

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

August 22, 2023

S T A N D A R D S A L L I A N C E - P H A S E 2



## Webinar Series

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

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# Introduction and Overview

1. Workshop objectives
2. Background: the role of governments and the private sector
3. Overview: What are Good Regulatory Practices?
4. Review of the regulatory process
5. Countries with GRPs and rules of transparency and regulatory impact assessment
6. Regulatory cooperation, regulatory convergence and central regulatory bodies
7. The relevance of the regulatory impact assessment
8. The interface between GRPs and trading:
9. Multilateral Treaty Overview: TBT Agreements and WTO Tools
10. ePing and Transparency Tool
11. Trade Policy Reviews
12. Specific trade concerns



# Objectives, Public Sector and Private Sector

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

- The 2012 OECD Recommendation highlights a number of **principles and tools** that can help policymakers develop, implement and update regulations that promote their policy goals in the public interest.
- The document recognizes the importance of **international regulatory cooperation** for regulatory quality and the relevance of the **tools of regulatory policy** – encompassing *ex ante* Regulatory Impact Assessment (RIA), stakeholder engagement and *ex post* evaluation – to base regulatory policy making 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.

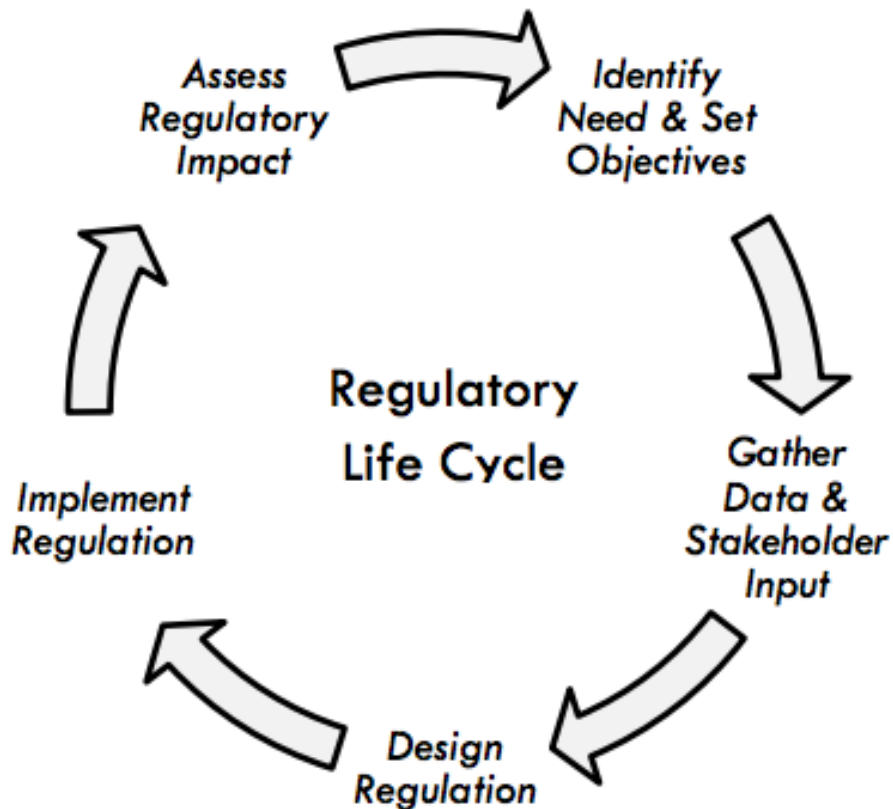
## Regulatory Convergence

- **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.





# 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, as well-designed regulations produce outcomes that generate fewer cross-border challenges.

# GRP Key components



# 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

- Good Regulatory Practices encompassing the use of regulatory impact assessments, stakeholder engagement and ***ex post* evaluation** are a **critical tool** in the hands of governments to ensure that regulation achieves its objectives.
- 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

- i. Unnecessary regulatory differences can impose costs that prevent businesses from engaging in trade.
- ii. The only international body dealing with rules of trade between nations (164 Members).
- iii. WTO agreements provide the legal ground-rules for international commerce.
- iv. They bind governments to keep their trade policies within agreed limits.
- v. Help trade flow as freely as possible (e.g. by removing obstacles, providing confidence, transparency and predictability).
- vi. The WTO plays an important role in supporting efforts to facilitate trade through regulatory cooperation among its members, offering a **multilateral platform for dialogue among governments on trade rules, and throughout the full rule-making cycle.**



# 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 GRP. It lays down specific legal disciplines, which directly address the preparation, adoption and application of domestic regulations on goods.





# 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.**
- 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.**
- 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.



# 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.***



# TBT Agreement - Definitions

## Annex 1 of the TBT Agreement

### 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.



# 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.



# ePing system - WTO

 **track product requirements in export markets**



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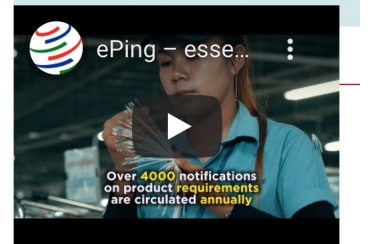
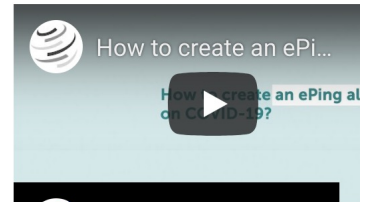
*ePing enables timely access to evolving product requirements and facilitates dialogue amongst the public and private sector in addressing potential trade problems at an early stage.*

**64108**

notifications included

#epingalert, #wtotbt, #wtosps

Step-by-step video on how to set up an email alert on COVID-19 related notifications



## 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



# ePing system - WTO



About Search notifications Enquiry points News & events Reference materials

Register

Log in

EN ▾

TBT Enquiry Points

SPS Enquiry Points

SPS Notification Authorities

Export to Excel

Country/territory	City	Address	Contact	Email	Phone	Website
Search by country/territory ✕						
Afghanistan		Jalalabad Highway Industrial Parks, Kabul P.O Box No: 5172 Central Post Office, Kabul	WTO/TBT Enquiry Point	noorhabib31@gmail.com	(+93) 75 20 86 743; (+93) 77 1 76 79 95	
Afghanistan		Kabul - Jalalabad Highway Industrial Parks Kabul P.O Box No: 5172 Central Post Office, Kabul	Afghan National Standards Authority (ANSA)	tbt@ansa.gov.af	(+ 93)75 20 86 74 3; (+93)77 17 67 99 5	<a href="http://ansa.gov.af">http://ansa.gov.af</a>
Albania		Rr: "Mine Peza", Nr.143/3	General Directorate of Standardization Tirana - Albania Contact person: Mr. Riza Hasanaj, General Director of General Directorate of Standardization Head of Sector of WTO/TBT	<a href="mailto:info@dps.gov.al">info@dps.gov.al</a> ; <a href="mailto:hasanaj.r@dps.gov.al">hasanaj.r@dps.gov.al</a> ; <a href="mailto:dea.nini@dps.gov.al">dea.nini@dps.gov.al</a>	+(355 42) 22 62 55; +(355 42) 22 71 76	<a href="http://www.dps.gov.al/">http://www.dps.gov.al/</a>



# 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.





## 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.

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

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

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

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

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

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# Q & A



# Thank You!



# Contact Information

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