzed, and criticized, not in the least by the European medical device industry itself. A stakeholders consultation organized in 2008 in preparation for the anticipated recast, revealed some shortcomings in the current legislation that are to be addressed in the forthcoming recast. One of the outcomes is the need to achieve a more uniform level of protection across the EU Member States. There are national variations in how the Directives are applied, and these lead to an inconsistent and fragmented approach. Further, there will be a focus on the monitoring of notified bodies. The 80-some notified bodies are appointed by competent authorities and have a wide spread in expertise. Central

oversight and improved information exchange between the NBs should lead to a decrease in forum shopping. Although the decentralized model is overall appreciated, some centralization is asked for when it concerns the regulation of new technologies that have difficulty finding a home under the current legislation. With regard to market surveillance and the centralized bodies, the long-awaited publicly available Eudamed database is expected to hold all information on CE marked devices, notified body assessments, and device vigilance issues.

Where Do Standards Fit in This Current and Future Framework?

The requirements for safety and performance are laid down in the European medical devices Directives and are given a technical, state-of-the-art, translation into specific technical solutions to these requirements via harmonized standards. Thus, standardization in the medical device sector must not only be seen in the technical sense but also in the political sense, as a key component of European and national public health policy. Standards provide the translation of the legislative text of the Directives into defined and measurable technical requirements based on state-of-the-art and technically feasible solutions, ie, standards define the technically feasible level of safety.

Manufacturers and other stakeholders, such as notified bodies and regulators, benefit from standardization as compliance to standards facilitates the conformity assessment process. From the

consultation effort, it appeared that the two-fold foundation of Directives on the one hand and supporting documentation on the other, will not be affected. In fact, the system should even be strengthened in order to reinforce flexibility and adaptability. Technical standards can be modified more readily in response to technological development, and their role should remain solidly anchored in the compliance process.

We are at a crossroads and need a strong reaffirmation of the political commitment to standardization and the strategic importance of standards. Lately, however, it seems that the strategic importance of standards and standardization is less evident in policy making in Brussels. In certain areas it is even under threat by a desire to return to the “old approach” with prescriptive legalized technical standards. In such an innovative and technically diversified area as medical devices, this is a step firmly in the wrong direction.

Sustainable Cost Model for Standardization

We need to define a sustainable, if possible even global, cost model for standards development and further encourage public funding to support academic and medical device user involvement in the development of standards. There is an increasing trend towards canvassing only industry and industry trade associations to fund Technical Committees and Secretariats of Technical Committees. Industry recognizes that standards development is also in their interest and contributes its fair share through direct participation and the

sponsorship of meeting venues and meeting events. In the US, regulators and user groups participate more readily in the standardization process thanks to a concerted funding effort. We have to investigate how that model could be applied to ISO and CEN.

The European “begging bowl” cost model to develop standards does not seem transparent, appropriate, or sustainable.

International versus European Standards

With more and more standards being developed at ISO level (and becoming European Standards via the Vienna agreement) how do we ensure that these International standards still support the European Directives? The future role of CEN would need to be discussed in this regard.

The medical device industry is a global industry; the device sold in Italy is the same as the one sold in China. The New Approach Directives were written in an era of European development of standards to support European Directives, which is not the case now.

Global Regulatory Trends

The European approach in standardization and regulation is a paragon for the global trend. We need our European approach in standardization and regulation to be championed within global regulatory developments.

The activities of the Global Harmonization task force for medical devices (GHTF) are taking a greater

interest in liaison with standards programs and other groups such as WHO. This is to be enthusiastically welcomed since standardization is an important pillar that supports many regulatory systems. Indeed, in a highly regulated sector such as medical technologies, standardization and regulatory processes are fundamentally intertwined.

The successful EU-China standards program is a good example and starting point.

We need to reform the way we develop standards and publicly fund the participation of authorities' experts. The same constraints on industry are also apparent for public health authorities. Direct European Member State participation in standards development, technical committees, and working groups is declining. This is of a particular danger in our sector, as it is key that public health policy and

requirements are built into standards at the development stage. Without this valuable and necessary input, a standard runs a high risk of non-harmonization at the final stage.

It is important that the reaffirmation of the importance of standards and, in particular, medical device standards, is accompanied by a strong plea that Member States and the Commission increase their participation in the development phase of standards.

Furthermore, harmonized standards and standardization in the medical device sector must not only be seen in the technical sense but also as key components of European and national public health policy. Therefore, the Commission should consider creating subvention mechanisms for national authorities' expert participation. ■



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