International Benchmarks for Medical Device Regulatory Frameworks and Authorities: TBT Agreement

31 January 2023

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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*)

Key principles and disciplines for NRAs

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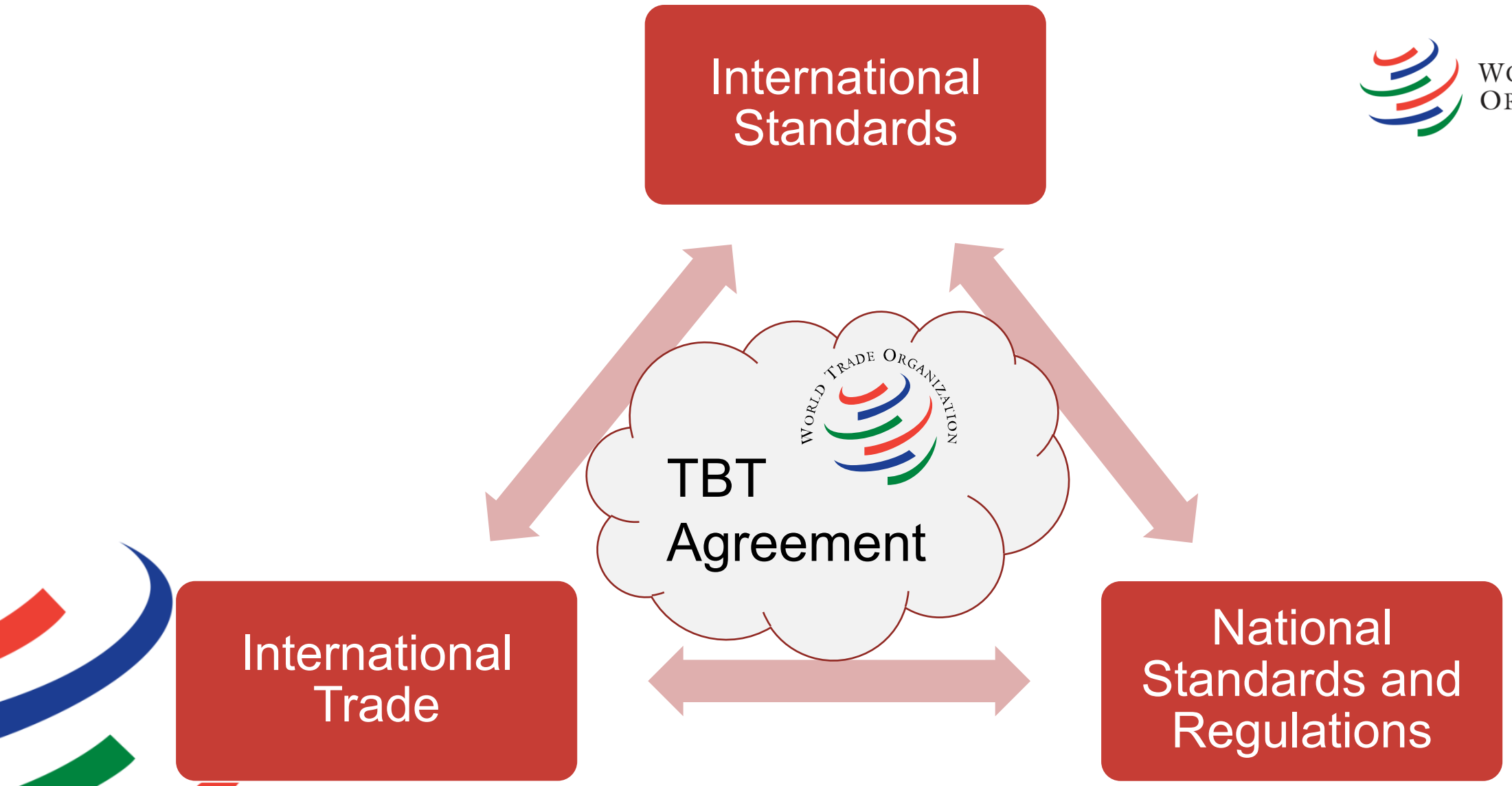
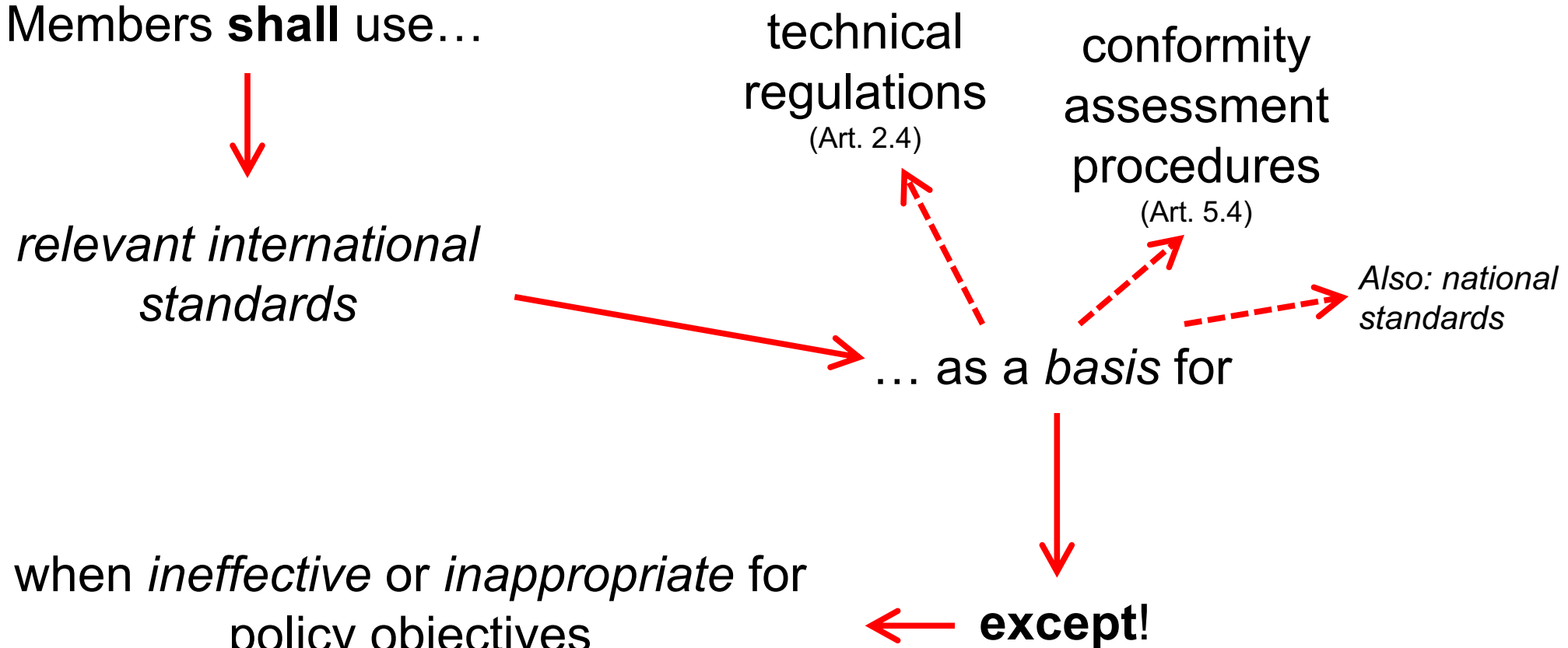
- Harmonization based on international standards
- Regulatory cooperation and coherence tools
- Transparency

International standards


International Standards
TBT Agreement
International Trade
National Standards and Regulations

TBT Agreement:
using international standards



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.”

Equivalence (encouraged in TBT the Agreement)

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Article 2:

> “Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations”.

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

+

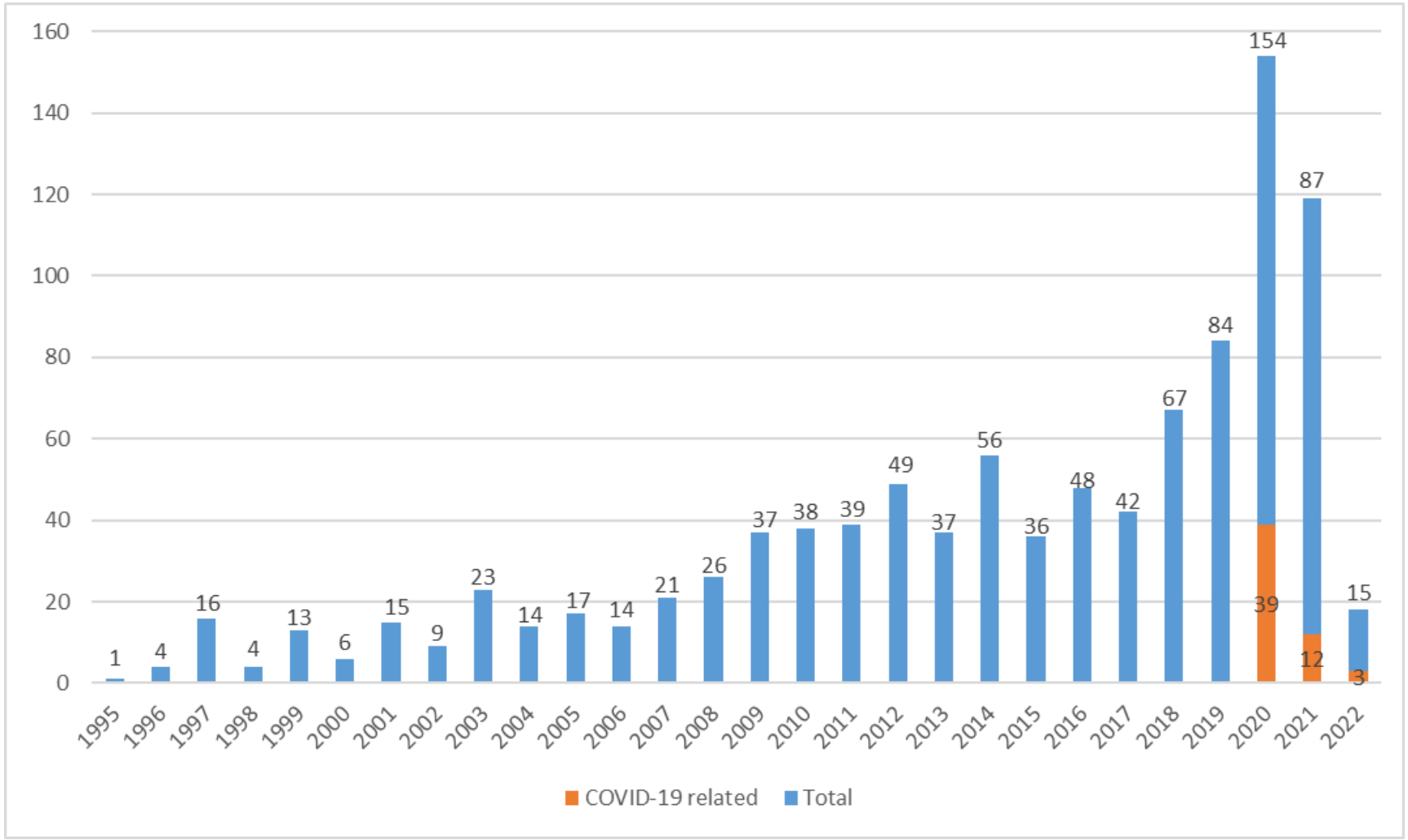
No existing international standard or Different from the international standard

+

Significant impact on trade (restricting or facilitating)

NOTIFY

Notifications related to medical devices, by year (as of March 2022)



Some examples of notifications

Uganda notified regulatory requirements for surgical gowns and drapes

(G/TBT/N/UGA/1317)

(27 April 2021)

1.	**Notifying Member:** UGANDA **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Uganda National Bureau of Standards Plot 2-12 ByPass Link, Bweyogerere Industrial and Business Park P.O. Box 6329 Kampala, Uganda Tel: +(256) 4 1733 3250/1/2 Fax: +(256) 4 1428 6123 E-mail: info@unbs.go.ug Website: https://www.unbs.go.ug **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:**
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 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):** Surgical gowns and drapes; Articles of apparel and clothing accessories, incl. gloves, mittens and mitts, for all purposes, of vulcanised rubber (excl. hard rubber and footwear and headgear and parts thereof) (HS 4015); Surgical instruments and materials (ICS 11.040.30)
5.	**Title, number of pages and language(s) of the notified document:** DUS 966-1:2021, Surgical clothing — Specification - Part 1: Surgical gowns and drapes, Second Edition (18 page(s), in English)
6.	**Description of content:** This Draft Uganda Standard specifies requirements, sampling and test methods for single-use and reusable surgical gowns and surgical drapes used as medical devices for patients, clinical staff and equipment intended to prevent the transmission of infective agents between patients and clinical staff during surgical and other invasive procedures. This standard does not apply to incision drapes or films.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Consumer information, labelling; Prevention of deceptive practices and consumer protection; Protection of human health or safety; Quality requirements

Some examples of notifications

Kenya notified minimum requirements, testing methods and use of flocked swabs during the COVID-19 pandemic

(G/TBT/N/KEN/1217)

(11 February 2022)

1.	**Notifying Member:** KENYA **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Kenya Bureau of Standards **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:** P.O. Box: 54974-00200, Nairobi, Kenya Telephone: + (254) 020 605490, 605506/6948258 Fax: + (254) 020 609660/609665 E-mail: info@kebs.org; Website: http://www.kebs.org
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):** Laboratory medicine in general (ICS 11.100.01)
5.	**Title, number of pages and language(s) of the notified document:** KS 2942:2022 Flocked swabs for medical use — Specification (9 page(s), in English)
6.	**Description of content:** This draft Kenya Standard prescribes the minimum requirements, testing methods and use of flocked swabs during the COVID-19 pandemic or any other emergency declared by the minister concerned with Health at the time
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety; Quality requirements

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)

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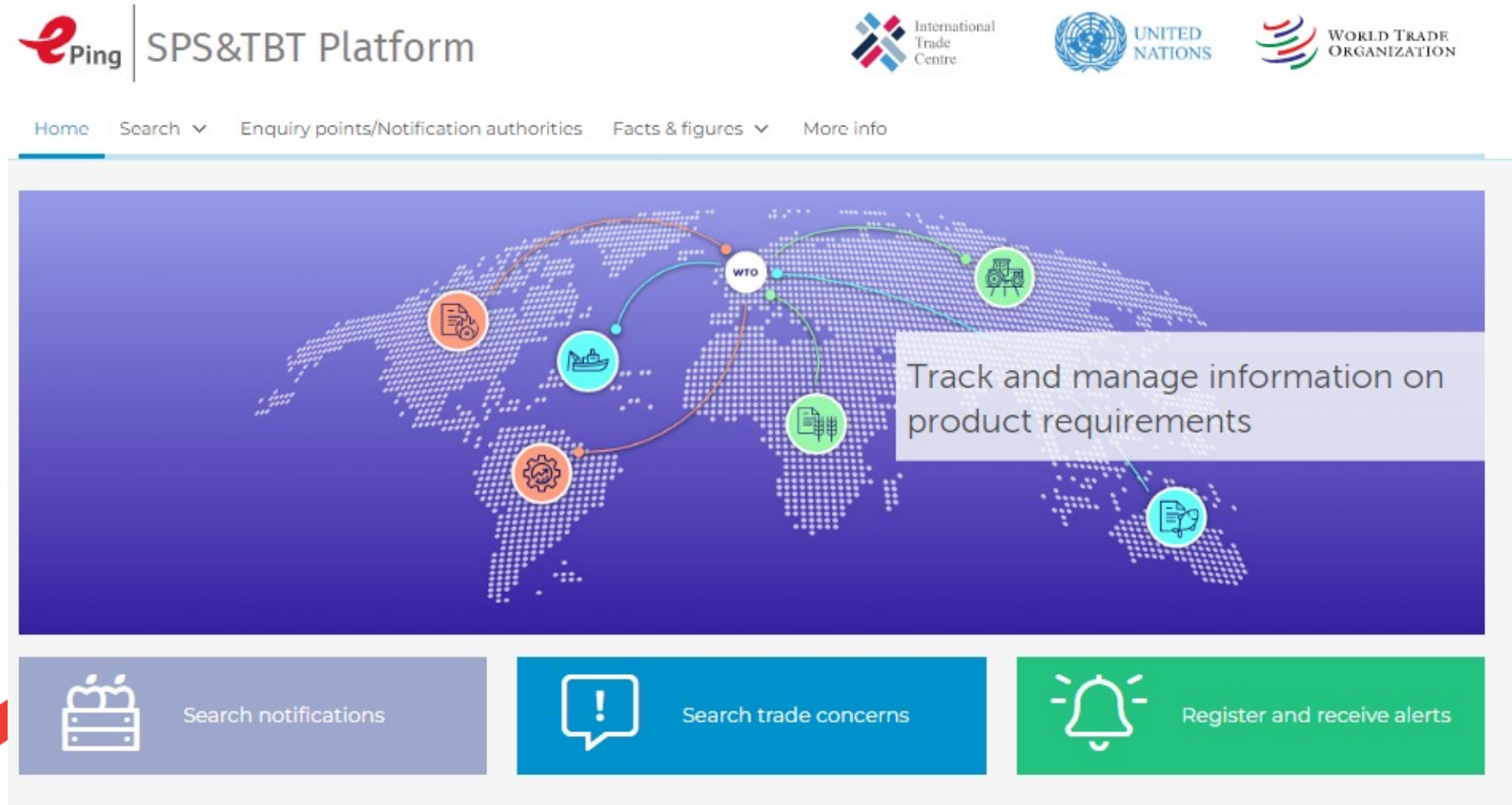

TBT Committee

WORLD TRADE ORGANIZATION

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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

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

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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

The TBT Committee

In the context of the Ninth Triennial Review of the TBT Agreement in November 2021, Members agreed, with a view to improving future pandemic preparedness, to:

> "*examine* and *compile* best practices for: understanding international standards; streamlining conformity assessment procedures (including temporary or emergency alternatives) to facilitate trade in select essential medical goods, including vaccines, during pandemics; and, enhancing international regulatory cooperation".

G/TBT/46, para. 8.4.

COVID-19-related regulatory practices discussed in the TBT Committee

- Using **relevant international standards** as a basis for technical regulations or standards on select essential medical goods, as well as **relevant international standards, guides or recommendations** as a basis for conformity assessment procedures associated with those measures
- Increasing **transparency** on, and providing **free and/or facilitated access to, standards** relevant to producing select essential medical goods on a temporary/emergency basis
- **Temporary/emergency suspension or relaxation of technical regulations** for select essential medical goods during pandemics
- **Temporary/emergency suspension or relaxation of conformity assessment procedures** for select essential medical goods during pandemics

COVID-19-related regulatory practices discussed in the TBT Committee

- Temporary/emergency **use of IT tools for conducting remote conformity assessment procedures** (in instances when such option is not already ordinarily available) for select essential medical goods during pandemics
- Promoting **recognition and acceptance of conformity assessment results** for select essential medical goods, including through reliance on accreditation, to facilitate trade in select essential medical goods
- Enhancing **international regulatory cooperation** on select essential medical goods and
- Providing **technical assistance** to support the application of the above practices

Key messages

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

Thank you for your attention!