The Need to Advance Global Convergence and Regulatory Reliance to Accelerate Access to Medical Technology

Executive Summary

The medical technology industry supports a strong regulatory system that ensures the safety and effectiveness of devices and promotes patients' timely access to medical technologies. Regulations should be clear, consistent, least burdensome, foster efficiency and support innovation and be convergent to international best practices and standards. Implementing global convergence and regulatory reliance as a way of advancing "smart regulation" will:

- Conserve and optimize the use of limited regulatory resources, elevate regulation to one high standard and accelerate access to safe, high-quality, effective, and innovative medical technologies to benefit patients, caregivers, and healthcare providers.
- Facilitate an environment conducive to the growth of the medical technology sector, enhancing innovation and providing knowledge-based jobs.
- Enhance global health equity through the acceleration of global access to safe, effective and innovative medical technologies.

To achieve this, GMTA outlines core tenets it recommends, and its members commit to carrying through to each jurisdiction.

Regulatory convergence and reliance advance smart regulation and underpin an efficient, resilient, and sustainable regulatory framework. GMTA recommends the implementation of globally convergent medical device regulation, reliance pathways, and the core tenets outlined below.

I. **Implement convergent regulatory frameworks based on internationally recognized best practices and standards.** Globally convergent regulation brings us closer to one transparent, predictable, and trusted standard, no matter the jurisdiction – thereby expediting access to safe and effective medical technologies.

II. **Implement regulatory reliance, including recognition**. The adoption of regulatory reliance, including recognition, is a powerful tool to facilitate accelerated access to safe and effective medical devices, by delivering significant efficiencies for economic operators and regulatory authorities, enhancing predictable decision-making and accelerating approvals. Recognition or leveraging Medical Device Single Audit Program (MDSAP) certificates for the purpose of domestic approvals by both, members of the International Medical Device Regulators Forum (IMDRF) and other regulators is an example of where reliance could be applied in practice.

III. **Implement core tenets of medical device regulations**. To further advance a smart regulatory framework, these tenets should include ensuring predictability and adequate resources, applying equal regulation to both domestic and global companies, adopting Good Regulatory Practices, harmonizing labeling requirements and adopting electronic labeling, avoiding requirements that lack patient safety benefit, accepting global clinical investigation data and leveraging real world evidence (RWE), implementing a risk-based approach to product changes, avoiding unnecessary barriers to access based on product's country of origin, and implementing a single dossier approach for pre-market review.

GMTA encourages all regulators to implement the foundational principles and core tenets outlined in this paper to benefit patients, promote public health and enable a robust and sustainable medical technology ecosystem in their home market and globally. GMTA also encourages all regulators to collaborate with each other and stakeholders to develop globally efficient, sustainable, and effective regulatory systems.

Introduction

The medical technology industry supports a strong regulatory system that ensures the safety and effectiveness of devices[1] and promotes patients' timely access to life-saving and life-enhancing medical technologies. Regulations should be clear, consistent, least burdensome, foster efficiency and support innovation, and be convergent to international best practices and standards. Implementing global convergence and regulatory reliance as a way of advancing "smart regulation" will:

- Conserve and optimize the use of limited regulatory[2] resources, elevate regulation to one high standard and accelerate access to safe, high-quality, effective, and innovative medical technologies to benefit patients, caregivers, and healthcare providers.
- Facilitate an environment conducive to the growth of the medical technology sector, enhancing innovation and providing knowledge-based jobs.
- Enhance global health equity through the acceleration of global access to safe, effective and innovative medical technologies.

To achieve this, GMTA outlines core tenets it recommends, and its members commit to carrying through to each jurisdiction.

Regulatory convergence and reliance advance smart regulation and underpin an efficient, resilient, and sustainable regulatory framework. GMTA recommends the implementation of globally convergent medical device regulation, reliance pathways, and the core tenets of medical device regulations.

Foundational Principles and Core Tenets

I. Implement convergent regulatory frameworks based on internationally recognized best practices and standards.

Regulatory convergence is a form of cooperation and collaboration between regulatory authorities and represents a voluntary process whereby the regulatory requirements and approaches across countries and regions become more similar or aligned over time as a result of the adoption of the same technical documents, standards and scientific principles (harmonization) and similar regulatory practices and procedures[3].

[1] For the purpose of this paper, the term "device" is intended to include both medical devices and *in vitro* diagnostics.
[2] For the purpose of this paper, when the term "regulator" is used, it is intended to include recognized institutions such as the World Health Organization.
[3] http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-180727-terms-of-reference.pdf

"*The future of medical products regulation is in convergence/ harmonization, collaboration, and networking based on reliance and trust*."[4] Globally convergent regulation brings us closer to one transparent, predictable and trusted standard, no matter the jurisdiction – thereby expediting access to safe and effective medical technologies.

In contrast, jurisdiction-specific requirements that depart from global best practice and standards create varying levels of regulation, build varying levels of product quality and safety, and slow patient access to innovations that transform healthcare through earlier disease detection, less invasive procedures, and more efficient treatments. Divergent regulations also create unnecessary market entry hurdles, reduce export opportunities, and result in non-tariff barriers. These regulatory hurdles can also impede international trade, hinder market access and growth, and increase costs.

Examples of jurisdiction-specific requirements that hinder access include unique registration requirements, in-country clinical trials, in-country lot testing, country-specific labeling requirements and prior approval in the country of origin and/or country of manufacturer. Other examples include re-registration requirements[5] and redundant inspections. These regulations create unnecessary complexity, are 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-sized enterprises (SMEs). In the medical technology industry, SMEs account for much of the industry's innovation.

Regulatory authorities, global health organizations, and industry have pursued regulatory convergence through international initiatives for many years to enhance regulatory capacity and efficiency and expedite patient access. These efforts towards regulatory convergence – whether through the International Medical Device Regulators Forum (IMDRF), the WHO, or others, remain highly important. Similar medical technology regulatory convergence work is taking place in the Global Harmonization Working Party (GHWP) and the Pan-American Health Organization (PAHO). **GMTA recommends the various organizations driving global convergence activities align efforts with each other.** Doing so will strengthen efforts and ensure regulations evolve into one globally recognized best practice.

At the center of global regulatory convergence is IMDRF. The IMDRF has a long history of establishing international best practices that optimize medical device regulatory frameworks. IMDRF's roots began in 1992 as the Global Harmonization Task Force (GHTF) when regulators and supply companies from the USA, Canada, Australia, Japan and Europe came together to enhance patient safety and increase access to safe, effective, and clinically beneficial medical technologies.

[4] Azatyan, S., MD, PhD (2020, November 3). WHO Activities: focus on reliance [Conference Presentation], 10th Asia Regulatory Conference. https://arc.ifpma.org/wp-content/uploads/2016/05/ARC_2020_S.Azatyan-WHO-01-11-2020.pdf, page 16. Accessed July 13, 2021.

[5] Re registration refers to the practice of requiring manufacturers to re-apply for registration of legally markets products on a periodic basis (e.g., 3, 5 or 10 years).

The WHO, in their Global Model Regulatory Framework, also references several GHTF documents as best practice. This is a testament to the quality of work and thought that went into the GHTF documents. Generally, GHTF documents use a risk-based approach and are underpinned by internationally recognized standards (e.g., ISO 13485 and IEC).

Building on this success, GHTF was replaced by the International Medical Device Regulatory Forum ("IMDRF") in October 2011. IMDRF 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, accelerate international medical device regulatory convergence and advance harmonization based on international standards. Through its diverse members, ideal practices build on GHTF documents and emerge in IMDRF Guidance.[6] IMDRF continues to elevate its convergence efforts. In 2022, IMDRF created an Affiliate membership option that broadens country participation in IMDRF and exposure to its best practices.

Implementation of internationally recognized standards is also key because standards are used to demonstrate a device meets the essential requirements for safety and performance.

II. **Implement Regulatory Reliance, including recognition**.

GMTA supports the inclusion of reliance principles as part of all medical device regulatory frameworks. The WHO defines regulatory reliance, which includes 'recognition,' as "***The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.***"[7] Today, factors such as globalization, rapidly advancing health technologies, international supply chains, evolutions in regulatory science and global pandemics have increased the focus and urgency for **regulatory reliance** to enhance regulatory capacity and efficiency worldwide. Organizations like the WHO increasingly see it as an integral part of regulatory operations. GMTA is aligned with the WHO's assessment that "***reliance represents a 'smarter' form of regulatory oversight***" and "***a decision to 'regulate through reliance' is the hallmark of a modern and efficient regulatory authority***."[8] In addition, GMTA also recommends the WHO practice recognition[9] on the decisions for stringent regulators (e.g., IMDRF Management Committee members). Doing so will avoid redundant performance evaluations, review of product changes, and inspections.

Regulatory reliance is a powerful tool to **facilitate accelerated access** in any market, but particularly in emerging markets with limited regulatory resources or a public health emergency. Benefits of reliance include:

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[6] For a list of current IMDRF members visit: https://www.imdrf.org/about

[7] The WHO Expert Committee on Specifications for Pharmaceutical Preparation, the fifty-fifth report, 2021, page 243.

[8] Id, page 256.

[9] Recognition is a subset of reliance and is the full acceptance of the regulatory decision of another regulator or trusted institution. Id, 243.

- Ensure faster patient access to safe, effective, and quality-assured devices.
- Deliver significant efficiencies for regulatory authorities and the WHO.
- Enable resilient health system preparedness and response (particularly during public health emergencies).
- Enhance the predictability of decision-making and streamline approvals,[10] product changes and inspections.
- Promote broad adoption of innovative technologies and reduce unnecessary complexity and burden.

Regulatory reliance provides an opportunity to **avoid duplication, improve resource allocation/utilization and enhance efficiency** of regulatory processes by focusing on functions that must be performed locally (e.g., vigilance and market surveillance) while informing other work (e.g., safety and effectiveness assessment) by looking to other trusted references, regulatory authorities, and/or by sharing regulatory workload and responsibility through cooperation. As many regulators recognized during the COVID-19 pandemic, regulatory reliance practices have increased value during public health emergencies as those practices expedite access to needed technologies to counter the emergency.

While GMTA encourages all regulators to adopt reliance models that include recognition of decisions by other trusted authorities or institutions, (e.g., MDSAP or marketing authorization), GMTA recognizes that regulators can benefit from both formal and informal work-sharing arrangements. The reliant regulatory authority will have to establish confidence in the counterpart authority and reach agreement on the exchange of confidential information. Such arrangements enable regulators to concurrently evaluate a premarket submission and rely on a single decision, which reduces some of the strain on an individual regulator's resources. In addition, such work-sharing arrangements can provide a centralized and efficient manner for manufacturers to submit a single, common application to multiple jurisdictions. This reduces resource burden while facilitating faster patient access to crucial medical technology. Finally, work-sharing can also build regulatory capacity through a gained understanding of review practices, tools, and decision-making. To achieve the best results, regulators are encouraged to develop a single dossier in collaboration with each other and a process where multiple jurisdictions can rely upon that single dossier.

GMTA encourages regulators to expand reliance principles beyond premarket assessments. For example, reliance is an important principle to remove duplicative post market inspections and reduce needed product change reviews. Post market reliance will ensure that manufacturers continue to develop and produce high-quality, safe and effective devices while reducing patient access delays. We encourage reliance on recently performed inspections by trusted partners, e.g., MDSAP-recognized auditing organizations. The MDSAP provides a good example of such an inspection reliance program, in which the MDSAP member countries, official Observers and Affiliate members accept MDSAP inspections in lieu of local inspections. Non-MDSAP members also benefit from relying on MDSAP inspections in lieu of performing a local

[10] For the purpose of this document the term "approval" is intended to represent the process whereby a regulator (or WHO) reviews the product information before it can be legally marketed. Different terms are used for this process internationally (e.g., approval, clearance, registration, market approval).

inspection through unilateral reliance[11]. By leveraging MDSAP audits as a replacement or supplement for local audits or a replacement for additional on-site audits, a more optimal use of resources would be granted, fostering of a common understanding of safety and effectiveness. For more information on reliance, please refer to Appendix A.

III. Implement core tenants of medical device regulation

GMTA sees convergence to internationally recognized best practices and standards, as well as reliance on foundational principles each jurisdiction should strive for. In addition to convergence and reliance, GMTA recommends the following approaches to key parts of the total product lifecycle:

1. **Ensure predictability and adequate resources**. Predictability and timeliness are essential when advancing an ideal regulatory framework. Therefore, GMTA recommends regulators commit to specific timelines for reviewing and approving medical technologies. This commitment ensures greater predictability for economic operators and health authority in the approval process to help ensure timely patient access – an especially important provision for devices with an average life cycle of 18 months. Further, to achieve commitments, GMTA recommends countries commit the resources commensurate with their regulatory framework. For example, if a country is going to require a premarket conformity assessment that includes an examination of a technical dossier and a premarket inspection, that country must have in place the number of qualified resources necessary to implement the requirements and meet its timeline commitments for all applications that may be submitted. For countries with fewer resources, implementing reliance and the foundational principles listed in this document can elevate the developing regulatory framework and accelerate access to safe and effective medical devices while minimizing the resource burden.

2. **Support innovation and apply equal regulation to both domestic and international companies.** To drive innovation, build economies, and ensure timely access, GMTA recommends jurisdictions apply regulation and non-discrimination equally to both domestic and international manufacturers and ensure that regulation can be administered in the same way.

3. **Adopt Good Regulatory Practices.** Good Regulatory Practices ("GRP") help ensure predictability, transparency, and uninterrupted access to innovative medical technologies. GRP includes impact assessment and sufficient opportunity and time for the public to comment on a draft regulation (at least 60 days recommended) as well as sufficient time to implement changed regulations (for significant updates, it can take five or more years and sometimes longer for industry to comply with new requirements). This approach helps ensure regulations converge to global best practices and allows sufficient time to adjust to accommodate new regulatory requirements. Lastly, adopting GRP also helps avoid technical barriers to trade because it ensures adequate stakeholder participation and process, including, at times, a cost assessment before updating or implementing the new

[11] Reliance and recognition may be unilateral, for example, when a country chooses to rely on or formally recognize an assessment from another country unilaterally and without reciprocity. The WHO Expert Committee on Specifications for Pharmaceutical Preparation, page 246.

regulation.

4. **Avoid requirements that lack a patient safety benefit.** For example, once a product is approved, countries should avoid imposing country-specific labeling requirements that are not essential for the safe use of the device, and instead, should country-specific information be required, accept that this is supplied electronically/via digital labels. In addition, countries should also avoid imposing periodic re-registration or reassessment requirements and allow approved products to remain on the market unless approval is explicitly withdrawn or if the product is recalled temporarily because of deficiencies. This practice is consistent with well-established regulators and leverages post market inspections, surveillance, and the established Quality System to ensure the manufacturer remains in control of the process and materials used to manufacture the product and that the device continues to comply with what was originally approved. A second example is lot testing. Lot testing is not recognized as a best practice because it requires enormous regulatory resources and does little to ensure product safety.

5. **Accept global clinical trial data and leverage Real World Evidence[12] ("RWE").** When required, regulators should accept clinical evidence collected and used for regulatory approval in other countries to meet their own regulatory requirements as long as the clinical data are collected in accordance with ethical standards and Good Clinical Practices, including those of international standard ISO 14155. Such a provision would have to be carefully crafted to allow countries to require domestic clinical trials when there are demographic differences supported by objective scientific evidence that affect safety and performance. However, some countries continue to require domestic clinical trials. In some cases, such requirements are carried over from the drugs sector, which is sometimes justifiable on the grounds of metabolic or genetic differences in populations. Such considerations rarely apply to medical devices.

   RWE has emerged as an important data source to supplement regulatory decision-making through the total product lifecycle. GMTA encourages regulators to implement regulation that supports the acceptance of RWE.

6. **Implement a risk-based approach to product changes.** Another important aspect of an ideal regulatory framework is the management of product changes. Only those changes significantly affecting the safety or performance of higher-risk devices should require regulatory review. Not all changes affect a device's safety or performance. For example, depending on the device, changes can occur to raw material suppliers, manufacturing, testing processes, and labeling without affecting the device itself. Additionally, innovative technologies, such as software, may necessitate a more rapid change to avoid patient safety risks (e.g., cybersecurity vulnerabilities). Mandating the review of changes that do not significantly affect safety or performance can slow innovation, unnecessarily interrupt the global supply chain, or drain regulator resources. For these reasons, device changes that

[12] FDA defines RWE as "clinical evidence regarding the usage, and potential benefits or risks, of a medical product derived from analysis of RWD." Real-World Data (RWD) are data relating to patient health status and/or the delivery of healthcare routinely collected from a variety of sources. See U.S. Food and Drug Administration. Use of Real-World Evidence to Support Regulatory Decision Making for Medical Devices: Guidance for Industry and Food and Drug Administration Staff. August 2017. Accessed August 20, 2020

do not significantly affect the safety or performance of a device should not require prior regulatory review. Furthermore, for those device changes that would require prior regulatory review, harmonization of efficient regulatory mechanisms to facilitate more rapid changes of devices will further patient access to these important changes. For example, predetermined change control plans provide manufacturers with the option to submit a plan to the regulator for specific postmarket changes during initial premarket review so that these changes can be made rapidly postmarket without additional regulator review. In addition, reliance on other regulators' evaluation of product changes would be an excellent use of reliance practices.

7. **Avoid unnecessary barriers to access based on product country of origin.** Regulators with pre-market approval frameworks in place 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 and delay patients' access to medical technologies.

8. **Implement a single dossier.** GMTA encourages regulators to develop a single dossier approach according to which results of the single pre-market review can be leveraged for improved patient access to medical devices in multiple jurisdictions, without the need for multiple reviews. Such an approach will further facilitate good reliance practices and strengthen the confidence and consistency in the regulatory decision-making process. Industry welcomes the initiatives of several regulators launching programs to streamline the review and approval process for medical devices (e.g., the eSTAR program between the U.S. FDA and Health Canada; the reliance project between Singapore and Thailand) and would be ready to contribute to the development of a Medical Device Single Review Program (MDSRP) -not limited to IMDRF members only.

9. **Adopt electronic instructions for use.** Electronic instructions for use (IFU) can benefit patients, physicians, caregivers, and manufacturers, by increasing the availability, utility, interactivity, and accessibility of IFU. In addition, supplying electronic IFU may have environmental benefits, including reduced ethylene oxide emissions, reduced paper usage, and a reduced carbon footprint. It should be noted that in all cases, users would have access to all of the relevant information. Users who do not have access to electronic copy users can request a paper version. The case for electronic IFU is particularly salient when the IFU relates to a software-based product or the software features of a device when the user of the device has access to online information.

10. **Embrace digital labels.** Current labeling regulations differ across countries and create significant logistical challenges, especially during device shortages. As a result, devices can only be used in their intended market due to localized labeling requirements. In addition to electronic IFUs, digital labels can provide additional information beyond what is printed on the device. Industry agrees that core information on the identification of a device and handling are needed, nevertheless we encourage a regulatory framework to enable additional information, especially information from country-specific regulations, to be made available to users via a digital label. Adoption of digital labels can improve the user experience.

Additionally, digital labels allow manufacturers to reduce the need for printing and packaging, leading to environmental benefit.

Summary

GMTA encourages all regulators to implement the foundational principles and core tenets outlined in this paper to benefit patients, promote public health and enable a robust and sustainable medical technology ecosystem in their home market and globally. GMTA also encourages all regulators to collaborate with each other and stakeholders to develop a globally efficient, sustainable, and effective regulatory system.

As recognized by the WHO, "*industry plays a crucial role in the successful application of reliance mechanisms by National Regulatory Authorities*"[13]. It is with this spirit in mind that the medical technology industry supports a strong regulatory system that ensures the safety and effectiveness of devices and promotes patients' timely access to medical technologies.

[13]WHO QAS/20.851/Rev.1: https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS20_851_Rev_1_Good_Reliance_Practices.pdf?ua=1

Appendix A. Benefits of Regulatory Reliance

Reliance is a strategy for efficiently utilizing resources, building regulatory expertise and capacity, and elevating access to safe and effective, quality-assured medical products, no matter the countries' regulatory maturity. Overall, reliance signifies a smart way to regulate in the modern environment.

The World Health Organization ("WHO") defines reliance as "***The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.***" [14] While not necessary to implement reliance, convergence facilitates the reliance process.[15] Regulatory convergence is often a gradual process that requires long-term engagement across countries with differing legal and regulatory frameworks as well as health systems and health needs.

Today, factors such as globalization, rapidly advancing health technologies, international supply chains, evolutions in regulatory science and global pandemics have increased the focus and urgency for reliance to enhance regulatory capacity and efficiency around the world. Organizations like the WHO increasingly see it as an integral part of regulatory operations. We are aligned with the WHO's assessment that "reliance represents a 'smarter' form of regulatory oversight" and "a decision to 'regulate through reliance' is the hallmark of a modern and efficient regulatory authority."[16]

Regulatory reliance provides an opportunity to avoid duplication, improve resource allocation/utilization and enhance the efficiency of regulatory processes by focusing on functions that must be performed locally (e.g., vigilance and market surveillance) while informing other work (e.g., safety and effectiveness assessment) by looking to other trusted reference regulatory authorities and/or by sharing regulatory workload and responsibility through cooperation. As many regulators recognized during the COVID-19 pandemic, regulatory reliance practices have increased value during public health emergencies as those practices expedite access to needed technologies to counter the emergency.

Regulatory reliance can be a powerful tool to facilitate accelerated access in any market, and particularly in emerging markets. The benefits of reliance include:

- **Ensure faster patient access to safe, effective, and quality-assured devices**.
- **Deliver significant efficiencies for regulatory authorities and the WHO.**
- **Enable resilient health system preparedness and response** (particularly during public health emergencies).

[14] The WHO Expert Committee on Specifications for Pharmaceutical Preparation, page 243.

[15] The WHO has made clear that "[d]ifferences in standards and practices do not prevent one authority from relying on another, particularly when the relying authority has limited capacity and expertise." Good Reliance Practices in the Regulation of Medical Products, Annex 10, page 255.

[16] The WHO Expert Committee on Specifications for Pharmaceutical Preparation, page 256.

- **Enhance the predictability of decision-making** and streamline **approvals,[17] product changes and inspections**.
- **Promote broad adoption of innovative technologies** and **reduce unnecessary complexity and burden**.

Regulatory reliance also has the potential to improve health globally. In today's complex economy, disease and illness are no longer contained within boarders. Our global health depends on the success of regulators around the world to ensure continued timely access to devices. In addition, by reducing the time lag between device availability in the wealthiest and less wealthy countries, effective use of reliance has the potential to enhance global health equity. Lastly, in time-sensitive situations, such as a pandemic or health emergency, reliance supports timely and effective responses at global, regional, and national levels – thus helping to insulate our global protection from rapidly spreading diseases. While there may be differences in national standards and practices, this does not impede the effective use of reliance. The WHO made it clear that, reliance is an effective pathway, even if standards and practices between jurisdictions differ.[18]

GMTA supports regulatory reliance as a timely and efficient way to increase access to safe, high-quality, effective, and innovative healthcare products that benefit patients. GMTA also believes accountability, strategic investment, and scope as well as transparency and information sharing are critical requirements and considerations to implement a successful reliance framework.

Accountability, Strategic Investment and Scope

Each national regulatory authority must retain independence, sovereignty and accountability for decision-making. Utilizing reliance does not sacrifice autonomy of responsibility and accountability. Sharing of scientific, clinical or technical information, or regulatory assessments and rationales, should be supported by confidentiality agreements between regulators and limited to only that data necessary to reach a decision.

All relevant stakeholders, including industry, should be informed and engaged during the development and implementation of reliance approaches and frameworks. Industry may be best placed to identify new areas that will benefit from reliance approaches. This offers the opportunity to provide feedback on the progress of international/regional/national efforts and to deliver valuable input based on direct experience of using new systems. Reliance systems must incorporate a framework for consulting with key stakeholders as policy is developed and ensure realistic timelines for transition to new requirements for both regulators and industry.

[17] For the purpose of this document the term "approval" is intended to represent the process whereby a regulator (or WHO) reviews the product information before it can be legally marketed. Different terms are used for this process internationally (e.g., approval, clearance, registration, market approval).

[18] Good Reliance Practices in the Regulation of Medical Products, page 255.

Transparency and Information Sharing

The choice of the reference regulatory authority for reliance purposes and the criteria used should be transparent. We support the World Health Organization's ("WHO") effort to establish and implement a framework for evaluating and designating national regulatory authorities ("NRAs") that meet a defined criterion. GMTA believes a trusted authority or institution is one that is well-resourced, competent and efficient in their performance of health regulation based on Good Regulatory Practices and internationally recognized standards to ensure human health and safety.

Reliance, as well as joint evaluation and collaborative reviews, are enabled by effective information sharing, convergence, and the harmonization of regulatory standards and guidelines. Reliance procedures and decisions should be available and shared between regulators whilst ensuring appropriate safeguards and consent systems to protect personal data and confidential commercial information. Reliance approaches must be based upon high quality, evidence-based assessments and implemented consistently. Decision-making processes must be transparent, enhancing public understanding of how decisions are made by a relied upon authority, as well as how decisions are made by the relying authority.