



Global Medical
Technology Alliance
Innovating for a Healthier World

The Need for Advancing Global Convergence of Medical Technology Regulation

Introduction

All countries have the right to protect the health and safety of their citizens and to establish laws and regulations to determine the safety and quality of health care products, including medical technologies, introduced on their territories. Medical technologies entering foreign markets should face the least burdensome regulatory system to achieve the safety and effectiveness of medical technology. Regulatory controls should be transparent, predictable, efficient, and not unreasonably burdensome. They should also not discriminate on the basis of national origin.

The challenge faced by medical technology companies is that countries impose varying regulatory requirements for controlling safety and performance of medical technology – the medical devices, diagnostic products and health information systems that are transforming healthcare through earlier disease detection, less invasive procedures and more efficient treatments.

Government regulations are one measure to provide patients high quality and safe products. However, differing regulations create unnecessary market entry hurdles, and often present as non-tariff technical barriers that impede international trade, hinder market access, delay patient access and increase costs.

As examples, such obstacles take the form of frequent burdensome re-registration requirements, prior approval in the country of origin and/or country of manufacture, excessive post-market reporting, and mandatory in-country clinical trials. These regulations are usually unreasonably burdensome and sometimes discriminatory *de jure* and/or *de facto* against foreign firms.

Such laws and regulations are especially burdensome for small and medium size enterprises (SMEs), which do not have the resources to comply with multiple requirements and cannot wait long periods with no income for product approval. In the medical technology industry, SMEs account for majority of companies and much of the industry's innovation.

Movement toward international regulatory convergence has been underway for nearly 20 years and should be further advanced by seeking a common regulatory approach, such as one based on the Global Harmonization Task Force (GHTF) guidance documents. Similar work on medical technology regulatory convergence is taking place in the Asian Harmonization Working Party, and the Pan-American Harmonization Working Party. The Asia Pacific Economic Communities (APEC) has committed to medical technology regulatory harmonization by 2020.

Key Elements to Promote Medical Technology Convergence.

- 1) The Global Harmonization Task Force (GHTF), has developed a long list of guidance documents to guide regulators of medical technology. The GHTF was created in 1992 bringing together international regulators and supply companies from USA, Canada, Australia, Japan & Europe. The objective was to enhance patient safety and increase access to safe, effective and clinically beneficial medical technologies around the world through harmonisation of regulatory systems.

The GHTF guidance documents that were developed comprise a harmonized regulatory model that has been used by economies developing their regulatory system for the first time. This is a good example of how this work could be used to promote regulatory convergence.

The GHTF has now been replaced by the International Medical Device Regulatory Forum (IMDRF) and was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the GHTF, and to accelerate international medical device regulatory convergence and advance harmonization based on international standards.

GHTF Guidance Documents are based on:

- Use of risk-based system to classify devices
 - Underpinned by ISO and IEC standards
 - Manufacturer declaration of conformity with set of essential principles
 - Conformity assessment for safety and efficacy
 - Labelling requirements with intended use and instructions for use
 - Post-market surveillance
- 2) Regulators should commit to specific timelines for reviewing and approving medical technology (for safety and, if relevant, for government reimbursement), which ensures greater predictability in market access – an especially important provision for products with an average life cycle of 18 months and for SMEs that have difficulty surviving with uncertain access. To

achieve commitments, countries must commit the resources commensurate with their regulatory requirements. For example, if a country is going to impose a pre-market conformity assessment requirement that includes examination of a dossier -- that country must have in place the number of qualified reviewers necessary to implement the registration requirement and meet its timeline commitments.

Also, there must be a way to ensure that, where required, the law imposing pre-market review can be applied to domestic firms in the same way as foreign firms; often, countries use customs/import controls to enforce regulatory requirements on foreign companies.

- 3) Once a product is approved, countries should agree to not impose periodic re-registration or reassessment requirements but should allow approved products to remain on the market unless approval is explicitly withdrawn or if the product is recalled temporarily because of deficiencies. Changes in design or manufacture are assessed under the manufacturer's quality management system and only significant changes require notification and assessment by the regulator.
- 4) Countries should not require prior approval in the manufacturer's home country or the country of manufacture before seeking, or as a condition of, approval in the domestic market. Such practices are burdensome, inconsistent with modern multilateral sourcing of supplies and, ironically, for a manufacturer to design a medical device or diagnostic for specific needs of a country.
- 5) Countries should allow clinical evidence, where required, used for approval in other countries as evidence for meeting requirements in their own regulatory system as long as the clinical data are collected in accordance with ethical standards and Good Clinical Practices, including e.g., those of international standard ISO 14155. Such a provision would have to be carefully crafted to allow countries to require domestic clinical trials when a unique, demonstrable risk must be considered – for example, for orthopedic knees when frequent bending is performed due to cultural practices. However, increasingly, countries require domestic clinical trials as a barrier to market entry or to give local clinical trial centers more business – despite their competency to perform the tests. In some cases, such requirements are carried-over from the drugs sector, where it is sometimes justifiable on the grounds of metabolic or genetic differences in populations. Such considerations rarely apply in the field of medical devices.
- 6) Countries should be encouraged to use of third party reviewers, at least to evaluate low to medium risk medical technology (low risk class devices are typically only subject to manufacturer self-declaration and not to pre-market review. The IMDRF has had a pilot study underway to introduce a Medical

Device Single Audit Programme (MEDSAP) – *one audit, one certificate, many countries*. A few manufacturers are using this means to demonstrate conformity assessment but the IMDRF is looking to encourage more manufacturers to use this programme.

- 7) All countries should commit to an active program to achieve regulatory harmonization based on international standards. Such a provision need not be overly prescriptive – i.e., they could refer to GHTF and International Standards Organization work

Support for Global Harmonization of Medical Technology Regulations

The medical technology industry supports a good regulatory system which ensures safety and efficacy of devices. Regulations which are clear, consistent and implemented in the least burdensome manner. Also, industry supports regulatory convergence but believes that industry and regulators would benefit from improved harmonization.

The benefits of a commitment to harmonize regulatory requirements for medical technology are compelling:

For Countries: Facilitates an environment conducive towards growth of the medical technology sector, enhancing innovation and growing knowledge-based jobs. Promotes patients' timely access to life-saving medical technology.

For Medical Technology Companies: Creates a predictable regulatory framework so that companies can grow and export in a sustainable manner.