



Inter-American
**Coalition for
Regulatory Convergence**

MEDICAL TECHNOLOGY SECTOR

Good Regulatory Practices, Technical Barriers to Trade and the Impact for the Medical Technology Sector

WTO-TBT Committee

Thematic Session on Good Regulatory Practices
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Medical Devices: Definitions

- ***‘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.**

* GHTF/SG1/N071:2012, REFERRED BY IMDRF AT IMDRF/SAMD WG/N10final:2013



Challenges for Medical Devices

Enourmous diversity of products



Sutures



Catheters



Knee Replacement Implants



3D Printers



Surgical Robots



Computerized Scan Tomography



Major Medical Technology Regulatory / Trade Challenges

1. TBT agreement not implemented with most medical device regulators

- Most medical device regulators (staff drafting regulations) either not aware of the TBT agreement or not required to implement it by trade ministries
- Most medical device regulators are not aware of the IMDRF guidance documents and the hundreds of relevant medical device 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



Good Regulatory Practices

1. Issue a Regulatory Forecast
2. Have a National Regulatory Register
3. **Provide Opportunity for Public Comment**
4. Publish Evidence and Conduct Regulatory Analysis
5. Respond to Stakeholder Input
6. **Use Quality Data and Sound Science**
7. Employ Risk-Based Approaches
8. **Conduct Regulatory Impact Assessments (RIAs)**
9. Conduct Pro-Competitive Analysis
10. **Asses the International Impact of a Regulation**
11. **Use International Standards as a basis for National Regulations**
12. Conduct Ex-Post Assessments of Regulatory Impacts
13. Establish a Central Regulatory Oversight Body



The relevance of the WTO for GRP

- Unnecessary regulatory differences can impose costs that prevent businesses from engaging in trade.
- 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. It lays down specific legal disciplines, which directly address the preparation, adoption and application of domestic regulations on goods.
- The TBT Agreement provides a unique multilateral transparency framework for regulations affecting the trade in goods.



TBT Agreement

- Article 2.2: Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of **creating unnecessary obstacles to international trade.**
- Article 2.3: Technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a **less trade-restrictive manner.**
- Article 2.4: Where technical regulations are required and relevant **international standards exist** or their completion is imminent, **Members shall use them**, or the relevant parts of them, **as a basis** for their technical regulations.



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Thank you!

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