Trade and Health – TBT transparency on medical devices

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Key messages

1. Trade and regulatory coherence (GRP) are vital for expediting access to essential medical products.
2. Transparency and the WTO/TBT framework can improve regulatory quality for better trade and health outcomes.
3. The WTO TBT Committee can help find cooperation solutions to trade and regulatory bottlenecks.

WHAT TO NOTIFY?

New or modified technical regulation or conformity assessment procedure

+

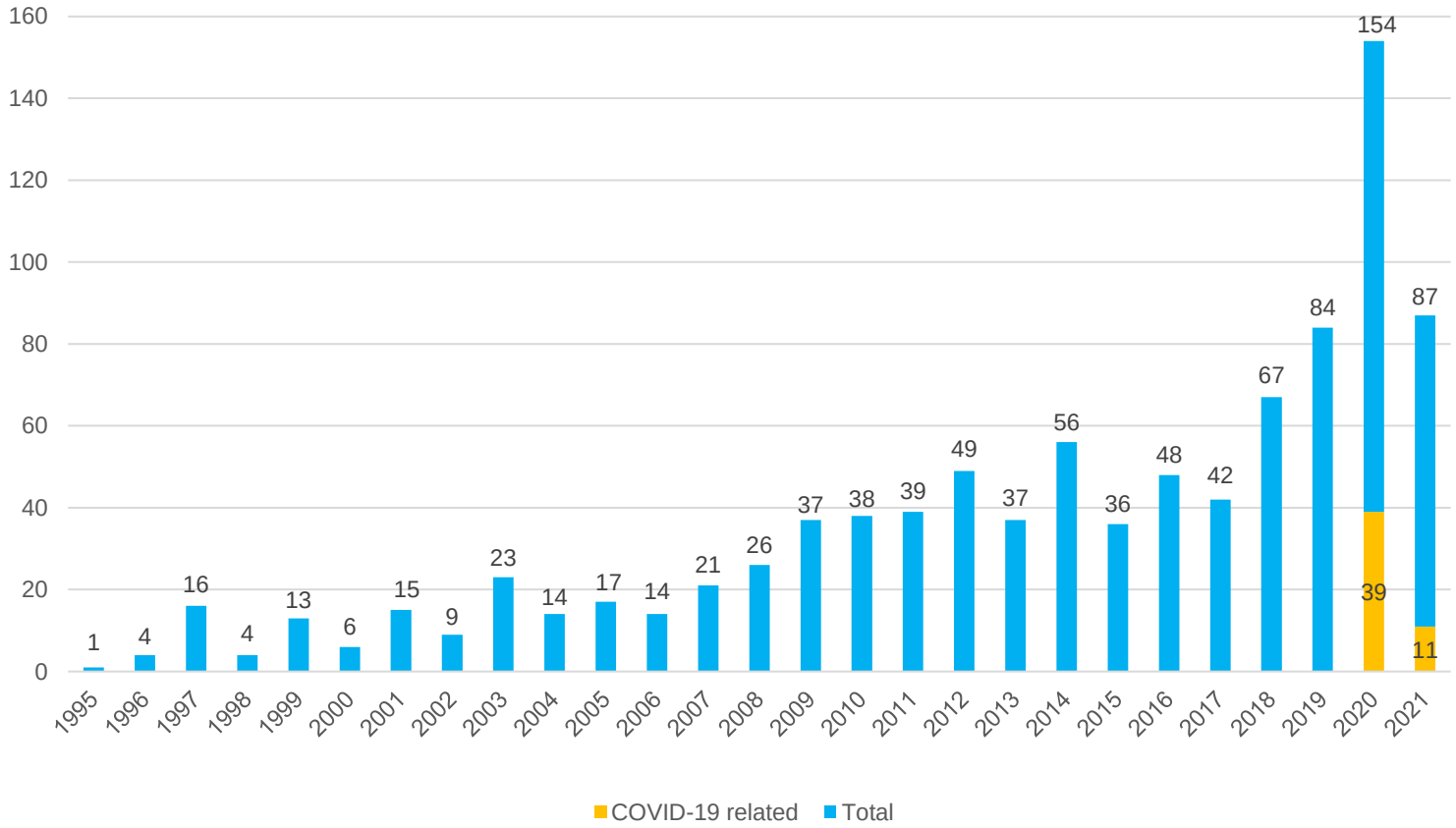
No existing international standard or Different from the international standard

+

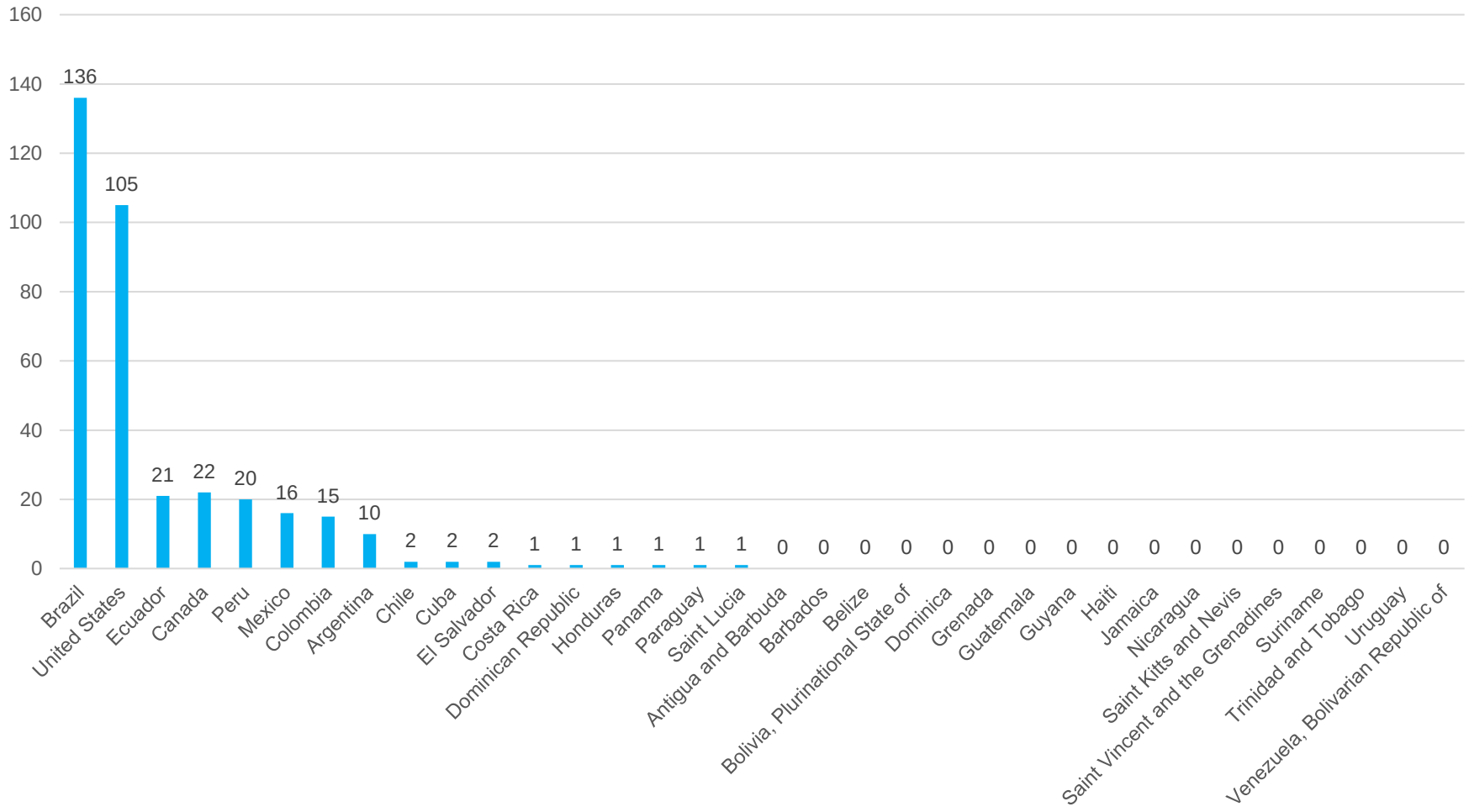
Significant impact on trade (restricting or facilitating)

NOTIFY

Notifications related to medical devices, by year



Notifications related to medical devices, by Member (Americas)



Some examples of notifications

Brazil set technical requirements for lung ventilators for intensive care units in light of Covid-19 pandemic

(G/TBT/N/BRA/1017)

(11/06/2020)

2.	**Agency responsible:** National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2145.3817 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas **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:** Brazilian Health Regulatory Agency (ANVISA)
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):** HS Code(s): Medical devices (2936, 2937, 3001, 3002, 3003, 3004, 3006)
5.	**Title, number of pages and language(s) of the notified document:** Resolution – RDC number 378, 28 April 2020 (3 page(s), in Portuguese)
6.	**Description of content:** This resolution extraordinarily and temporarily establishes technical requirements for the import, marketing, and donation of lung ventilators, vital signs monitor, infusion pump sets, oximetry machine, and used capnographs, indispensable for intensive care units, due to the international public health emergency related to the Covid-19.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health

Recognizing certification by others: **regulatory cooperation**

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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)

United States
reclassified non-invasive bone growth stimulators to reduce regulatory burdens

(G/TBT/N/USA/1643)

(14/09/2020)

2.	**Agency responsible:** Food and Drug Administration (FDA), Health and Human Services (HHS) [1672] **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:** Please submit comments to: USA WTO TBT Enquiry Point, Email: usatbtep@nist.gov
3.	**Notified under Article 2.9.2 [ ], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other [X]:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Non-invasive bone growth stimulators; Medical equipment (ICS 11.040)
5.	**Title, number of pages and language(s) of the notified document:** Physical Medicine Devices; Reclassification of Non-Invasive Bone Growth Stimulators (9 page(s), in English)
6.	**Description of content:** Proposed amendment; proposed order; request for comments - The Food and Drug Administration (FDA) is proposing to reclassify non-invasive bone growth stimulators, postamendments class III devices (product codes LOF and LPQ), into class II (special controls), subject to premarket notification. FDA is also proposing a new device classification with the name "non-invasive bone growth stimulators" along with the proposed special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of these devices. FDA is proposing this reclassification on its own initiative. If finalized, this order will reclassify these devices from class III (premarket approval) to class II (special controls) and reduce the regulatory burdens associated with these devices, as these devices will no longer be required to submit a premarket approval application (PMA), but are subject to premarket notification (510(k)) requirements and general and special controls.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety

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.

TBT Committee

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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

WTO OMC

Regular work at the WTO helps members ease trade tensions

1995 - 2021*

*until 31 July

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English: https://www.wto.org/english/res_e/booksp_e/tbt10keys2021_e.pdf

Spanish: https://www.wto.org/spanish/res_s/booksp_s/tbt10keys2021_s.pdf

7

The WTO's main tool to disseminate TBT notifications and enhance transparency on standards and regulations is ePing, an online alert system. **By the end of 2020, ePing had more than 12,000 users**, with private and public sector users roughly equal.

www.epingalert.org

ePing users by sector