

**Talking Points - Renata Amaral**  
**WTO/TBT Committee, Feb. 25, 2020**

**Initial Remarks**

- The Inter-American Coalition for Regulatory Convergence is composed by medical technology associations of the Western Hemisphere and other private and public sector stakeholders.
- **What is MedTech?** Medical Technology is essentially anything you might see at a hospital or clinic that is not a drug, not the personnel, and not the hospital. And in many cases, you don't see the medical technology, because it's inside of you.
- *Our Vision* is to have **1 Standard, 1 Test, accepted everywhere** for any medical technology scope.
- *Our Mission* is to lead the coordination of all materially affected stakeholders to achieve this Vision. This includes:
  - promoting regulatory cooperation across the Western Hemisphere to **achieve internationally aligned medical technology regulations, standards and conformity assessment requirements** within a continual process of convergence to maximize patient access to live-saving and improving medical technologies.

**Slides 2: The Medical Devices Sector**

- What is encompassed by the medical devices sector?
- **'Medical device'** means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, **intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:**
  - *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
  - *diagnosis, monitoring, treatment, alleviation of or compensation for an injury,*
  - *investigation, replacement, modification, or support of the anatomy or of a physiological process,*
  - *supporting or sustaining life,*
  - *control of conception,*

- *disinfection of medical devices,*
- *providing information by means of in vitro examination of specimens derived from the human body;*
- *and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.*

### **Slide 3: Challenges for Medical Devices**

- One of the main challenges of the medical devices sector is the enormous diversity of products (*which means **different regulations, different standards, different and complex supply chains** around the world*);
- There are multiple sites involved in the manufacturing of a single medical device – complex process even to define the “Country of Origin” which may differ from a Direct Marking in an individual component of the Medical Device:
  - Individual Production includes multilingual/multi-country labels;
  - One Legal Manufacturer – responsible for the quality and performance of the Medical Device under a Quality Management System implemented in every manufacturing site.
- Very complex and lengthy registration processes:
  - Lack of mutual recognition as registration requirements vary per geography/country.

### **Slide 4: Major Medical Technology Regulatory / Trade Challenges**

- It is our understanding that there are two major medical technology regulatory and trade challenges that our sector faces:
  1. **The TBT agreement is not implemented with most medical device regulators:**
    - Most medical device regulators (staff drafting regulations) either are not aware of the TBT agreement or not required to implement it by trade ministries;

- Most medical device regulators are not aware of the International Medical Device Regulators Forum (IMDRF) guidance documents and the hundreds of relevant medical device international standards upon which they should be basing their regulations (ISO, IEC, et al.)
- Most medical device regulators still opting to dedicate their limited public health resources towards developing their own country/agency-unique requirements;
- If there is awareness of the TBT agreement, implementation is *ex post* and not *ex ante*.

## 2. Medical devices improperly regulated as drugs.

- A key obstacle that medical devices face is that they are often improperly regulated as drugs. **Devices are not drugs!**
- There is more commonality between the medical technology and ICT sector (something around 85%) than there is with the pharmaceutical sector (around 15%).
- I am oversimplifying a bit, but it is not too much of an exaggeration to say that a drug is a molecule in a box. It takes billions of dollars to develop a drug, but once developed, its manufacture and sale is relatively straightforward as a molecule in a box.
- A good example of a medical device is a smart phone: 200,000 components that change every 18 months. Medical devices are completely different products with different components and vastly more complex global supply chains.
- Often the regulatory staff come from the pharma side and have little to no medical device experience. Often the draft regulation is based on pharma. For example, there was a proposed draft regulation in Mexico that would have required the manufacturers to retain product samples according to the same protocols applied for drugs – sufficient number of units **per batch** to perform two complete series of analysis, for a period that concludes one year after “**expiration date**”. Imagine this for a Magnetic Resonance Imaging (MRI) machine!

### **Slide 5: Good Regulatory Practices**

- The **global** medical devices sector believes that governments can foster economic growth and social well-being through high-quality regulatory policy design.
- Quality regulatory policy is based on codifying good regulatory practices (GRP), the internationally recognized processes, systems, tools and methods used to ensure the quality, transparency, and inclusive development of regulations.

- In our understanding, **key elements of GRP include**: stakeholder engagement; reliance on quality data and sound science when introducing new regulation, impact analysis of proposed and implemented regulations; use of international standards; and transparency measure such as regulatory forecasting.
- In our view, the US-Mexico-Canada Chapter on Good Regulatory Practices represents the state of the art in terms of what we have codified on GRP in a trade agreement. The chapter includes the following sections:
  - **Central Regulatory Coordinating Body**
  - Internal Consultation, Coordination, and Review
  - Information quality
  - Early Planning
  - Dedicated Website
  - Use of Plain Language
  - Transparent Development of Regulations
  - Expert Advisory Groups
  - Regulatory Impact Assessment
  - Final Publication
  - Retrospective Review
  - Suggestions for Improvement
  - Information About Regulatory Processes
  - Annual report
  - Encouragement of Regulatory Compatibility and **Cooperation**
  - Committee on Good Regulatory Practices
  - Contact Points
  - Dispute Settlement
- We view these GRP provisions as a positive evolution based on the previous “Regulatory Coherence” of the TPP and CPTPP which was in turn an evolution of the “Regulatory Reform” work with the APEC/OECD integrated checklist.
- Important to highlight here the benefit for industry of the USMCA Sector Annex on Medical Devices, and specifically the outcome of the Medical Device Single Audit Program of medical device manufacturers being accepted in several West Hem members – US, Canada, Brazil, Argentina, and soon Mexico (possibly upon implementation of USMCA).
- The Annex also includes obligations that formalize/codify on best regulatory practices in the medical device sector (e.g. following a risk-based approach for the classification of med devices).
- This is a good example / practical outcome of regulatory compatibility.

#### **Slide 6: The relevance of the WTO for GRP**

- Unnecessary regulatory differences can impose costs that prevent businesses from engaging in trade.
- As this audience is well aware, the WTO plays an important role in supporting efforts to facilitate trade through regulatory cooperation among its 164 members, offering a **multilateral platform for dialogue among governments on trade rules, and throughout the full rule-making cycle.**
- The disciplines of the TBT Agreement can help contribute with effectiveness and efficiency of regulations through GRP. The Agreement lays down specific legal disciplines, which directly address the preparation, adoption and application of domestic regulations on goods.
- The TBT Agreement, and this Committee, provide a unique framework for international regulatory co-operation contributing to ease trade frictions through, for example, including the notification of draft measures, the harmonization with international standards, and discussion of specific trade concerns.

#### **Slide 7: Specific provisions of the TBT Agreement**

- The TBT Agreement (as well as the SPS) strongly encourage WTO members to use relevant international standards as the basis for their measures, including disciplines on equivalence and recognition of foreign conformity assessment which help to ensure that traders do not face duplicative requirements or procedures when regulations differ across markets.
- These disciplines encourage the reduction of regulatory diversity and associated trade costs.
- We call attention specifically to the disciplines of Articles 2.2, 2.3 and 2.4 of the TBT Agreement, all related to the “Preparation, Adoption and Application of Technical Regulations by Central Government Bodies”.
- As we all know, those provisions call for the members’ obligation of not creating unnecessary obstacles to trade, as well as recall the relevance of observing international standards where they exist.
- Of course, legitimate differences in societal preferences and priorities may result in the diversity in product requirements, but most of times the diversity in domestic requirements result from undesirable regulatory systems working in silos.

- International regulatory cooperation between members can help reduce trade costs while respecting differences in regulatory objectives. This cooperation may take several forms and depths of engagement, many of which are directly relevant to trade outcomes.
  
- As we all know, the TBT Agreement contain obligations that strongly promote alignment of national regulations with international standards. More specifically, the Agreement:
  - (i) require the use of relevant international standards as a basis for national regulations, except if the regulation would be ineffective or inappropriate to accomplish the member's legitimate objective;
  - (ii) incentivize members to fully harmonize measures with international standards; and
  - (iii) strongly encourage members to participate in the development of international standards.
  
- The use of international standards as the basis of national TBT measures is an impetus towards regulatory alignment on a global basis. However, only governments can decide if and when to regulate.

### **Final Remarks:**

- We think the society of the future will look back at early 21<sup>st</sup> century healthcare and view patient waiting lines as barbaric as bloodletting.
  
- It is said that good things come to those who wait. And patience is a virtue.
  
- And it is possible that I might be less consumerist if I wait a few minutes before clicking that 'buy now' on my Amazon app.
  
- But delays in the health supply chain are not just a trade barrier, or a burden to manufacturers, or a disruption to the global supply chain. Patients are waiting, patients with life critical conditions are waiting.
  
- You and I think it's bad waiting in the airport security line, or at the Department of Motor Vehicles, or at the a notary public's office. But imagine that your wait is for a technology to save your life, or to improve your quality of life, or for your loved ones.

- Health care systems around the world are a mix of public and private services, but independent of the model of a country's healthcare system, the supply chain is global and market-based.
- **Market-based systems require regulation.** If you're a medical device regulator, the question is: how much regulation, and what regulation? The answers lie in applying Good Regulatory Practices, and in applying the TBT Agreement as a Good Regulatory Practice.
- It's hard to imagine a scope of professional activity in the 21<sup>st</sup> century that starts with a clean sheet of paper. Certainly, kindergarten art class! But not much else. Smartphones, while revolutionary, were incremental improvements and bundlings of existing technologies.
- I think it's fair to say, that for 99% of us, if in the modern world, we start a project absolutely from zero, we're probably not doing our task as efficiently and as best we could.
- I often think of regulation like walking into a restaurant with a friend: if it's empty, there's a problem.
- Why would a medical device regulator opt to create an agency or country unique technical regulation for medical devices?
- Given what must be hundreds of other health priorities, are medical device regulatory agencies following the World Health Organization guidance to rely on the regulatory outputs of partner agencies?
- Dozens of guidance documents are available on the IMDRF website, and hundreds of international standards exist, many of which the IMDRF recommends in its essential principles.
- Sadly, in most of the world, including across most of Latin America, medical device regulatory agencies with perhaps one hundredth of the FDA's medical device division of 2000 employees, are purposing limited public health resources toward the creation of unique technical regulations and conformity assessment regimes, introducing and not removing barriers to patients and global trade.
- We believe that GRP and the TBT agreement as a GRP together with your assistance can help us in removing these unworthy barriers.

Thank you!