Good Regulatory Practices

Global Perspective

STANDARDS ALLIANCE - PHASE 2

11/13/2020







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What are Good Regulatory Practices?

- The concept Good Regulatory Practices (GRP) highlights to the quality and consistency of the national regulatory process.
- It refers to internal coordination and review process under which the entire government works to ensure that rules and regulations are drawn up openly, transparently and participatively. Those results are based on risk and the best available data.



Good Regulatory Practices

- 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.



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Regulatory Cooperation and Convergence

Cooperation: 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 results

Convergence: a form of cooperation – when different countries each decide to modify their existing or proposed regulatory frameworks to bring them to a closer alignment. This may happen over time, but the timing of regulatory development in the respective countries is often independent of each other and difficult to synchronize.



The regulatory process

- Regulatory cooperation can occur during the design, monitoring, enforcement or ex post administration of regulations;
- It is very difficult for regulatory cooperation to succeed without the application of good regulatory practices.

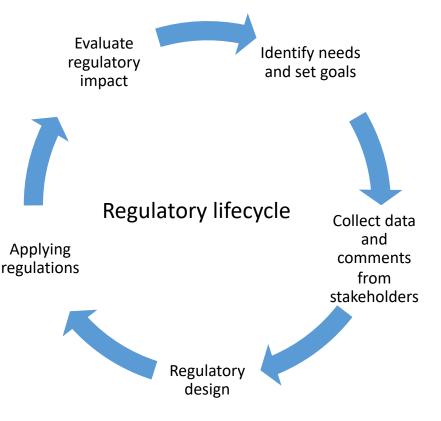


Image 2: Regulatory lifecycle

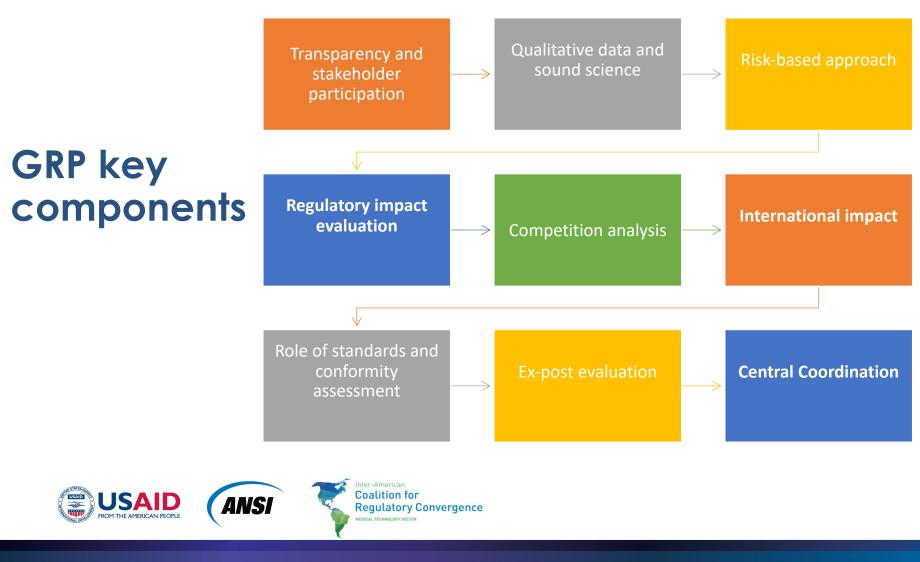


GRP and Cooperation

Implementing good regulatory practices is a significant step towards cooperation, as **well-designed regulations produce outcomes that generate fewer cross-border challenges.**







Regulatory impact assessment

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.





Countries with interesting GRP processes







International Forums

- International Standards Development Forums (IMDRF, PAHO, International Standards Development Committees related to medical devices.
- For in which Colombia currently participates or contributes.



The interface between GRP and International Trade

In recent years attention has been given to commercial costs' growth related to regulatory divergences.

In fact, regulatory divergences can raise costs of goods and services across borders.



Overview of International Treaties

Focus on the World Trade Organization's (WTO) Agreement on Technical Barriers to Trade (TBT)

The TBT works as an instrument for:

Encourage members to use less traderestrictive measures;

Harmonize the use of relevant international standards;

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Transparency;

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Avoid trade disputes related to technical standards or regulations.

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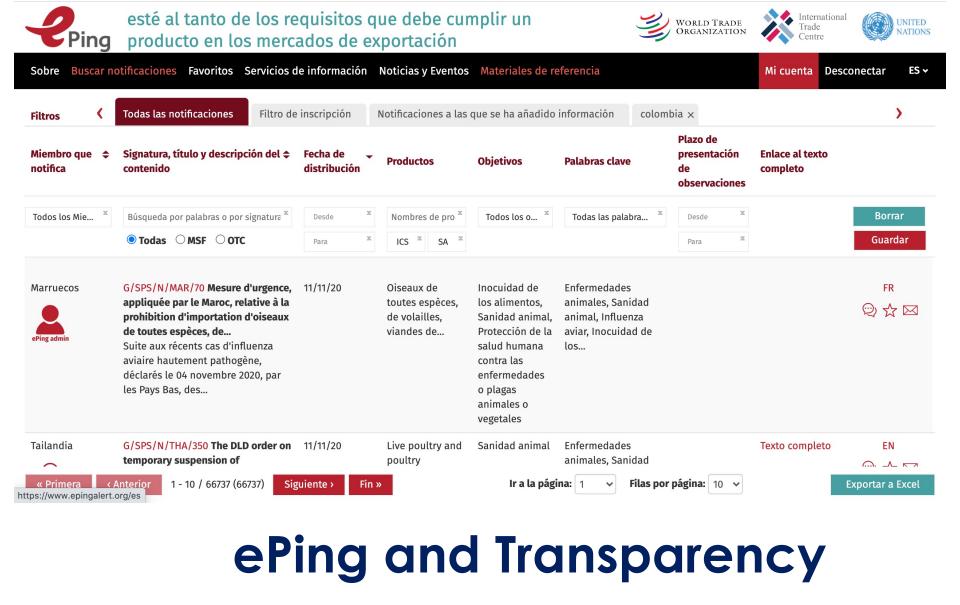
Inter-American Coalition for Regulatory Convergence MEDICAL TECHNOLOOY SECTOR ePing and Transparency The ePing website is an alert system where you can register to receive email notifications about the planned reviews of regulations regarding the products and/or markets that interest you.

> MSF/TBT information services often serve as a liaison between national stakeholders and other WTO Members and can help follow and address issues related to future regulations.

> > An administration page dedicated to government officials dealing with MSF and TBT transparency issues helps manage ePing at a national level.



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Trade Policy Reviews

Other Mechanisms Available at the WTO

Specific Trade Concerns

Commercial Disputes









