TBT Agreement and medical device NRAs

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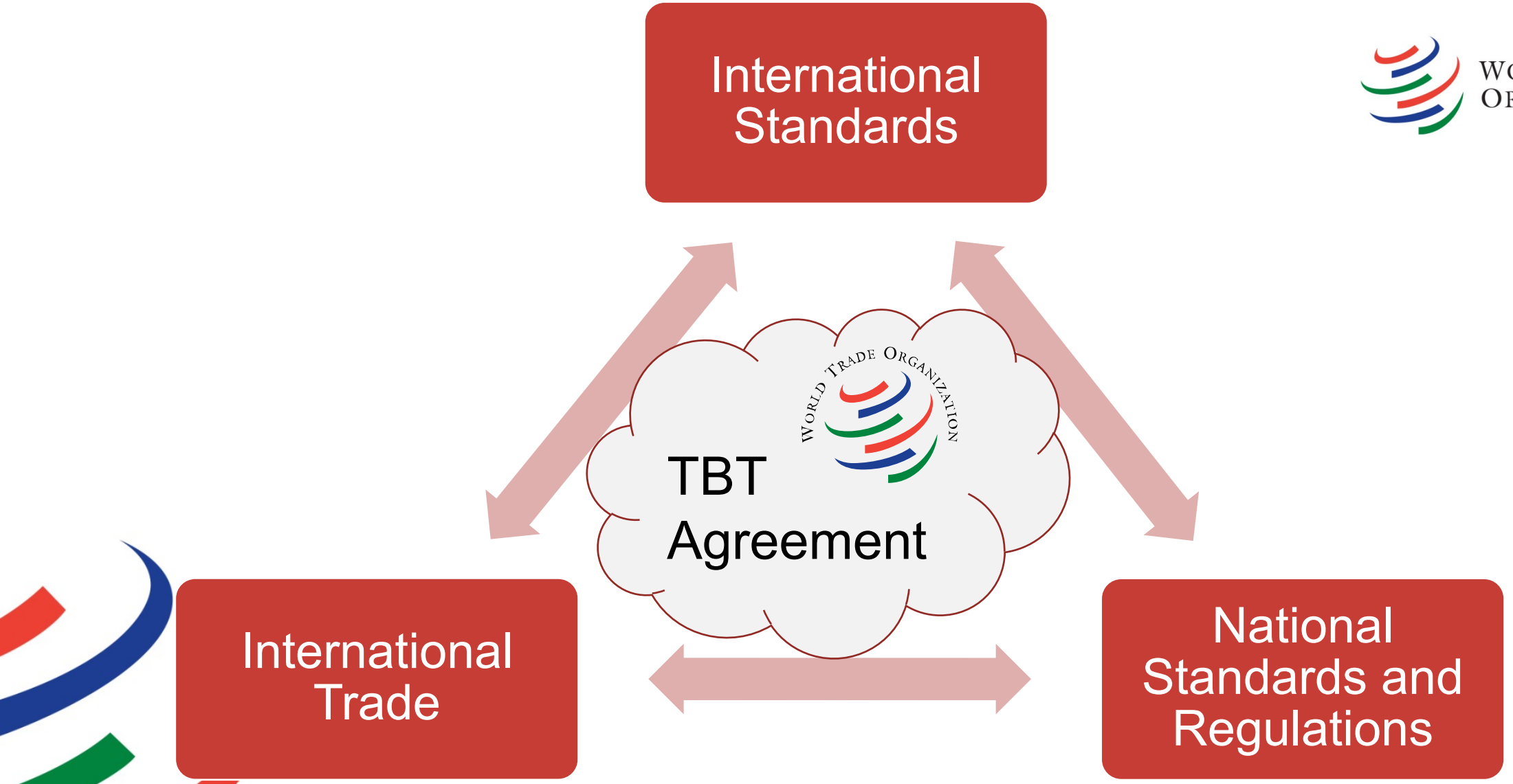
Outline

1. Trade and regulatory cooperation are vital for expediting access to essential medical products.
2. Core TBT obligations of relevance to NRAs:
    1. International standards
    2. Transparency
    3. Facilitating conformity assessment procedures
3. The WTO TBT Committee can help find cooperative solutions to trade and regulatory bottlenecks.

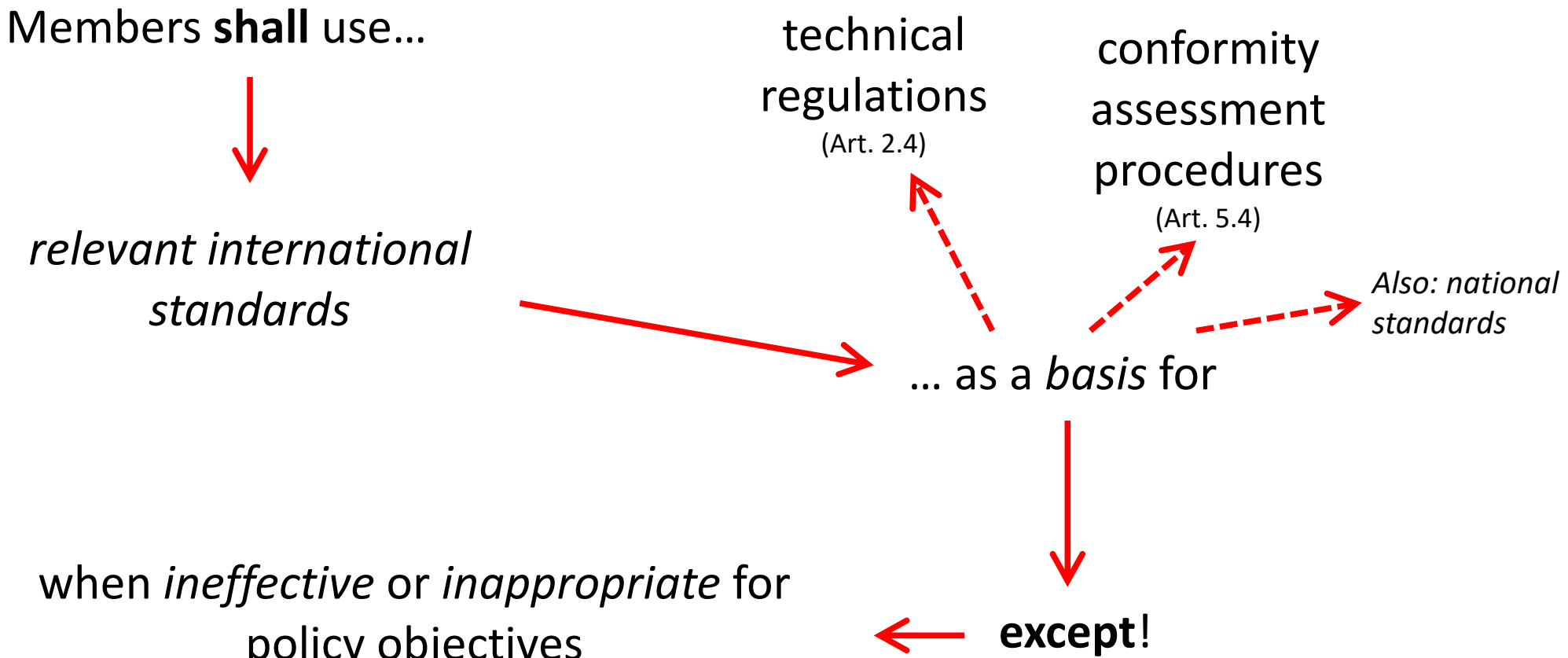
Regulatory cooperation and trade

- 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 be contend with increasingly complex technologies embedded in medical devices
- Strengthening use of good regulatory practices (such as transparency, public consultation, and internal coordination) supports these efforts


International Standards
TBT Agreement
International Trade
National Standards and Regulations

International standards

TBT Agreement:
using international standards



Facilitating conformity assessment procedures

Arrangements to facilitate CAP

(encouraged in TBT Agreement)

- International or regional systems for conformity assessment (article 9)
  - “Members shall, wherever practicable, formulate and adopt international systems for conformity assessment”
- Recognition of foreign conformity assessment results (article 6)
  - “verified compliance, for instance through **accreditation**, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence”
  - Encouragement to negotiate **MRAs**

Transparency

WHAT TO NOTIFY?

New or modified technical regulation or conformity assessment procedure

+

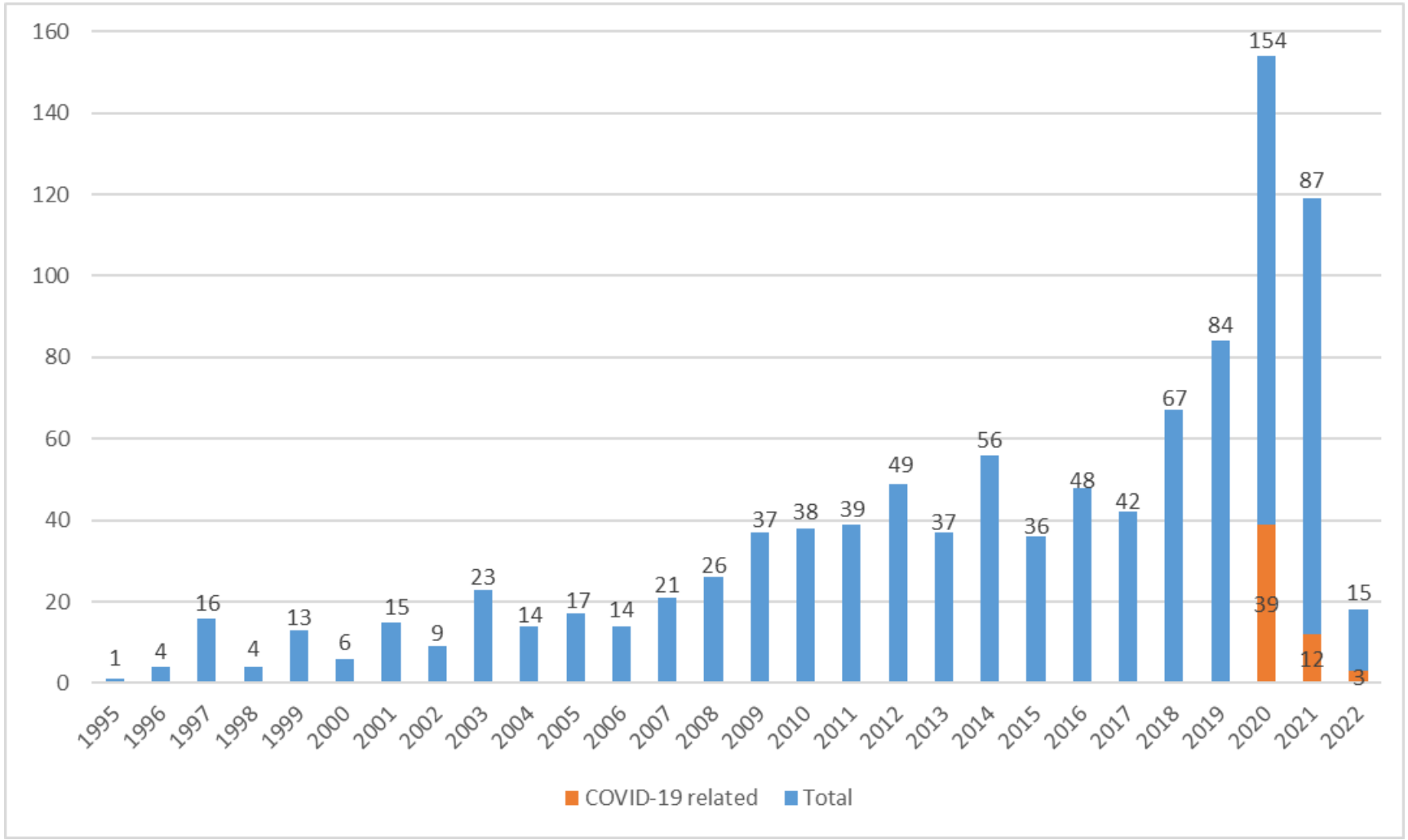
No existing international standard or Different from the international standard

+

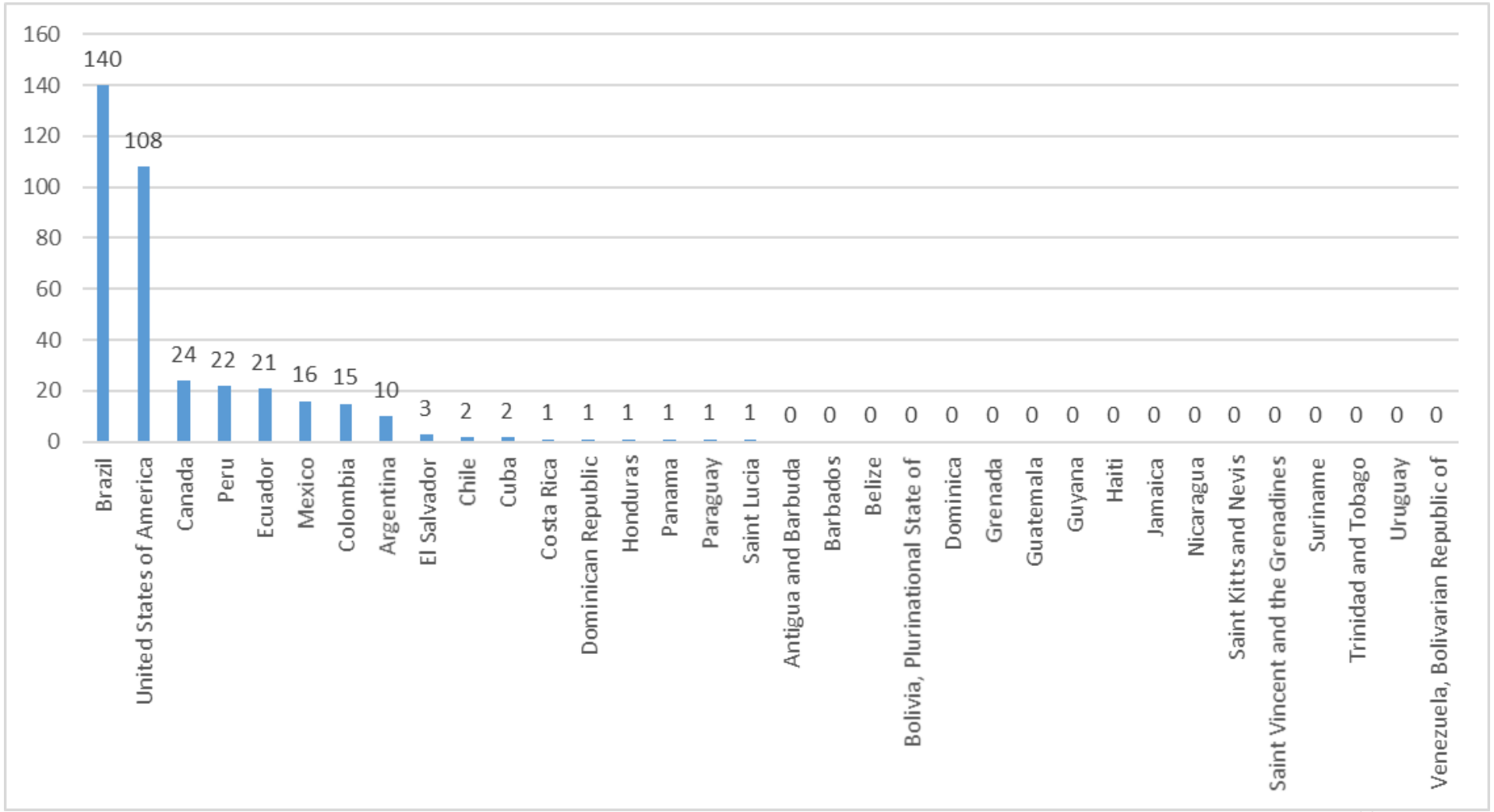
Significant impact on trade (restricting or facilitating)

NOTIFY

Notifications related to medical devices, by year



Notifications related to medical devices, by Member (Americas)



Some examples of notifications

Peru adopted Guidelines for the manufacture of reusable cloth face-masks for use by the community (G/TBT/N/PER/131)

(06/05/2021)

NOTIFICACIÓN

Se da traslado de la notificación siguiente de conformidad con el artículo 10.6.

1.	**Miembro que notifica:** PERÚ **Si procede, nombre del gobierno local de que se trate (artículos 3.2 y 7.2):**
2.	**Organismo responsable:** Ministerio de Salud - Sede Central Av. Salaverry 801, Jesús María, Lima, Lima Teléfono: (+51-1) 315-6600 Correo electrónico: webmaster@minsa.gob.pe **Nombre y dirección (incluidos los números de teléfono y de fax, así como las direcciones de correo electrónico y sitios web, en su caso) del organismo o autoridad encargado de la tramitación de observaciones sobre la notificación, en caso de que se trate de un organismo o autoridad diferente:** Ministerio de Comercio Exterior y Turismo – MINCETUR Calle Uno Oeste Nº 50 - Urb. Corpac - Lima 27 – Perú Tel.: (+51-1) 513-6100, Ext. 1223 y 1239 Email: otc@mincetur.gob.pe
3.	**Notificación hecha en virtud del artículo 2.9.2 [ ], 2.10.1 [X], 5.6.2 [ ], 5.7.1 [ ], o en virtud de:**
4.	**Productos abarcados (partida del SA o de la NCCA cuando corresponda; en otro caso partida del arancel nacional. Podrá indicarse además, cuando proceda, el número de partida de la ICS):** 6307.90.30.00 Mascarillas de protección
5.	**Título, número de páginas e idioma(s) del documento notificado:** Documento Técnico: "Lineamientos para la Confección de Mascarillas Faciales Textiles de Uso Comunitario Reutilizables". (32 página(s), en Español)
6.	**Descripción del contenido:** La Resolución Ministerial Nº 558-2021/MINSA aprueba el Documento Técnico: "Lineamientos para la Confección de Mascarillas Faciales Textiles de Uso Comunitario Reutilizables", dirigido a las personas y empresas dedicadas a la confección de mascarillas faciales textiles de uso comunitario para reducir la propagación del SARS-CoV-2, virus que causa la COVID-19, con el objeto de establecer los parámetros de materiales, diseño, confección, acabados, etiquetado, empaque y métodos de prueba de ensayo, de las mascarillas faciales de uso comunitario reutilizables
7.	**Objetivo y razón de ser, incluida, cuando proceda, la naturaleza de los problemas urgentes:** Protección de la salud de las personas, a través de la reducción de la propagación del SARS-CoV-2, virus de la COVID-19; Protección de la vida o la salud de los animales o preservación de los vegetales

Mexico laid out minimum requirements for the design, development, manufacture, warehousing and distribution of medical devices, based on level of risk

(G/TBT/N/MEX/454)

(21/06/2019)

2.	**Agency responsible:** *Secretaría de Salud* (Ministry of Health) **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** José Alonso Novelo Baéza, Chair of the *Comité Consultivo Nacional de Normalización de Regulación y Fomento Sanitario* (National Advisory Committee on Standardization for the Regulation and Promotion of Health), located at Oklahoma número 14, planta baja, colonia Nápoles, código postal 03810, Demarcación Territorial Benito Juárez, Ciudad de México, Tel.: 50805200, Ext. 1333, Email: rfs@cofepris.gob.mx
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medical devices
5.	**Title, number of pages and language(s) of the notified document:** *Proyecto de Norma Oficial Mexicana PROY-NOM-241-SSA1-2018, Buenas prácticas de fabricación de dispositivos médicos* (Draft Mexican Official Standard PROY-NOM-241-SSA1-2018: Good manufacturing practices for medical devices) (70 pages, in Spanish)
6.	**Description of content:** This Standard is binding in Mexican territory on all establishments engaged in the manufacture of medical devices and warehouses which package, store and distribute medical devices. It sets forth minimum requirements for the design, development, manufacture, warehousing and distribution of medical devices, based on their level of risk.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** The purpose of the notified Standard is to set forth the minimum requirements for the design, development, manufacture, warehousing and distribution processes for medical devices, based on their level of risk, so as to ensure their consistent compliance with quality, safety and operational requirements for use by the end consumer or patient. Protection of human health or safety.

Recognizing certification by others: **regulatory cooperation**

WORLD TRADE ORGANIZATION

G/TBT/N/BRA/984/Add.1

15 June 2020

(20-4190) Page: 1/1

Committee on Technical Barriers to Trade Original: English

NOTIFICATION

Addendum

The following communication, dated 11 June 2020, is being circulated at the request of the delegation of Brazil.

The Resolution – RDC number 346, 12 March 2020 – previously notified through G/TBT/N/BRA/984 – which establishes extraordinary and temporary criteria and procedure for Good Manufacture Practice Guidelines for market authorization and post-market registration amendments of Active Pharmaceutical Ingredients, medicines, and healthcare products due to the international public health emergency of the new coronavirus (Covid-19), was changed by the Resolution – RDC number 385, 12 May 2020.

The final text is available only in Portuguese and can be downloaded at:

http://portal.anvisa.gov.br/documents/10181/5809525/RDC_385_2020_.pdf/d2868bf9-e33c-4107-80f0-1ba983ee5332

Instead of conducting its own inspections of pharmaceuticals and medical device manufacturers, **Brazil** is accepting information from other regulators that participate in the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the Medical Device Single Audit Program (MDSAP). (G/TBT/N/BRA/984)

TBT Committee

WORLD TRADE ORGANIZATION

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

Examples of specific trade concerns (on agenda of March 2022 TBT Committee)

EU – Medical device regulation and In Vitro Diagnostic Medical Devices Regulation (STC No 594)

- *Raised 8 times since June 2019 by Canada, China, Japan, Korea, Mexico, Singapore, US*
- Issues include:
  - insufficient number of conformity bodies accredited to certify and test medical devices
  - insufficient number of implementing acts providing detailed guidance on compliance

China – Registration fees for drugs and medical device products (STC No 466)

- *Raised 20 times since June 2015 by Australia, Canada, Korea, Malaysia, US*
- Issues include:
  - Lack of equal treatment between exporters and domestic producers in imposing registration fees due to fee for foreign inspection