Technical Barriers to Trade and the Impact for the Medical Technology Sector
Outline

• WTO General Rules
• Non-Tariff Trade Barriers
• Coverage of the TBT Agreement
• Main Principles of the Agreement
• Relevant Provisions
• ePing System
WTO General Rules

• The only international body dealing with rules of trade between nations (164 Members).

• WTO agreements provide the legal ground- rules for international commerce.

• They bind governments to keep their trade policies within agreed limits.

• Help trade flow as freely as possible (e.g. by removing obstacles, providing confidence, transparency and predictability).
Non-Tariff Barriers to Trade

- Technical measures (e.g. in standards)
- Internal taxes or charges
- Customs rules and procedures
- Quantitative import restrictions
- Public procurement practices
- Subsidies and related government supports
- Investment restrictions or requirements
- Transport regulations or costs …
Non-Tariff Barriers to Trade
Coverage of the TBT Agreement

• Technical measures (e.g. in standards)
• Internal taxes or charges
• Customs rules and procedures
• Quantitative import restrictions
• Public procurement practices
• Subsidies and related government supports
• Investment restrictions or requirements
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The TBT Agreement

• The acts as an instrument to:
  • Encourage Members to use less-trade restrictive approaches to meet regulatory objectives
  • Harmonize through the use of relevant international standards
  • Provide transparency
  • Avoid and resolve trade disputes related to standards matters
• The Agreement safeguards against:

  • The use of technical requirements as disguised restrictions on trade

  • The development of inefficient technical requirements and procedures
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: main principles

• Non-discrimination
• Avoidance of unnecessary barriers to trade
• Harmonization through the use of international standards, guides and recommendations
• Transparency (notifications and enquiry points)
• Concepts of equivalence of technical regulations and mutual recognition of results of conformity assessment procedures
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.
Principles to Develop International Standards

- The WTO Committee on Technical Barriers to Trade adopted a set of principles to which an organization engaged in the development of international standards must comply.

- These principles have been captured in document “G/TBT/ 1/REV. 8. Section IX,” titled *Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement.*
## TBT Agreement - Definitions

**Annex 1 of the TBT Agreement**

<table>
<thead>
<tr>
<th><strong>Technical Regulation:</strong></th>
<th><strong>Standard:</strong></th>
<th><strong>Conformity Assessment:</strong></th>
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<td>A document that lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory.</td>
<td>A document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance <strong>is not</strong> mandatory</td>
<td>Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. Includes, inter alia, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval.</td>
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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
ePing system - WTO

ePing is an SPS & TBT notification alert system is a publicly available and self-subscribing service, whereby subscribers are able to receive email alerts regarding SPS and TBT notifications covering particular products and/or markets of interest to them.

In addition, users can search notifications, share notifications, upload additional information and participate in discussions.

ePing also offers an Enquiry Point Management Tool to facilitate domestic as well as international information sharing and discussion.
ePing system - WTO

track product requirements in export markets

ePing enables timely access to evolving product requirements and facilitates dialogue amongst the public and private sector in addressing potential trade problems at an early stage.

Search
Search notifications on product requirements, filtering by specific products or export markets

Receive alerts
Register for free to receive email alerts on new SPS & TBT notifications

Collaborate
Once registered, benefit from additional features such as the national forum
<table>
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<tr>
<th>Country/territory</th>
<th>City</th>
<th>Address</th>
<th>Contact</th>
<th>Email</th>
<th>Phone</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afghanistan</td>
<td>Jalalabad</td>
<td>Jalalabad Highway Industrial Parks, Kabul P.O Box No: 5172 Central Post Office, Kabul</td>
<td>WTO/TBT Enquiry Point</td>
<td><a href="mailto:noorhabib31@gmail.com">noorhabib31@gmail.com</a></td>
<td>(+93) 75 20 86 743; (+93) 77 17 79 95</td>
<td></td>
</tr>
<tr>
<td>Afghanistan</td>
<td>Kabul - Jalalabad</td>
<td>Kabul P.O Box No: 5172 Central Post Office, Kabul</td>
<td>Afghan National Standards Authority (ANSA)</td>
<td><a href="mailto:tbt@ansa.gov.af">tbt@ansa.gov.af</a></td>
<td>(+93) 75 20 86 74 3; (+93) 77 17 67 99 5</td>
<td><a href="http://ansa.gov.af">http://ansa.gov.af</a></td>
</tr>
<tr>
<td>Albania</td>
<td>Rr: &quot;Mine Peza&quot;, Nr.143/3</td>
<td>General Directorate of Standardization Tirana - Albania Contact person: Mr. Riza Hasanaj, General Director of General Directorate of Standardization Head of Sector of WTO/TBT</td>
<td><a href="mailto:info@dps.gov.al">info@dps.gov.al</a>; <a href="mailto:hasanaj.r@dps.gov.al">hasanaj.r@dps.gov.al</a>; <a href="mailto:dea.nini@dps.gov.al">dea.nini@dps.gov.al</a></td>
<td></td>
<td>+355 42 22 62 55; +355 42 22 71 76</td>
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</table>
Thank you!

Renata Amaral
Technical Secretariat
Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector

Renata@interamericancoalition-medtech.org