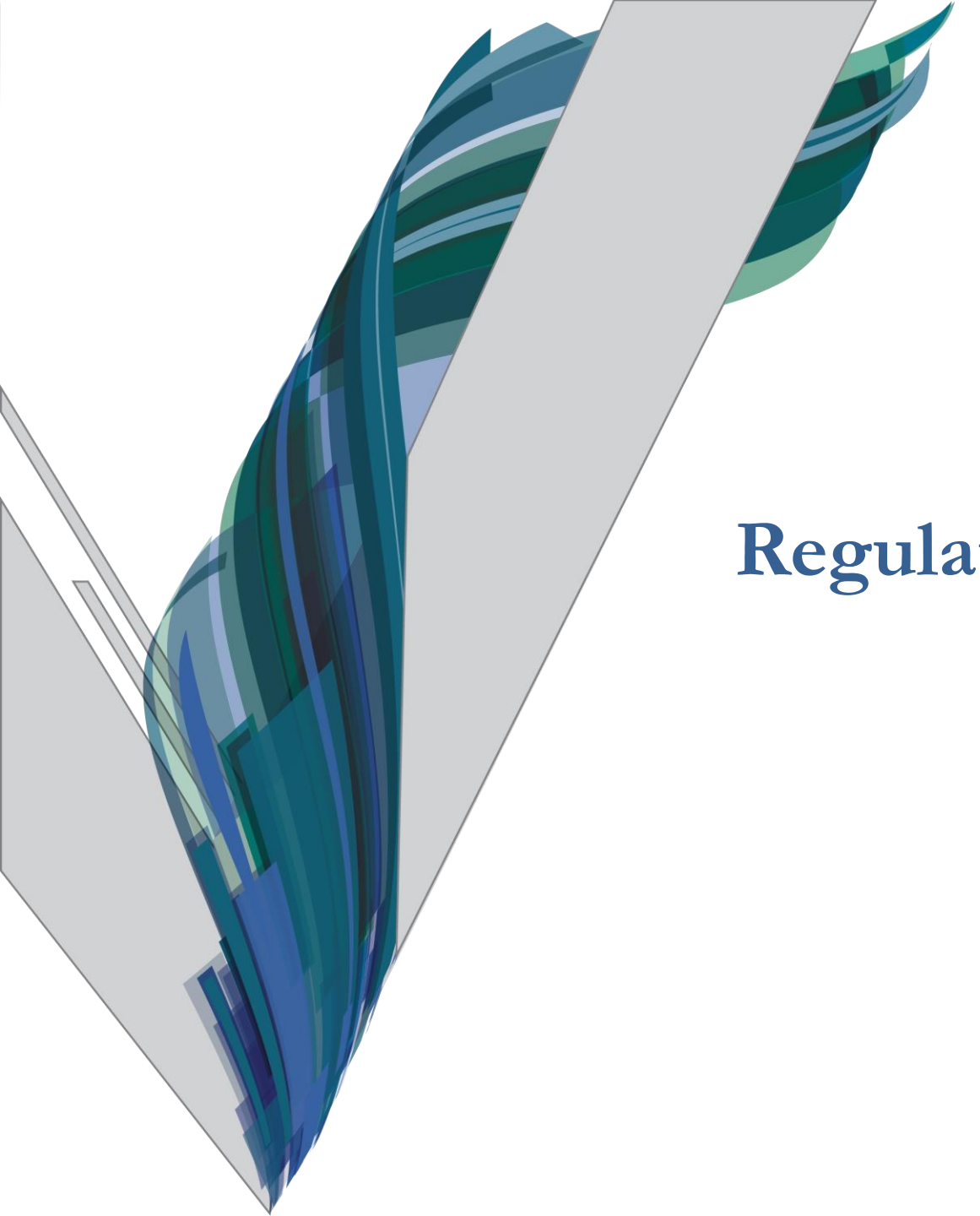

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Regulatory Coherence in Colombia

September 2018

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Agenda

- Overview of the AdvaMed Standards Alliance Project
- Overview of Regulatory Coherence?
- Central Coordination in Colombia
- Implementation of Good Regulatory Practices in Colombia
  - Regulatory Forecasting
  - National Regulatory Register
  - Public Comment Process
  - Regulatory Analysis
  - Use of Standards in Regulation
  - Entry into Force
  - Judicial Review
  - Ex Post Assessment
  - Life Cycle of a Regulation
- Closing Thoughts

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Project Overview

- Regulatory Coherence in the Americas
- AdvaMed, in cooperation with ANSI, under USAID grant
- Promote regulatory coherence and provide capacity building to certain developing countries in Latin and South America
- Five-country study: Colombia, Costa Rica, Mexico, Peru, USA
  - Tier 1: Regulatory Coherence Initiative
  - Tier 2: Medical Device Sector

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Project Overview (continued)

- Tier 1: Regulatory Coherence Initiative
  - Phase 1: Develop Regulatory Coherence Implementation Guide
    - The Bridge to Cooperation: Good Regulatory Design (U.S. Chamber)
  - Phase 2: Regulatory Coherence Assessment and Gap Analysis
    - Elements of five-country study under Tier 1, Phase 2:
      - Examination of key legal instruments
      - Factual analysis of each regulatory system using the U.S. Chamber document as a guide
      - Step-by-step flow charts to track the life cycle of a typical regulation
      - Validation of findings through discussions with government officials
      - Presentation of findings

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Overview of Regulatory Coherence

- What do we mean by regulatory coherence?
  - Central coordination
  - Good regulatory practices
- Why is regulatory coherence important?
  - Better regulatory outcomes
  - Enhance legitimacy and predictability
  - Avoid creating unnecessary obstacles to trade and unnecessary regulatory differences

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Central Coordination in Colombia

- National Planning Department (Departamento Nacional de Planeación or "DNP")
  - Regulatory Improvement Group (Grupo de Mejora Regulatoria or "OMR")
- Función Pública
- Ministry of Commerce, Industry, and Tourism (MINCIT)
- Industry and Commerce Superintendencia (SIC)
- Legal Department for the Office of the President

Regulatory Forecasting in Colombia

- Annual Regulatory Agenda
  - Publication
  - Timing
  - Amendment
  - Information requirements
  - Requirements differ for Regulatory Commissions
  - Agency roles

Colombia's National Regulatory Register

- Official Gazette (Diario Oficial)
- Sistema Unico de Información Normativa ("SUIN")
- Unique System of Public Consultation (Sistema Unico de Consulta Pública or "SUCOP")

Public Comment Process

- A regulator must publish proposed regulations on its website and request public comments
  - Time period for comments
  - How to submit comments
  - WTO notification process for RTs
- A regulator must respond to the public comments
  - Compilation of a comment matrix (Global Report)
  - WTO notification process for RTs

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Regulatory Analysis in Colombia

- Justification Report (Memoria Justificativa)
  - A list of any existing regulations related to the subject/matter;
  - A justification for regulating the subject/matter;
  - An explanation of how the regulation will be implemented;
  - Preliminary Studies;
  - The available budget to implement the proposed regulation;
  - A Regulatory Impact Manifest (Manifestación de Impacto Regulatorio) or MIR (when required); and
  - A matrix that compiles and summarizes all comments received (Global Report), and proof that the proposed regulation was published for comment on the agency's website.

Regulatory Analysis in Colombia (continued)

- Regulatory Impact Assessment (RIA)
  - In its infancy
  - Currently required just for RTs
- Scientific analysis
  - No policy on use of valid and reliable data and sound science
  - No requirement to use a risk-based approach
  - For RTs, the RIA includes a risk analysis and an agency must identify and categorize the level of risk

Regulatory Analysis in Colombia (continued)

- Pro-competitive analysis
  - Threshold: when the draft regulation could have an economic impact
  - Performed by SIC
  - Process
  - Analysis is non-binding
- Assessment of international impact
  - Threshold for assessment: international impact and/or the draft regulation is an RT
  - Submission to MINCIT to solicit a prior opinion (Concepto Previo)
  - Documentation requirements for a prior opinion
  - Prior opinion is binding

Use of Standards in Regulation

- Under Colombian law, RTs should be based on international standards that have been adopted by international organizations.
  - The law does not define "international standards" or "international organizations," nor does it contain a hierarchy of standards bodies
  - If an international standard is insufficient to address the problem the proposed RT is intended to solve, ICONTEC may develop its own standard "based on scientific evidence"
  - In cases where a regulator does not intend to use a relevant international standard, the issue can be discussed through the SICAL process

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Entry into Force and Judicial Review in Colombia

- Reasonable period for entry into force (RPT)
  - In general, there is no minimum RPT
  - RPT for TRs is at least 90 days after WTO notification
- Opportunity for judicial review
  - Three potential grounds for challenging a final regulation in court
    - Constitutional
    - Jurisdictional
    - Procedural irregularities in the regulatory development process

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Ex Post Assessment in Colombia

- Retrospective review is not required for regulations of general applicability
- But it is required for RTs
  - Timing
  - Objective
  - Consequences of non-performance
  - Effective date
- Different requirements for Regulatory Commissions

Life Cycle of a Colombian Regulation

- Sources of authority to regulate
  - Required by law
  - Promulgated under an agency's general authority
- Step 1: Developing a proposed regulation
  - Regulator develops a draft regulation
  - Regulator analyzes the draft (Publication Documents)
- Step 2: Regulator publishes the proposal for public comments
- Step 3: Regulator analyzes the public comments

Life Cycle of a Colombian Regulation (continued)

- Step 4: Regulator prepares final regulation for President's signature
  - Report on budget and staff to implement the regulation
  - Memoria Justificativa
  - Signature of agency head
- Floating Step: Draft regulation is analyzed by other agencies
  - MINCIT: binding "prior opinion" on international impacts
  - SIC: non-binding opinion on competition ("Abogacía de la Competencia")
  - Función Pública: binding opinion on administrative burden

Life Cycle of a Colombian Regulation (continued)

- Step 5: Proposed regulation is notified to the WTO
  - Applies only to RTs
  - At least 90 days for comment
  - MINCIT runs the process
- Step 6: Final regulation is reviewed by the Office of the President
  - Package includes: Memoria Justificativa; the Regulatory Impact Manifest (when required); opinions from other agencies (i.e., Función Pública, SIC, and/or MINCIT) where applicable; and the draft final regulation signed by the agency head
  - Presidential review process
- Step 7: Final regulation is published

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Closing Thoughts on Colombia

- Exciting new initiatives
  - SUCOP
  - Ex post review
  - RIA for RTs
- Potential new developments
  - RIA for other regulations
  - Role of OMR to expand?
  - Pacific Alliance: additional regulatory alignment initiatives?

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Questions?

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