Standards Alliance Phase 2 COVID-19 Medical Devices Regulatory Convergence (MDRC) Project

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Webinar Series

Medical Devices Regulatory Convergence (MDRC) Project Introduction and Overview on Good Regulatory Practices (GRPs): Global, WTO, OECD

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Objectives

- The objective of today's workshop is to build joint knowledge about Good Regulatory Practices (GRP) in the medical device sector.

- The participation of the public and private sectors will allow us to exchange unique experiences and information among the stakeholders involved in the regulatory process.

Good Regulatory Practices

The term Good Regulatory Practices (also referred to as GRPs) speaks to the **quality and consistency** of the domestic rulemaking process.

It refers to the **internal coordination** and **review process** under which the whole of government works to ensure that rules and regulations are crafted in an **open, transparent and participatory manner**, and that outcomes are **risk-based** and grounded in the best available **data**.

Good Regulatory Practices (3 things to remember)

- GRPs are not about more regulation or less regulation. They try to facilitate **better regulatory outcomes.**
- Political processes generate directional decisions, but GRPs create a **professional rule-making process** that follows the stabled political course. They achieve this by adhering to a **transparent and participatory regulatory** process and evidence-based decision-making.
- GRPs are an important precursor to **regulatory cooperation.** Only quality regulatory results can benefit from regulatory cooperation opportunities.

OECD Guidelines for GRP

- 2012 OECD Recommendation: **principles and tools** that help policymakers develop, implement and update regulations.

- Recognizes the importance of **international regulatory cooperation** for regulatory quality and the relevance of the **tools such as *ex ante* Regulatory Impact Assessment (RIA), stakeholder engagement and *ex post* evaluation** to base regulatory policymaking on **evidence**, including the evaluation of the likely **benefits, costs and effects** of regulation and the consideration of the **voice of the regulated.**

Regulatory Cooperation

Cooperation: refers to any interaction between regulators from different countries that results in some form of cooperation, with a view to increasing efficiency, while achieving the desired regulatory result.

Regulatory Convergence

Convergence: is a form of cooperation – when different countries decide, individually, to modify their existing or proposed regulatory frameworks to bring them to a closer alignment. This can take place throughout the time, but the moment of drawing up regulations in the respective countries is often independent of each other and difficult to synchronize.

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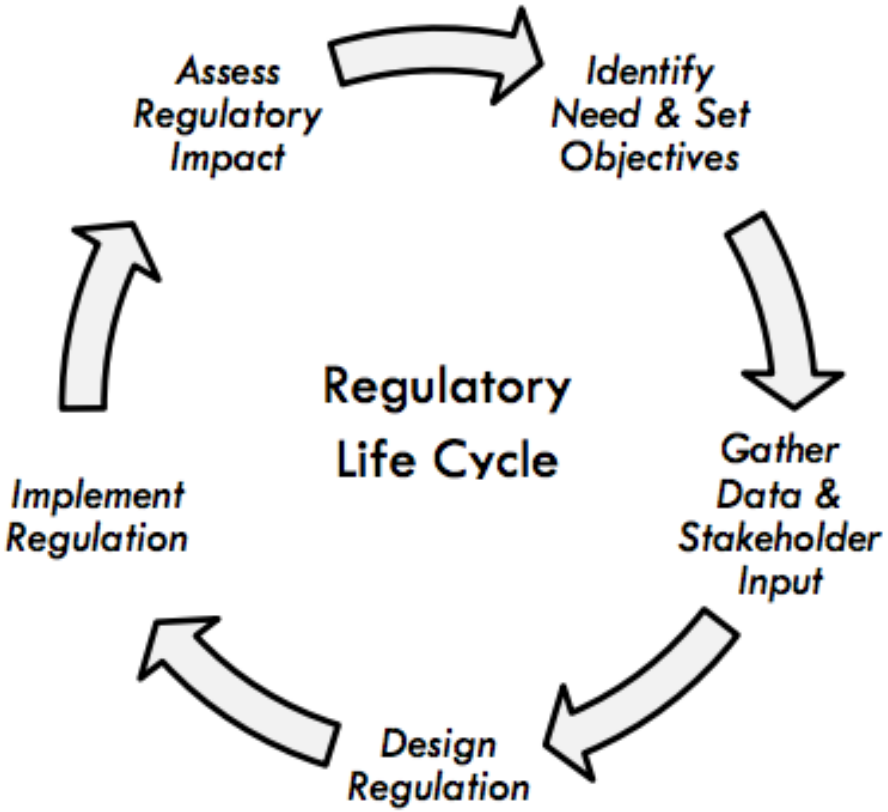
Regulatory Life Cycle

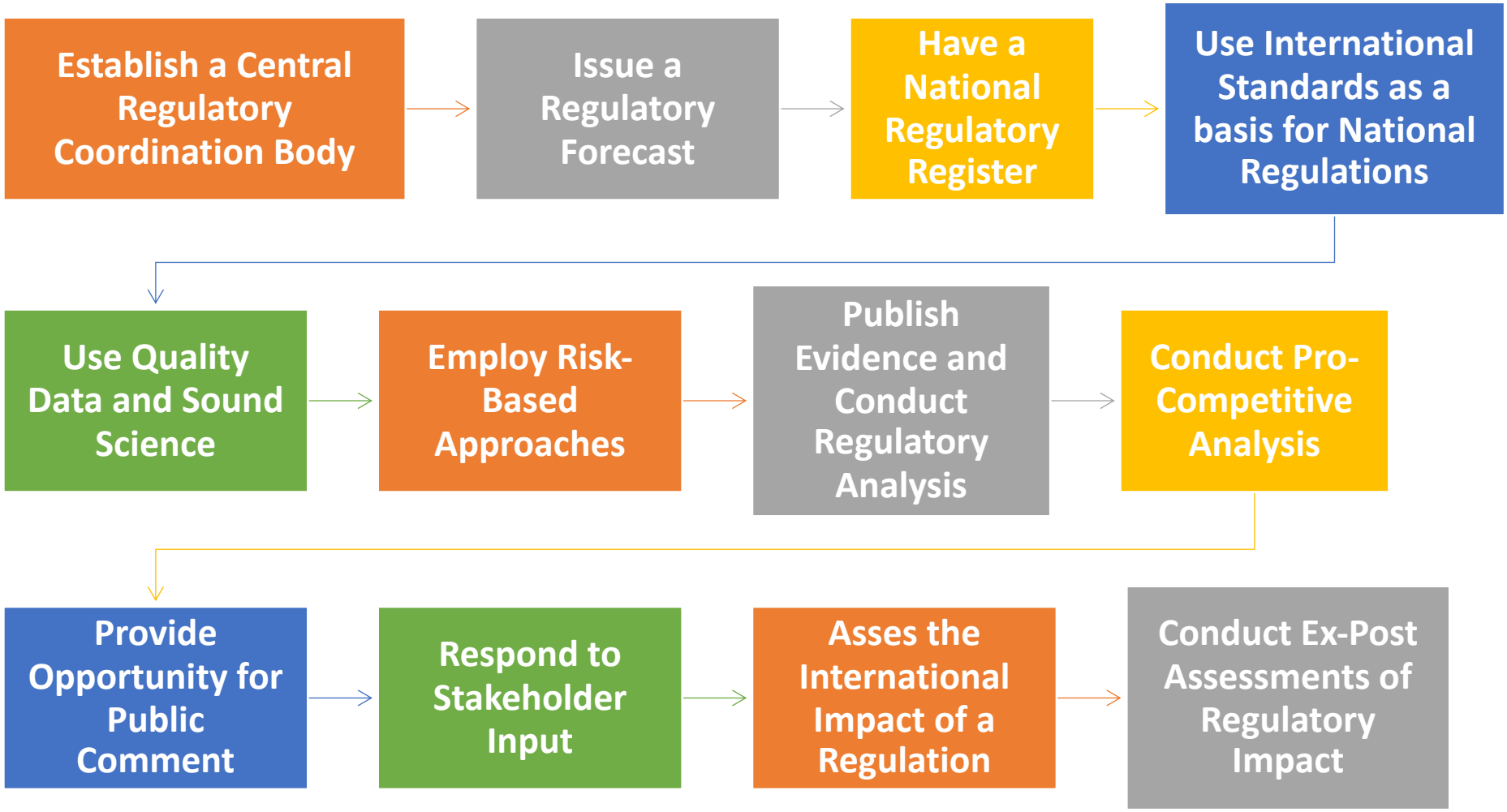


i. **Regulatory cooperation** can occur during the design, monitoring, enforcement or ex post administration of regulations.

ii. It is very difficult for regulatory cooperation to succeed without the application of GRP.

iii. **Important!** The implementation of GRP is a significant step towards cooperation, once well-designed regulations produce outcomes that generate fewer cross-border challenges.

GRP Key components



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Regulatory Impact Analysis (RIA)

Good regulations anticipate the impact they will have on the market. They project the benefits, specifically economic benefits, that a given regulation will have over market costs.

The GRPs guide regulators' efforts to better calculate costs and benefits by developing guidelines and developing a common methodology used among regulatory authorities.

USMCA: GRP Chapter

- Good Regulatory Practices is a Chapter of the recently signed agreement between the U.S., Mexico and Canada.

- State of the art in terms of what could be codified on GRP in a trade agreement.

- The same chapter is reflected in the agreements/protocols signed between the U.S. and Brazil, and U.S. and Ecuador.

USMCA GRP Chapter

- Central Regulatory Coordinating Body
- Internal Consultation, Coordination, and Review
- Information quality
- Early Planning
- Dedicated Website
- Use of Plain Language
- Transparent Development of Regulations
- Expert Advisory Groups
- Regulatory Impact Assessment
- Final Publication
- Retrospective Review
- Suggestions for Improvement
- Information About Regulatory Processes
- Annual report
- Encouragement of Regulatory Compatibility and Cooperation
- Committee on Good Regulatory Practices
- Contact Points
- Dispute Settlement

Interface between GRP and International Trade

- Regulations may have, as a secondary result, the impact of being **overly trade restrictive** and may create **unnecessary obstacles** to the free flow of goods.

- Over the past several years, attention has grown for the **trade costs of regulatory divergence**.

- Diverging regulation may **increase the costs** to trade goods and services across borders.

The relevance of the World Trade Organization (WTO) for GRP

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Focus on the TBT Agreement

Encourage members to use less trade-restrictive measures	Harmonize the use of relevant international standards	Transparency	Avoid trade disputes related to technical standards or regulations.

The disciplines of the TBT Agreement can help contribute with effectiveness and efficiency of regulations through the application of GRP. It lays down specific legal disciplines, which directly address the preparation, adoption and application of domestic regulations on goods.

TBT Agreement - Definitions

Technical regulation	• A document that lays down **product characteristics** or their related **processes and production methods**, including the **applicable administrative provisions**, with which **compliance is mandatory**.
Standard	• 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 **is not** mandatory
Conformity Assessment	• 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.

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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**. **ASSESS**

- 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**. **REVIEW**

- 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. **LOOK AT THE WORLD**

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.***

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.

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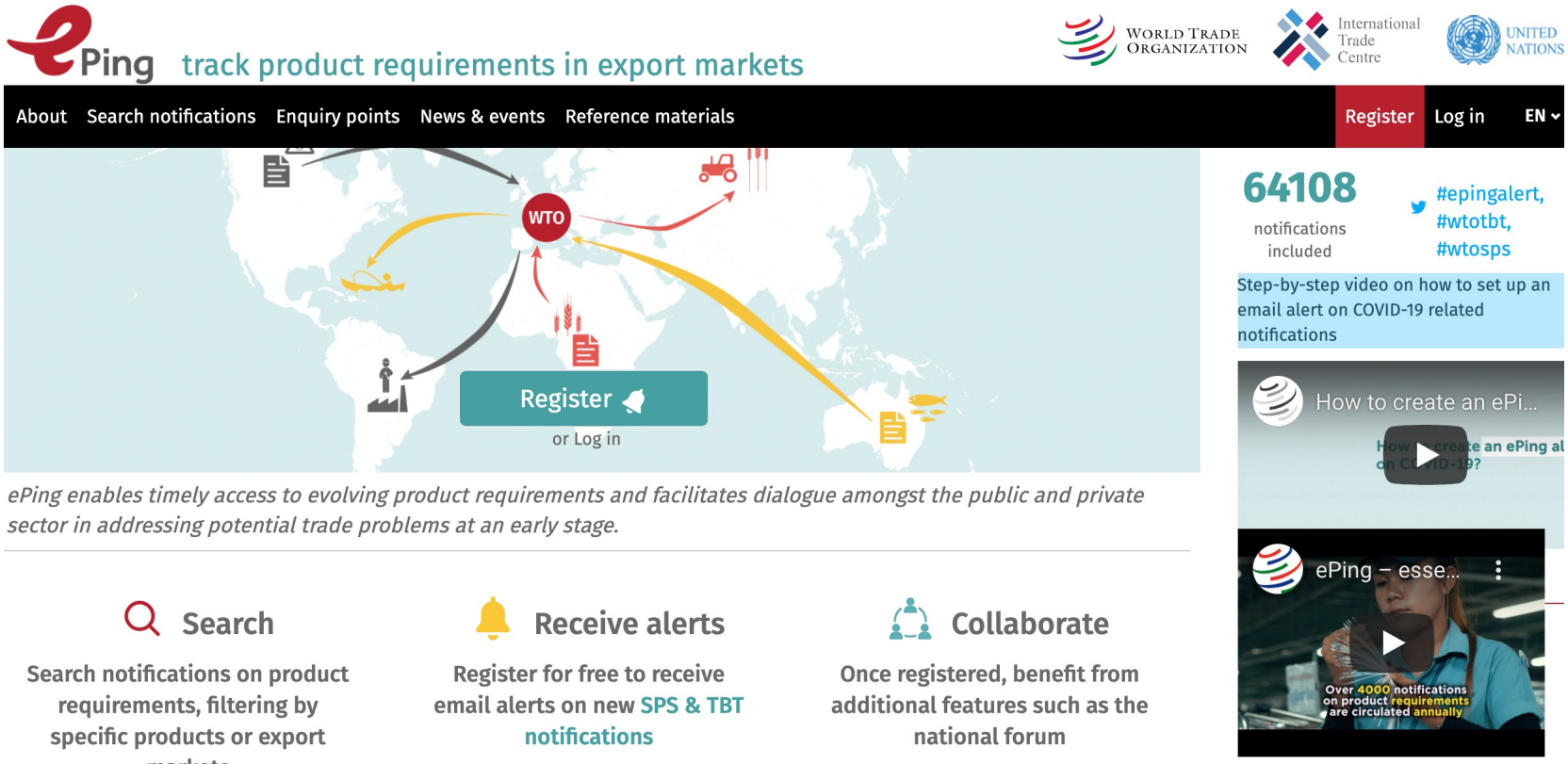
ePing system - WTO



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

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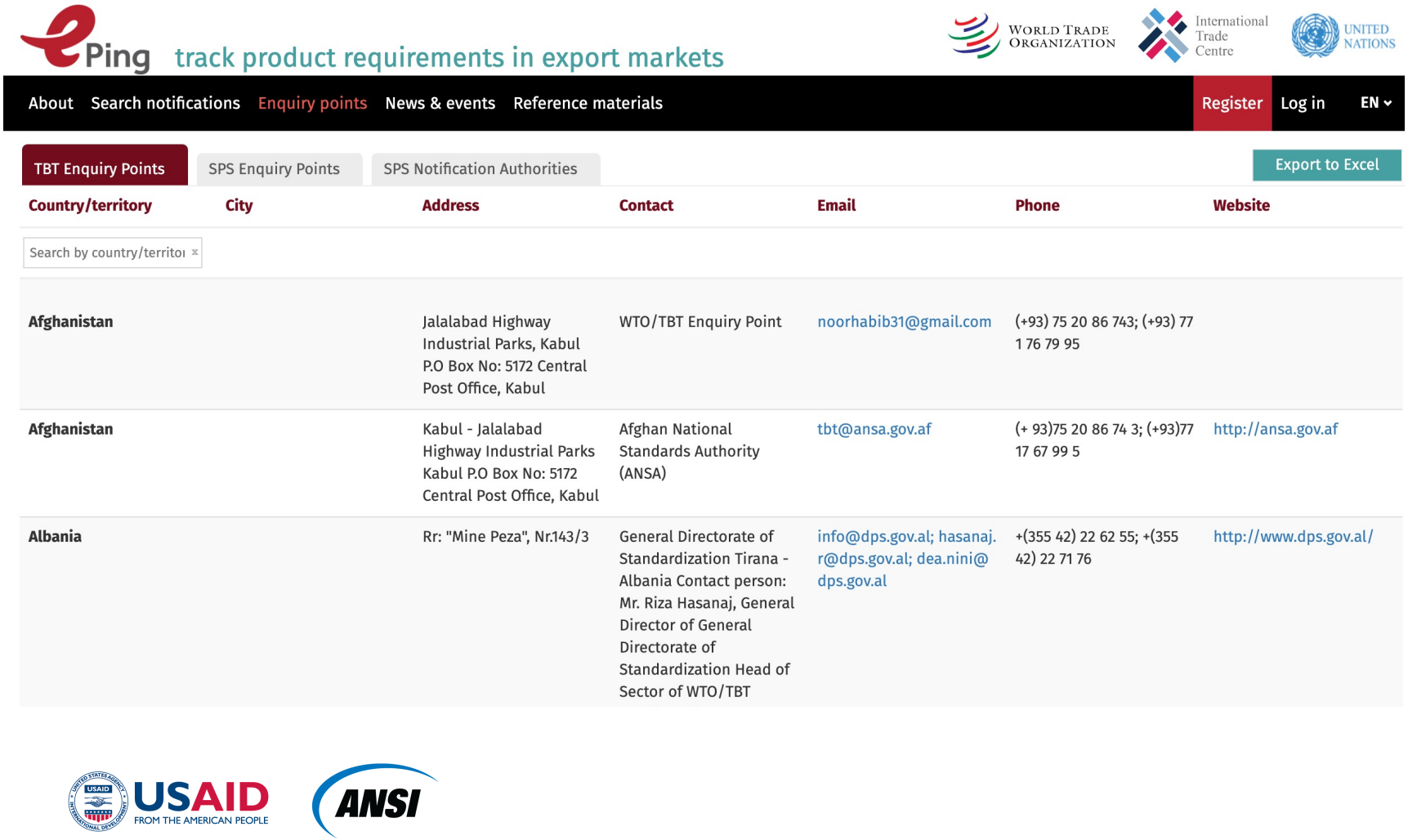
ePing system - WTO



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AfCFTA – Annex on TBT

- Reaffirms TBT Agreement
- Objectives:
  - Reinforces international best practices in regulation and standards setting;
  - Promotes the use of relevant international standards as a basis for technical regulations; and
  - Identify and assess instruments for trade facilitation such as harmonization of standards, equivalence of technical regulations, metrology, accreditation and conformity assessment.

AfCFTA

Standards
The Parties shall
Develop and promote the **adoption and/or adaptation of international standards;**
Promote the adoption of standards developed by the **ARSO and the AFSEC;**
Where a relevant international standard required to facilitate trade does not exist, **request the ARSO and/or the AFSEC to develop the required standard** to facilitate trade between State Parties;
Designate **liaison focal points** to ensure that all State Parties are well informed of the standards developed or to be developed by the ARSO and the AFSEC;
Apply harmonized rules and procedures for the development and publication of national standards in accordance with international requirements and best practices;

AfCFTA

Technical Regulation
The parties shall promote:
Compliance with the **WTO TBT Agreement;**
Use of international standards and/or parts thereof as a basis for technical regulations; and
Application of **Good Regulatory Practices.**

Conformity Assessment
The parties shall:
Make use of **relevant international standards** and conformity assessment procedures;
Facilitate the development of conformity assessment capacity and technical competence that can support trade;
Promote the use of accredited conformity assessment bodies as a tool to facilitate trade amongst the State Parties;
Promote **mutual acceptance of conformity assessment results of conformity assessment bodies** which have been recognized under appropriate multilateral agreements between their respective accreditation bodies and the relevant mutual recognition arrangements of the AFRAC, ILAC and IAF;

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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.**

Key Take-Aways

A **Technical Regulation** is a document with which compliance is mandatory.

A **Standard** is a document with which compliance is voluntary.

The best mechanism to harmonize cross-border requirements is for regulators to use **harmonized international standards** (either directly or as a basis for their regulations).

Standards Organizations (SDOs) have **Technical Committees** that develop the international standards for medical devices

Every country in the world has access to the SDOs.

One of the most expensive activities a government can engage is **rulemaking**.

This is particularly the case if the rule is **ineffective** or if it is overly **burdensome** given the regulatory purpose.

Governments have the independence to **prioritize** their **health** resources.

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Key Take-Aways

What is the likelihood that an agency working alone will:
i. Identify a new regulatory issue not yet identified elsewhere globally?

ii. Develop a policy that does not conflict with existing policies globally? GRP is the QA system for a government's regulatory process.

GRP is the **compliance** system for a government's regulatory process.

The WTO TBT Agreement is a GRP and **legally binding** international treaty obligation.

Countries (and all of their government agencies) are required to **use international standards** as a basis for their technical regulations.

Not doing so is **inconsistent** with the TBT Agreement.

The WTO **requires** medical device regulators to use international standards.

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Q & A

Thank You!

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