



VENABLE

Regulatory Coherence in Peru

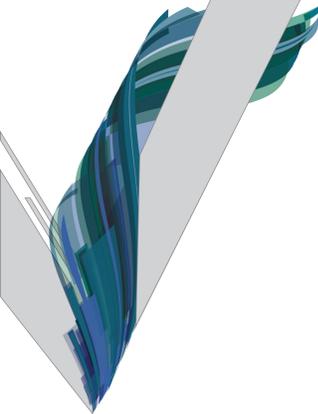
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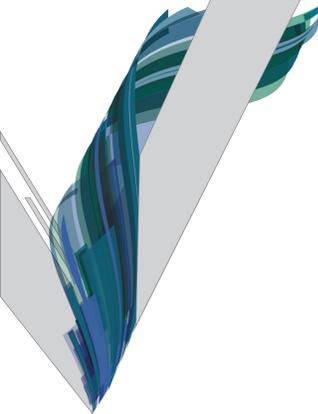
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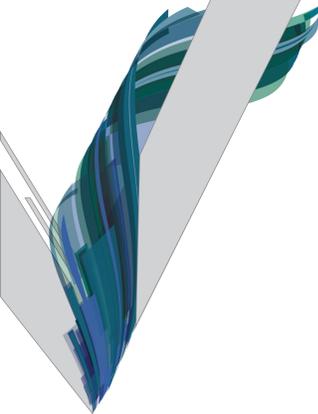
Agenda

- Overview of the AdvaMed Standards Alliance Project
- Overview of Regulatory Coherence
- Central Coordination in Peru
- Implementation of Good Regulatory Practices in Peru
 - 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
 - International Regulatory Cooperation
- Closing Thoughts



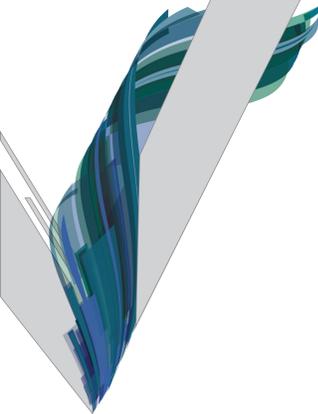
Project Overview

- 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



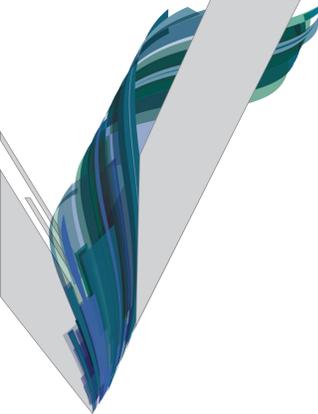
Project Overview (continued)

- 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



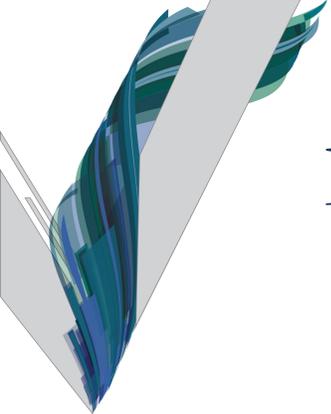
Overview of Regulatory Coherence

- 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



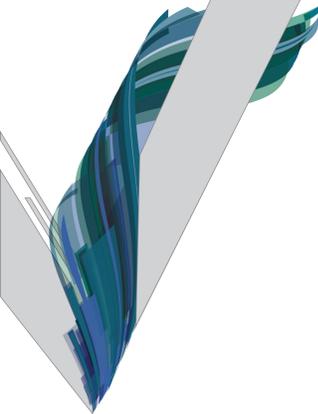
Central Coordination in Peru

- There is no single central coordinating body in Peru. Coordinating functions are split among three entities:
 - The Presidency of the Council of Ministers (PCM)
 - The Multi-Sectorial Regulatory Quality Commission (CCR), which is comprised of:
 - the General Secretary of PCM or his/her representative;
 - the Vice Minister of Economy, Ministry of Economy and Finance (MEF), or his/her representative; and
 - the Vice Minister of Justice, Ministry of Justice and Human Rights (MINJUS), or his/her representative; and
 - The Vice-ministerial Coordinating Council (Comisión de Coordinación Viceministerial or CCV), which is comprised of 35 participating vice-ministers.



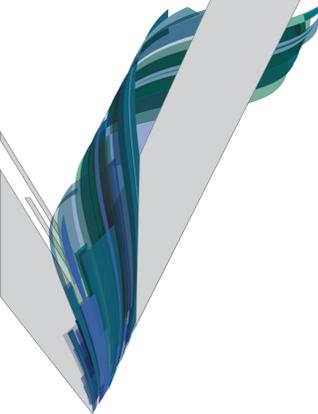
Regulatory Forecasting/National Regulatory Register

- Annual Regulatory Agenda
 - No regulatory agenda or structured planning system for regulation
 - Strategic Standardization Plan
- National Regulatory Register
 - Official Gazette (*El Peruano*)
 - Technical regulations portal



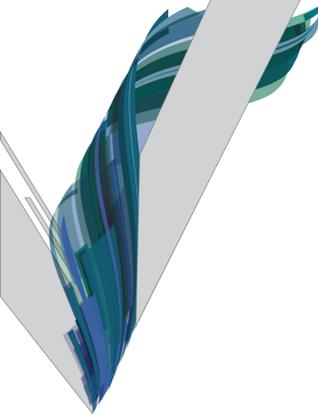
Public Comment Process

- A regulator must publish proposed regulations in *El Peruano* and request public comments
 - Time period for comments
 - Publication requirements
 - WTO notification process for RTs: Notification Information and Technical Regulation System (SIRT)
- Regulator response to public comments
 - Generally not required for general administrative acts
 - Required for RTs



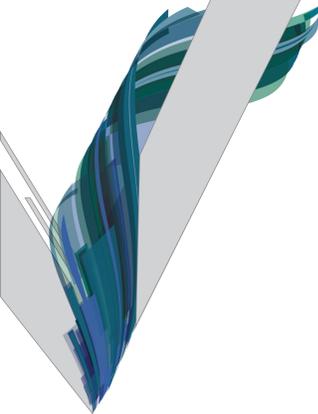
Regulatory Analysis

- Description of Motivation
 - Justify the need for the draft regulation
 - Explain the most relevant aspects of the draft
 - Summarize pertinent background information, including data relied upon
 - Analyze constitutionality and legality of the draft measure, and its consistency with other national laws and international commitments
- RIA



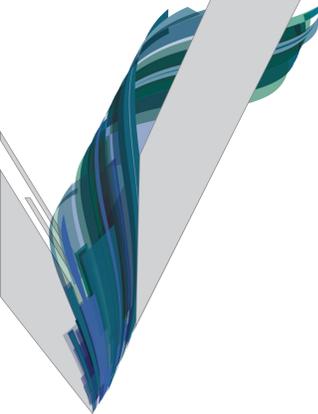
Regulatory Analysis (continued)

- Other types of analysis
 - Science
 - Competition
 - International impacts
- Use of Standards in Regulation
 - Definition of international standard is limited
 - Geneva-based bodies (e.g., ISO, IEC)
 - Regional standards (e.g., CEN, CENELEC, Andean)
 - National standards (e.g., DIN, BSI)
 - Association standards



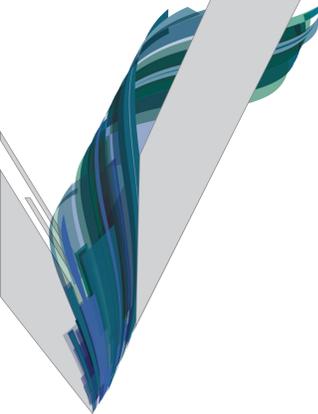
Entry into Force and Judicial Review

- Reasonable period for entry into force (RPT)
 - In general, the minimum RPT is 30 days
 - RPT for TRs is at least 180 days after WTO notification
- Opportunity for Judicial Review
 - No review by the courts
 - Bureaucratic barrier elimination process



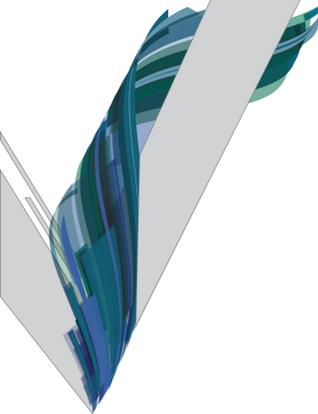
Ex-Post Assessment

- New system for Analysis of Regulatory Quality (ACR)
 - CCR developed and is implementing the ACR process
 - Systematic process for reviewing regulations from the perspective of reducing administrative burdens
 - Requires review of all existing and draft regulations that establish administrative procedures every three years
 - Measures reviewed to ensure they are: legal, necessary, proportionate, and effectively contribute to achieving the goal of the procedure and are not unnecessarily complex
 - First report due at the end of 2018



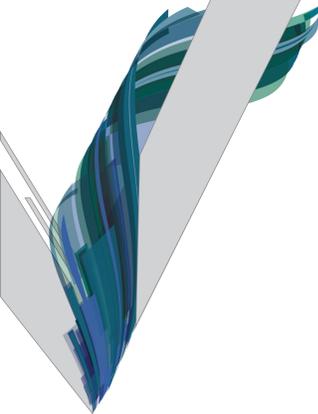
Life Cycle of a Regulation in Peru

- Sources of authority to regulate
 - Required by law
 - Promulgated under an agency’s general authority
- The process for issuing new regulatory measures generally follows two different paths.
 - If a draft regulation would not add or modify an administrative burden and it would not require the approval of three or more regulatory entities, there is no review of the draft regulation. In general:
 - The agency develops a draft regulation with a “description of motivation”
 - Agency lawyers conduct a legal review
 - The agency publishes the proposal for public comment
 - The agency head approves and signs the regulation (as does the President, if required)
 - A final regulation is published in *El Peruano*



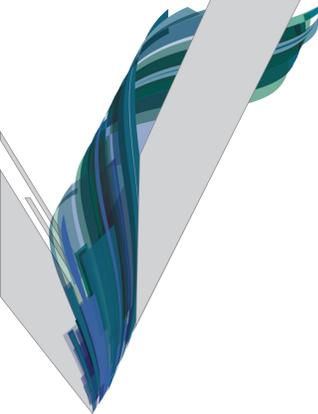
Life Cycle of a Regulation (continued)

- By contrast, a draft regulation that would add or modify an administrative burden and/or requires the approval of three or more regulatory entities proceeds through the following review process.
- Step 1: Developing a proposed regulation
 - Regulator develops a draft regulation and a “description of motivation”
 - Regulator’s legal department reviews



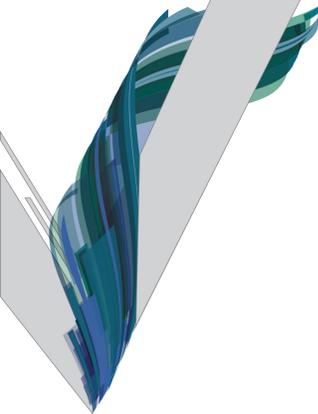
Life Cycle of a Regulation (continued)

- Step 2: Regulator submits the draft regulation to SC-PCM
 - SC-PCM forwards the draft to PCM’s Secretary of Public Management Department (“SGP-PCM”) to review and determine whether the draft regulation adds or modifies an administrative burden.
 - If it doesn’t, the regulator can proceed to Step 3
 - If it does, the draft is sent to CCR for a binding opinion pursuant to the ACR process; the regulator cannot progress to Step 3 if it doesn’t make the adjustments recommended by CCR
- Step 3: SC-PCM submits the draft regulation to three entities for further review:
 - the Ministry of Economy and Finance (“MEF”) for an analysis of the draft regulation’s budgetary and economic impacts;
 - the Ministry of Justice and Human Rights (“MINJUS”) for an analysis of the draft regulation’s constitutionality and legality; and
 - PCM for an assessment of whether the draft regulation is consistent with the guidelines of administrative simplification



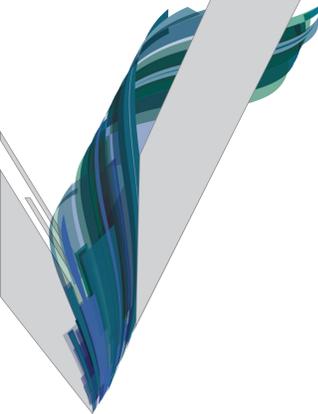
Life Cycle of a Regulation (continued)

- Step 4: SC-PCM submits the draft regulation to CCV
 - any of the 35 participating vice-ministers may raise substantive or procedural issues
- Floating Step: Proposed regulation published for public comment
 - In general, 30 days in *El Peruano*
 - For RTs, 60 days in *El Peruano* and 90 days for international comment periods (i.e., WTO, Andean, free trade agreement partners)
- Step 5: Final regulation is sent to the Office of the President for review, signature, and publication in *El Peruano*



International Regulatory Cooperation

- Responsibility for IRC is split between two agencies:
 - PCM: lead agency interfacing with OIRA, COFEMER, and other central coordinating bodies on cross-cutting regulatory policy issues
 - MINCETUR: lead agency with respect to TBT matters, assisted on standards, accreditation and metrology matters by INACAL
 - Key fora:
 - OECD
 - APEC
 - Andean Community
 - Comprehensive & Progressive Agreement for Trans-Pacific Partnership
 - Pacific Alliance



Closing Thoughts on Peru

- Exciting new initiatives
 - Development of CCR
 - Results of the first ex-post review
 - Possible start to regulatory agendas
- Potential opportunities
 - Ongoing work with the OECD
 - Regulatory coherence/cooperation opportunities in CPTPP and Pacific Alliance

Questions?



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