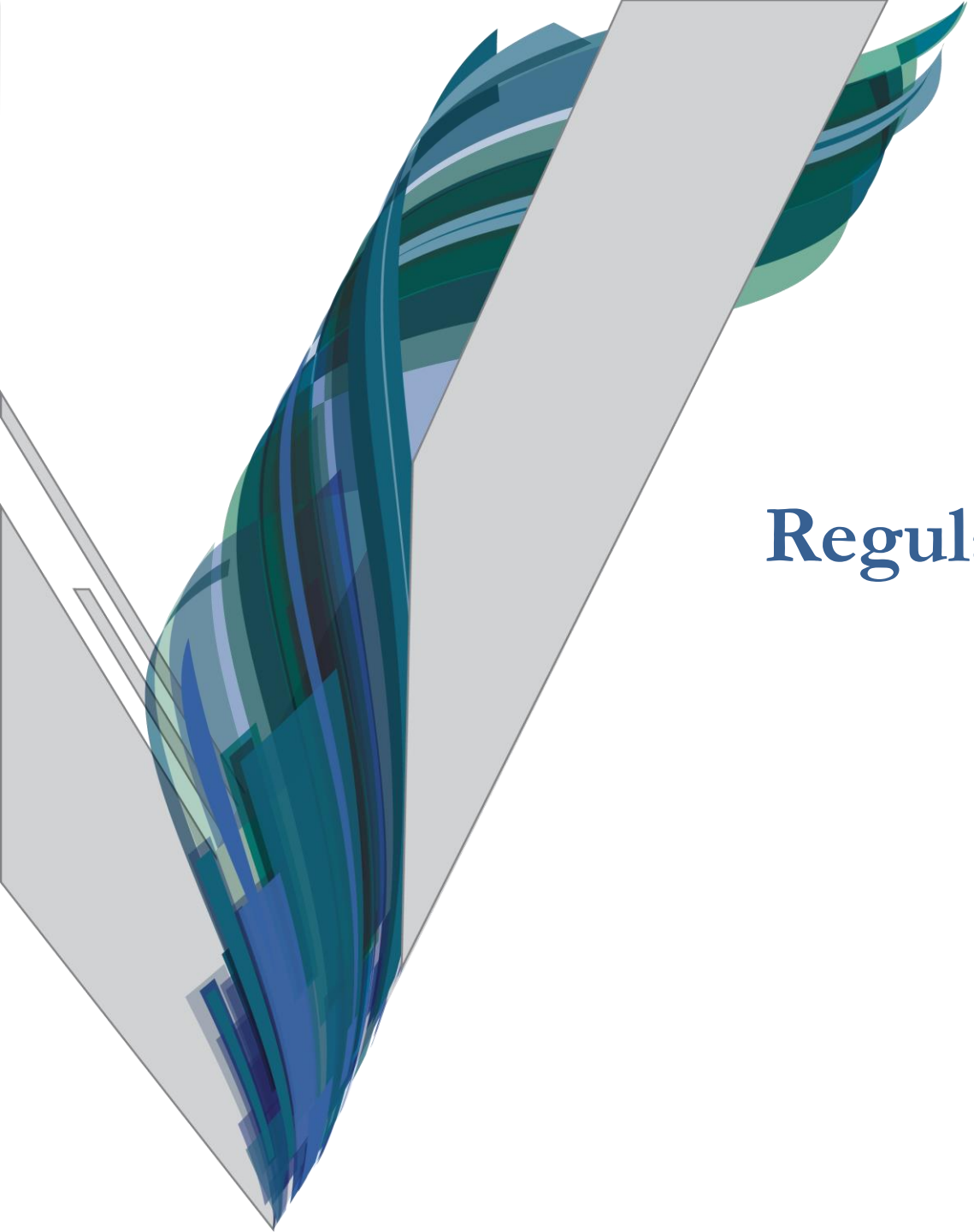

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Regulatory Coherence in Costa Rica

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Agenda

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

- The Ministry of Economy, Industry, and Commerce (MEIC), through its Regulatory Improvement Office (DMR), oversees the regulatory process
  - DMR reviews only draft regulations (including draft revisions to existing regulations) that add or modify an administrative burden
  - Its opinion on such regulations is binding on all regulators, except independent agencies
  - DMR review occurs before draft regulations are published for comment

Central Coordination in Costa Rica (continued)

- DMR also plays a systemic coordinating function in implementing Costa Rica's regulatory improvement policies
  - DMR presides over the institutional committee for regulatory improvement;
  - It develops training plans for regulatory improvement;
  - It coordinates development of agencies' Regulatory Improvement Plans; and
  - It recommends modifications, simplification, or elimination of unnecessary procedures (whether duplicative or without legal basis) to the Regulatory Improvement Commission (CMR).

Central Coordination in Costa Rica (continued)

- DMR coordinates international regulatory cooperation for Costa Rica. This includes activities with:
  - CONAMER/Mexico – exchanging experiences and participating in training on regulatory improvement
  - Central American Community – participating in development of regional/Central American technical regulations
  - OECD – as part of accession process, attending OECD trainings and following OECD recommendations on regulatory improvement
  - Inter-American Development Bank – participating in the Latin American and Caribbean Network on Good Regulatory Practices

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Central Coordination in Costa Rica (continued)

- With respect to technical regulations (RTs), the Technical Regulation Office (ORT), an inter-ministerial commission attached to MEIC, plays the key role
  - ORT comprises seven agencies: MEIC and the Ministries of Trade; Health; Agriculture & Livestock; Infrastructure & Transportation; Environment & Energy; and Science, Technology, and Telecommunications
  - ORT is responsible for ensuring WTO compliance of RTs and has published a guide for regulators on how to develop an RT
  - ORT's Technical Secretariat (ST ORT) reviews draft RTs, notifies them to the WTO, runs the process for reviewing and responding to comments, and issues binding opinions

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Regulatory Forecasting

- No requirement for agencies to prepare an annual regulatory agenda for regulations
- ORT members must prepare an agenda for RTs, and MEIC then develops a four-year National Plan of Technical Regulations
- INTECO develops annual National Standardization Plan

National Regulatory Register

- Costa Rica provides a database of all laws and regulations on the website of the Attorney General's Office
- Diario Oficial La Gaceta
- Proposed regulations that add or modify an administrative burden are found on the SICOPRE website, which is administered by DMR
- Domestic RTs and non-Costa Rican RTs that may create a technical barrier to trade are archived on the ReglaTec website, which is administered by ORT

Public Comment Process in Costa Rica

- Proposed regulations that do not add or modify an administrative burden are open for comment on website of the relevant agency
- Proposed regulations that do add or modify an administrative burden are open for comment on SICOPRE, as well as through the relevant agency's website
- Proposed RTs are open for comment on ReglaTec, and the opportunity to submit comments must be published in the Official Gazette and in a national newspaper
  - After close of domestic comment period, if ORT determines that a proposed RT may create a TBT, it notifies the measure to the WTO

Public Comment Process (continued)

- For regulations of general applicability, no requirement for regulators to respond to stakeholder comments
- For proposed RTs, regulators must review the comments and take them into account
  - The review process could occur twice: once after the domestic comment period and again after the WTO comment period
  - Regulator responses are organized in a matrix that is made public

Regulatory Analysis in Costa Rica

- For a draft regulation that does not add or modify an administrative burden, a regulator does not need to make available the evidence or analysis relied upon
- For a draft regulation (including RTs) that does add or modify an administrative burden, a Regulatory Impact Assessment is required
  - Review of the "Cost-Benefit Assessment" (as the RIA is known in Costa Rica) is conducted by DMR
  - Regulator must eliminate all unnecessary procedures and administrative burdens identified by the RIA, or justify those it decides to maintain
  - DMR is developing an RIA form specific to RTs

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Regulatory Analysis in Costa Rica (continued)

- Regulator must publish elements of the RIA on SICOPRE, including:
  - Description of the measure and the problem it would address
  - Information on the measure's impact on administrative burdens
  - Explanation of the agency's legal authority
  - List of approaches considered and corresponding cost-benefit analyses
  - Justification for selecting chosen option as best alternative to solve identified problem
  - Discussion of how the regulator will evaluate measure's effectiveness
  - Description of consultation process

Regulatory Analysis in Costa Rica (continued)

- Science/risk analysis
  - No requirements regarding use of science/risk-based approach
  - For RTs, regulators are encouraged to consider the quality of the data relied upon, including: source, deficiencies, and distortions/estimates
  - In the case of a standard that is international or developed by a recognized agency, it is presumed to have solid scientific support
  - MEIC provides guidance to agencies on tools they should use when analyzing potential impact of an RT. This includes risk analysis
    - The RIA form that DMR is developing for use with RTs would require the regulators to perform a risk analysis

Regulatory Analysis in Costa Rica (continued)

- Competition analysis
  - No requirement to perform such an analysis
  - However, DMR sends draft regulations to MEIC's competition office for an analysis and issuance of a non-binding opinion
  - DMR also sends draft regulations to MEIC's small business office for an analysis and non-binding opinion on potential effects on SMEs
- International impact analysis
  - No requirement to perform such an analysis
  - However, DMR sends draft regulations to ORT for its binding opinion on whether a measure is an RT and review of compliance with international commitments

Use of Standards in Regulation

- Costa Rican RT development guidance encourages regulators to select a standard that has been internationally accepted
- The hierarchy of standards in Costa Rica is as follows:
  - international standards: e.g., Codex, the World Organization for Animal Health (OIE), International Plant Protection Convention (IPPC); other organizations of which Costa Rica is a member (e.g., ISO and IEC);
  - regional standards: e.g., COPANT, CEN, and CENELEC;
  - national standards: e.g., INTECO, BSI, DIN, and AFNOR;
  - association standards: e.g., ASME, ASTM, API, and SAE; and
  - private sector standards

Use of Standards in Regulation (continued)

- For draft RTs, the regulator must prepare a study to determine whether an international standard should be adopted in whole or in part
- If the international standard is adopted in whole, it is unnecessary to find technical and scientific support for the proposed RT
- If the international standard is partially adopted, the regulator must identify the technical and scientific support that justifies and explains why the international standard is not an adequate solution to the problem identified by the draft RT

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Entry into Force

- No reasonable period of time requirement for regulations prior to entry into force
- Administrative custom allowing six months for final RTs to enter into force based on WTO recommendations

Ex Post Review

- Legal requirement for regulators to analyze, revise, and eliminate any administrative burdens that impede or distort transactions in the marketplace, domestic or international, unless doing so would negatively impact health, security, environment
- No formal process for ex post review of regulation
- The Regulatory Improvement Commission (CMR) continuously monitors regulations

Life Cycle of a Regulation in Costa Rica

- Sources of authority to regulate
  - Legislative mandate
  - Regulator self-initiation under its general authority
- Two regulatory development processes in Costa Rica
  - Technical regulations
  - Other measures of general applicability

Life Cycle of a Regulation (continued)

- STEP 1: Development of a draft regulation
  - Agency staff puts together an outline of the draft regulation and, if the regulation would add or modify an administrative burden, an RIA
  - Agency's legal department reviews and drafts legal text
  - Agency head reviews draft text and the RIA and signs it
  - Agency uploads draft regulation to SICOPRE

Life Cycle of a Regulation (continued)

- STEP 2: DMR reviews the draft regulation
  - If DMR finds no added or modified burden, DMR review of the measure ends
  - If DMR does find a new or modified burden, it sends draft regulation to:
    - MEIC's ORT
    - MEIC's competition office
    - MEIC's small business office

Life Cycle of a Regulation (continued)

- STEP 3: DMR requests public comments on the draft regulation
  - Comment period is a minimum of ten business days
  - While not legally required, the agency generally responds to public comments on SICOPRE within 10 days
- STEP 4: DMR reviews the draft measure and comments
  - DMR reviews the draft regulation in depth in light of the public comments and issues an opinion on the measure's administrative burdens
  - If the regulator is part of the executive branch, DMR's opinion is binding
  - If the regulator is an independent agency, DMR's opinion is non-binding

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Life Cycle of a Regulation (continued)

- STEP 5: DMR's opinion is published on SICOPRE
  - If DMR's opinion requires minor changes to the draft regulation, the agency (if not an independent agency) must make the changes
  - If DMR's opinion requires substantial changes to the draft regulation, the agency (if not an independent agency) must make them and DMR reviews again
- STEP 6: Final regulation is reviewed
  - If the final regulation is a Decree, the agency sends it to the President's office for signature
  - If the final regulation is another type of regulation, it goes to the head of the agency for final approval
- STEP 7: Final regulation is published
  - The final regulation is published in the Official Gazette and it enters into force on the date specified in the regulation

Life Cycle of a Technical Regulation in Costa Rica

- STEP 1: Regulator analyzes the problem
  - Is RT the only solution?
  - If so, what is the objective of the RT?
  - MEIC encourages regulator to include stakeholders and other regulators in the development process
- STEP 2: Regulator analyzes its legal authority
  - What is the scope of its authority?
  - What domestic laws, if any, cover the subject matter?
  - Are there existing RTs that cover the same subject matter?
  - Do other regulators have authority over the same subject matter?
  - Are there foreign RTs of relevance in countries similar to Costa Rica or developed by an international organization?

Life Cycle of a Technical Regulation (continued)

- STEP 3: Regulator drafts the RT
  - The regulator must identify the areas in which the draft RT will have an impact to determine which stakeholders should be involved in the development process
    - Ministries
    - Private sector (chambers and associations)
    - Academia
    - Consumer groups
  - The regulator must identify the technical and scientific analysis underpinning the RT
    - Use of international standard as a proxy

Life Cycle of a Technical Regulation (continued)

- STEP 3: Regulator drafts the RT
  - The regulator must determine whether any new requirements, administrative burdens, or procedures are legally permissible
    - Are they duplicative or otherwise unnecessary?
    - Are they strictly necessary to ensure the RT's objective is fulfilled?
    - Would they limit competition or create a barrier to trade or market entry?
    - Are they supported by a scientific, legal, and technical basis?
    - How would the RT be enforced, which agency will enforce it, and is there adequate staff and budget to enforce it?
  - The regulator must convene interested stakeholders to form a technical working group and reach a consensus (or explain why that would be unnecessary)

Life Cycle of a Technical Regulation (continued)

- STEP 4: ORT analyzes the draft RT
  - The regulator submits the draft RT to ST ORT for its opinion
    - ORT members may send comments on the draft RT to ST ORT and ST ORT must respond to the comments
    - If ST ORT finds that the draft RT complies with all legal requirements, including WTO rules, ST ORT allows the regulator to proceed to the next step
    - If ST ORT finds that the draft RT will not adhere to WTO rules, the regulator must modify the draft RT before proceeding to the next step
- STEP 5: ORT publishes the draft RT for comment in the Official Gazette
  - Minimum comment period of 10 business days

Life Cycle of a Technical Regulation (continued)

- STEP 6: Regulator reviews and responds to public comments
  - The regulator develops a matrix that includes all comments and their responses
  - If the regulator agrees with a comment, it revises the RT
  - If it disagrees with a comment, the regulator needs to justify its rejection
  - ST ORT sends complex comments to a technical working group for examination and response
- After end of domestic comment period, MEIC determines whether the RT needs to be notified to the WTO
  - If not, the final RT is signed and published in the Official Gazette
  - All RTs are Decrees and must be signed by agency head and the President
  - If the RT does need to be notified…

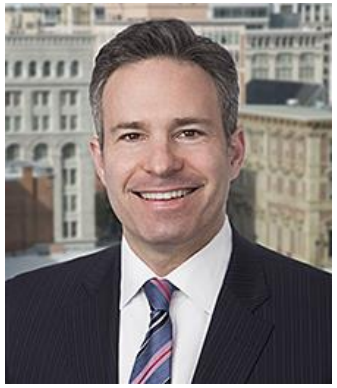
Life Cycle of a Technical Regulation (continued)

- STEP 7: ST ORT notifies the draft RT to the WTO
  - Other free trade agreement partners are also notified
  - Comment period is 60 days
  - ST ORT sends comments to the regulator
- STEP 8: Regulator reviews and responds to the comments
  - Same matrix is developed as for domestic comment period and comments are taken into account
  - Regulator must respond to comments within 30 business days
  - ST ORT makes the matrix available on the MEIC website
- STEP 9: Final RT is signed and published in the Official Gazette

Closing Thoughts on Costa Rica

- Potential new developments
  - OECD process
- Possible areas for future work
  - Ex post review
  - RIA
  - Central American Technical Regulations

Questions?



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