

# Training on GRPs and their Implementation in the Medical Device Sector



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# Diagnosis and Awareness of International Trade Agreements

# I. International negotiations and commitments

## TRADE IN GOODS

**GENERAL AGREEMENT ON TARIFFS  
AND TRADE**



**AGREEMENT ON TECHNICAL  
BARRIERS TO TRADE**

**AGREEMENT ON THE APPLICATION  
OF SANITARY AND PHYTOSANITARY  
MEASURES**



Good  
Regulatory  
Practices



Regulatory  
Cooperation

## TRADE IN SERVICES

**GENERAL AGREEMENT ON TRADE IN  
SERVICES**



**ARTICLE VI  
NATIONAL REGULATIONS**

**ARTICLE XIV  
GENERAL EXCEPTIONS**

# Good regulatory practices

- At the multilateral level, its development has been based on the Reviews of the Operation and Implementation of the **TBT Agreement** (every 3 years) and the **SPS Agreement** (every 4 years).
- The greatest progress in the elaboration of commitments has occurred through regional and bilateral initiatives, mainly through **Free Trade Agreements**, as well as in the work in international organizations such as the OECD and APEC.
- The concept of Good Regulatory Practices coincides with that of **Regulatory Coherence and Regulatory Improvement**.
- **Regulatory Cooperation** is one of the Good Regulatory Practices.

# Good regulatory practices

## **G/TBT/1/Rev.14 September 24th, 2019):**

- "The adoption of good regulatory practices can contribute to the improved and effective implementation of substantive obligations under the TBT Agreement. Effective implementation through best practices is seen as an important means of avoiding unnecessary obstacles to trade.
- Institutionalizing the various mechanisms, processes and procedures of good regulatory practices through laws, regulations and guidance, as well as through the creation and designation of institutions within Member governments to oversee regulatory processes, is seen as a means of giving effect to good regulatory practices.
- Effective internal policy coordination, including among regulators, standardizing bodies and trade officials implementing the TBT Agreement, is stressed.
- Additionally, regulatory cooperation between Members is an effective means of disseminating good regulatory practices."

# Good regulatory practices

## 6th Triennial Review of the TBT Agreement-2012 (G/TBT/32):

The TBT Committee agreed to *identify* a non-exhaustive list of voluntary mechanisms and related principles of good regulatory mechanisms, which included, *inter alia*, the following mechanisms:

- ✓ Transparency and public consultations;
- ✓ Evaluation of Policy Options (RIA);
- ✓ Internal (national) coordination;
- ✓ Options that minimize the burden on economic operators;
- ✓ Implementation and compliance (practical guidelines for compliance);
- ✓ Review of existing technical regulations and conformity assessment procedures; and
- ✓ Special and differential treatment for developing country members.

# Good regulatory practices



Design of the regulations



Regulatory institutions



Regulatory impact assessments



**Asia-Pacific  
Economic Cooperation**



Consultation mechanisms: transparency



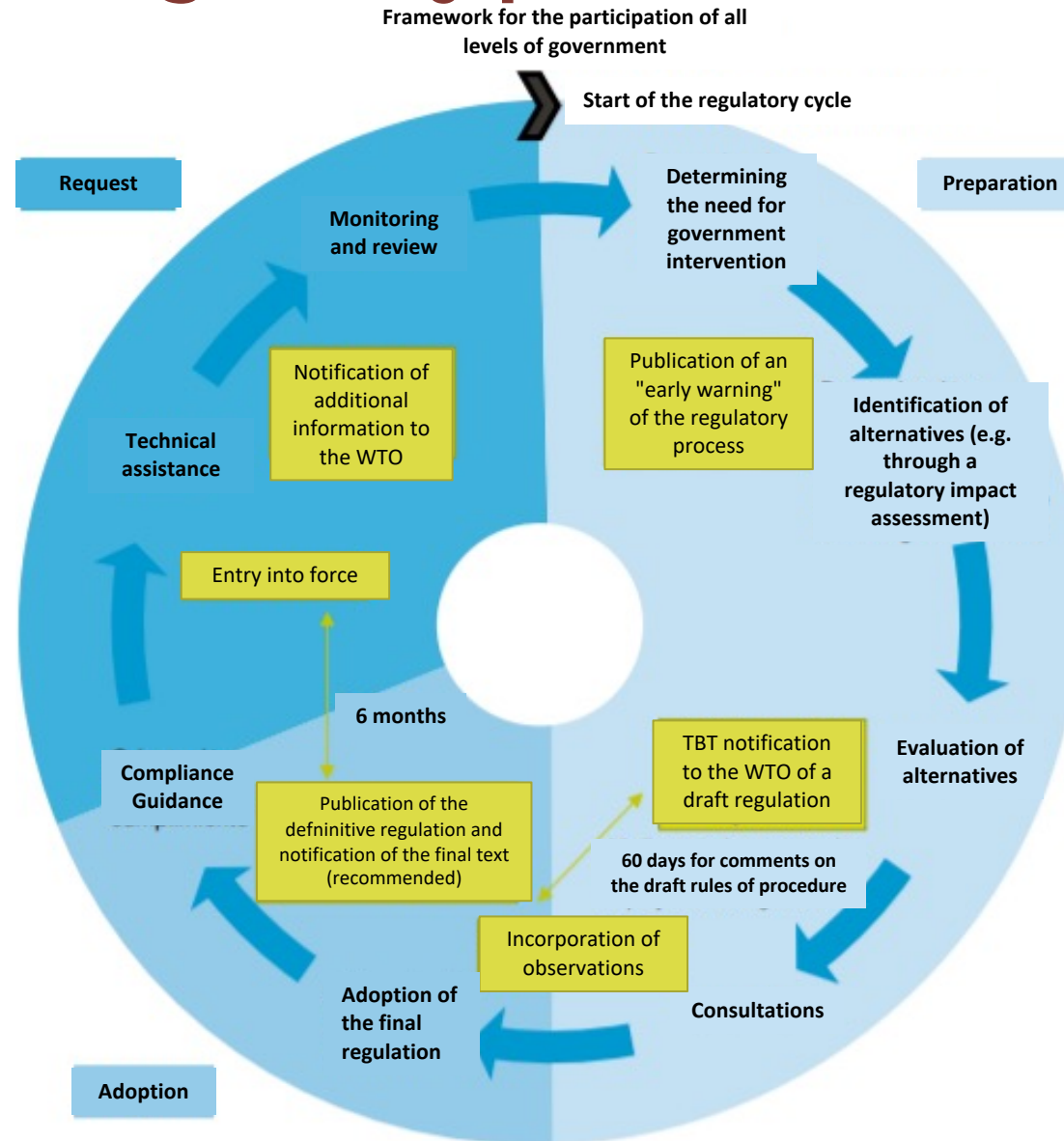
Mechanisms for the implementation of  
regulations: *Ex Post* Reviews



Regulatory alternatives



# Good regulatory practices in a TBT measure



# Good regulatory practices

- ✓ Promotes competitiveness.
- ✓ Prevents or eliminates barriers to trade.
- ✓ Reduces regulatory burdens.
- ✓ Promotes economic competition.
- ✓ Fosters transparency.
- ✓ Increases productivity.
- ✓ Improves quality of regulations.
- ✓ Generates self-discipline in the agencies.
- ✓ Democratizes the regulation.
- ✓ Favors regulatory cooperation.



**Level the "playing field"**

# Free Trade Agreements



Chapter 25



Chapter 15bis



Chapter 28

- Scope: planning, design, issuance, implementation and review.
- Covered regulations are not limited to the scope of TBT and SPS.
- Maintaining a central regulatory coordination body.
- Internal coordination and review processes and mechanisms.
- Specific GRP commitments: RIA; information quality, transparency; retrospective review.
- Chapter Committees ➡ “Living” dialogue.
- USMCA – Dispute Settlement.

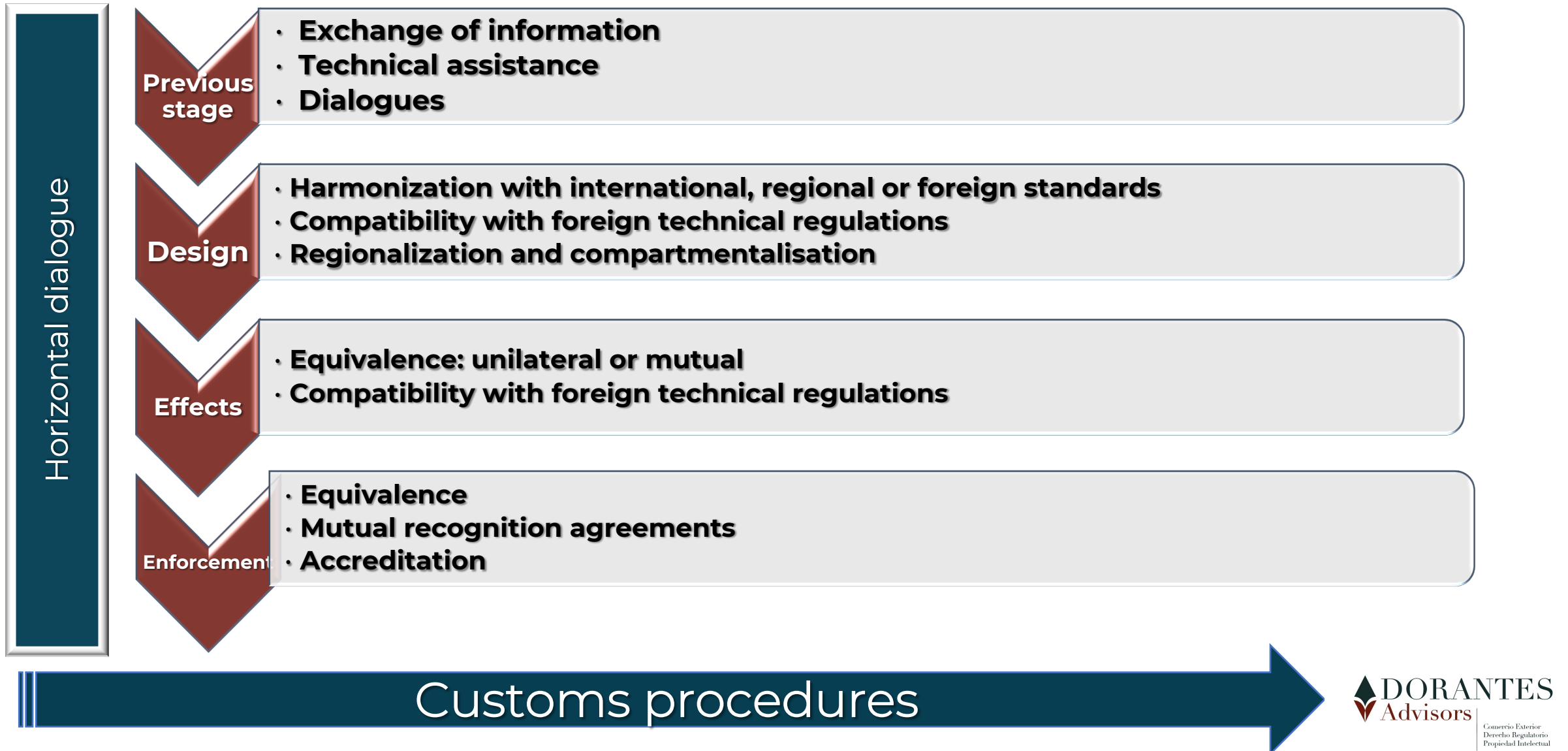
## II. Regulatory Cooperation

# Regulatory Cooperation

"Cooperation to improve the achievement of legitimate objectives,  
while facilitating trade"

- **Contentious approach:** the Agreement on Technical Barriers to Trade and the Agreement on the Application of Sanitary and Phytosanitary Measures seek to ensure that **unnecessary barriers to international trade** are not created.
- **Cooperative approach:** both agreements, but fundamentally the **Agreement on Technical Barriers to Trade contemplate** "Regulatory Cooperation".

# Regulatory Cooperation



# Regulatory Cooperation

## + Institutional Integration



Coincidence of authority, legislation and multisectoral surveillance: REACH, food, SPS, consumer products.



Coincidence of binational authority, legislation (Food Standards Code of AU and NZ) and technical standards.



Harmonization of regulations in priority sectors.



## Sectoral Annexes

- Wines and spirits
- Information technology products
- Energy performance
- Cosmetic products, pharmaceuticals and medical devices
- Proprietary formulas for prepackaged foods and food additives
- Organic products
- Chemical Substances

## - Institutional Integration

## T-MEC Annex 12-E

### Medical Devices

- **Scope.** TBT Approach.
- **Identification of Competent Authorities.**
- **Enhancing Regulatory Compatibility.**
  - ✓ Definition of "medical device".
  - ✓ Collaboration in international initiatives.
  - ✓ Audits of quality management systems.
  - ✓ Support in international efforts.
- **Application of Regulatory Controls.**
  - ✓ Non-discrimination.
  - ✓ Classification according to risk.
  - ✓ Efficiency in requirements.
- **Marketing Authorizations.**



# Conclusions

- GRPs have been included in multilateral trade instruments since the creation of the WTO.
- The application of GRPs is not limited to measures covered by specific trade disciplines.
- Considering their scope, the adoption of the GRP refers to a structural effort.
- Its international discussion has evolved, incorporating specific commitments into chapters of international trade agreements.
- Regulatory cooperation, an expression of the GRP, has also been incorporated into regional integration processes, regardless of the level of institutional integration among its members.



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Thank you for your attention.

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