Regulatory Coherence in Colombia

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By Jeffrey G. Weiss, Esq.
Partner, Venable LLP
JWeiss@Venable.com
+1.202.344.4377
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
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
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
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
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
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.
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
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
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?
Questions?

Jeffrey G. Weiss  
Partner  
Venable LLP  
jweiss@venable.com  
+1 (202) 344-4377