

TBT Agreement and medical device regulation

*ASEAN Regional Workshop on Good Regulatory Practices and
Medical Device Regulation*

Devin McDaniels

devin.mcdaniels@wto.org

Objectives of the TBT Agreement

*Pursuit of trade
liberalization*

Members' right to regulate...

**avoiding
*discriminatory and
unnecessary*
barriers to trade**



**allowing Members
to fulfill legitimate
objectives
at levels they
consider
appropriate**

**international standards
(*harmonization*)**

Examples of key principles and disciplines for NRAs



- Harmonization based on international standards
- Regulatory cooperation and coherence tools
- Transparency



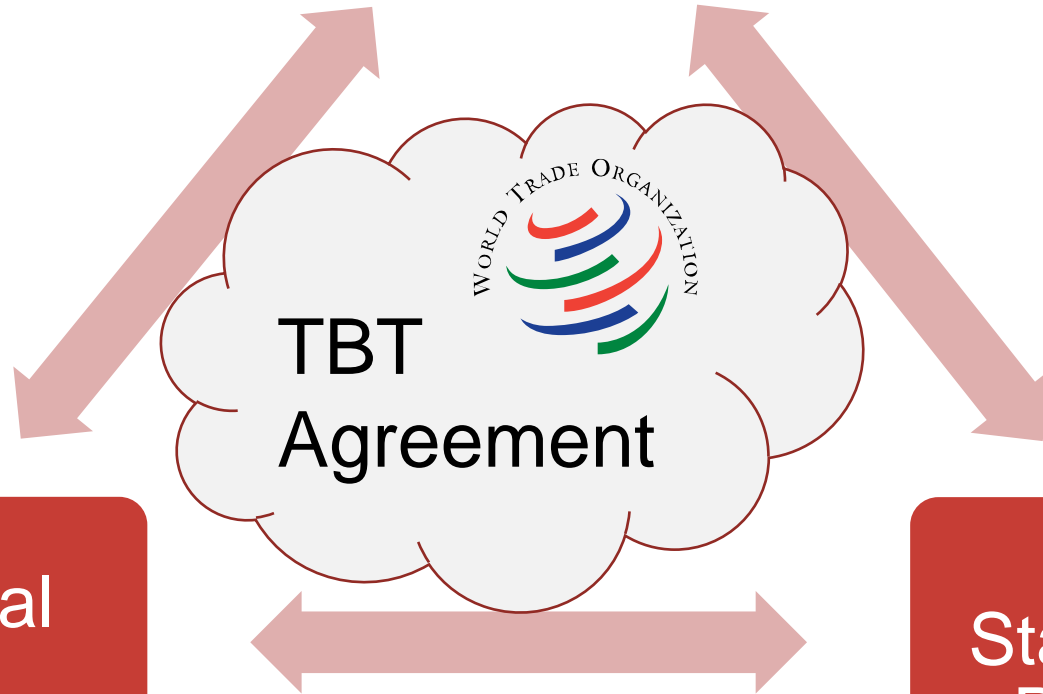
International standards

International
Standards

TBT
Agreement

International
Trade

National
Standards and
Regulations



TBT Agreement: using international standards



Members **shall** use...



relevant international standards

technical regulations
(Art. 2.4)

conformity assessment procedures
(Art. 5.4)

Also: national standards

... as a *basis* for

when *ineffective* or *inappropriate* for policy objectives

(e.g. fundamental climatic or geographical factors, or technological problems)

except!



Regulatory cooperation and coherence tools

Recognition of foreign conformity assessment results (encouraged in the TBT Agreement)



Article 6:

- “Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures.”
- Encouragement to negotiate **MRAs**.

International or regional systems for conformity assessment (encouraged in the TBT Agreement)



Article 9:

“Where a positive assurance of conformity with a technical regulation or standard is required, Members shall, wherever practicable, formulate and adopt international systems for conformity assessment.”

Regulatory cooperation and trade



- **Regulatory cooperation and reliance** avoids duplication and promotes more efficient use of resources by regulators and manufacturers.
- Narrowing unnecessary differences in regulation between countries has **benefits for both health and trade** (e.g. expediting registration, facilitating operation of supply chains).
- Cooperation is especially important for NRAs with less resources to contend with increasingly complex technologies embedded in medical devices.
- Strengthening use of **good regulatory practices** (such as transparency, public consultation, and internal coordination) enables these efforts.

Transparency

Transparency obligations



- Notification of draft regulations
- Publication of regulations
- Establishment of enquiry point
- Designation of notification authority
- Statement of implementation
- Notifications from standardizing bodies

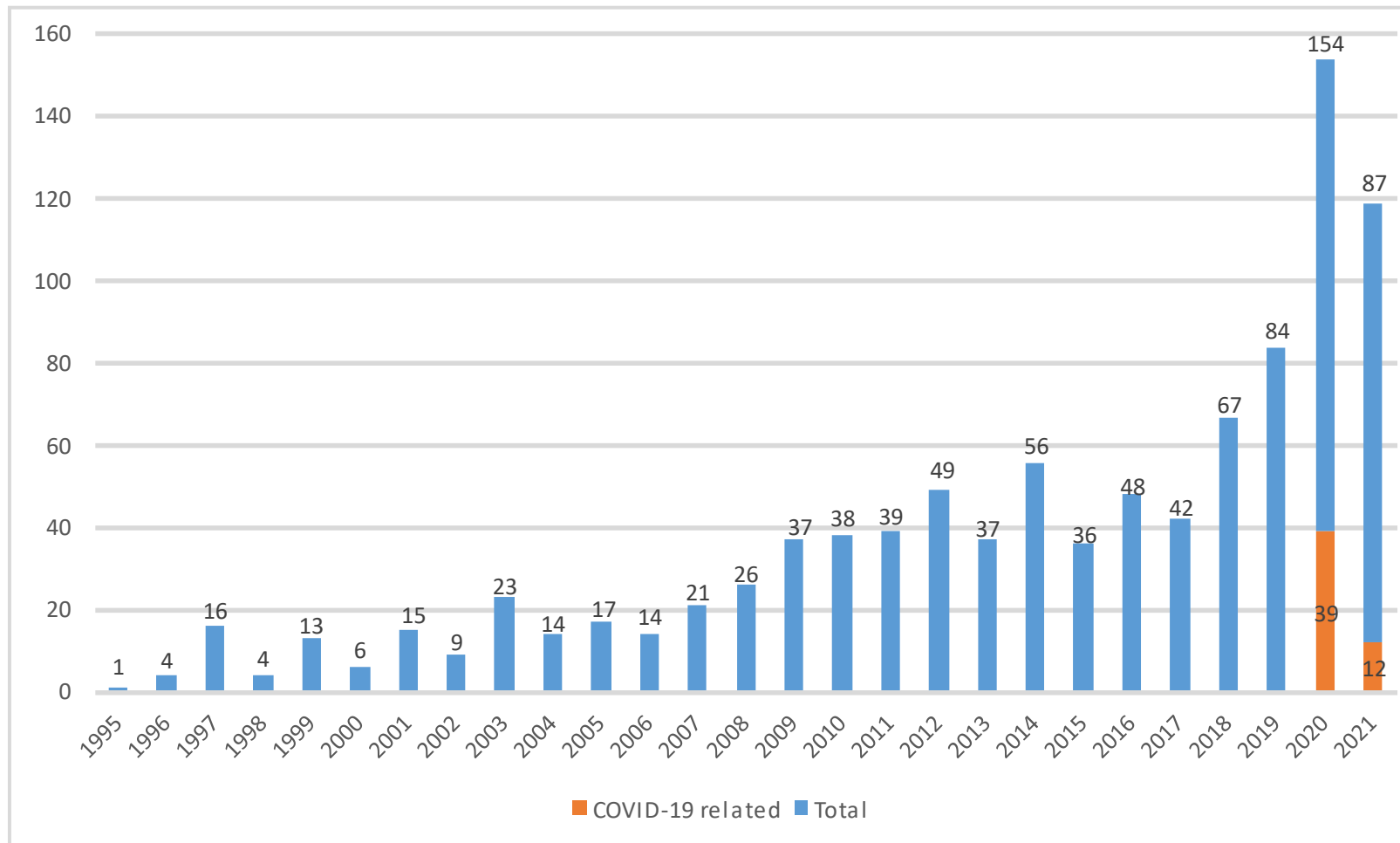
WHAT TO NOTIFY?


New or modified technical regulation or
conformity assessment procedure
+
No existing international standard or
Different from the international standard
+
Significant impact on trade
(restricting or facilitating)



NOTIFY

Notifications related to medical devices, by year





Track and manage information on product requirements

Search notifications

Search trade concerns

Register and receive alerts

TBT Committee



Two main themes of Committee work

1 review of measures
"specific trade concerns"
(mostly based on
notifications)

2 Information exchange
on cross-cutting
issues
(harmonization,
transparency, ...):
leading to decisions
and recommendations



Key messages

1. Core TBT obligations of relevance to NRAs:
 1. International standards
 2. Regulatory cooperation and coherence tools
 3. Transparency
2. Trade and regulatory cooperation are vital for expediting access to essential medical products.

Thank you for your attention!