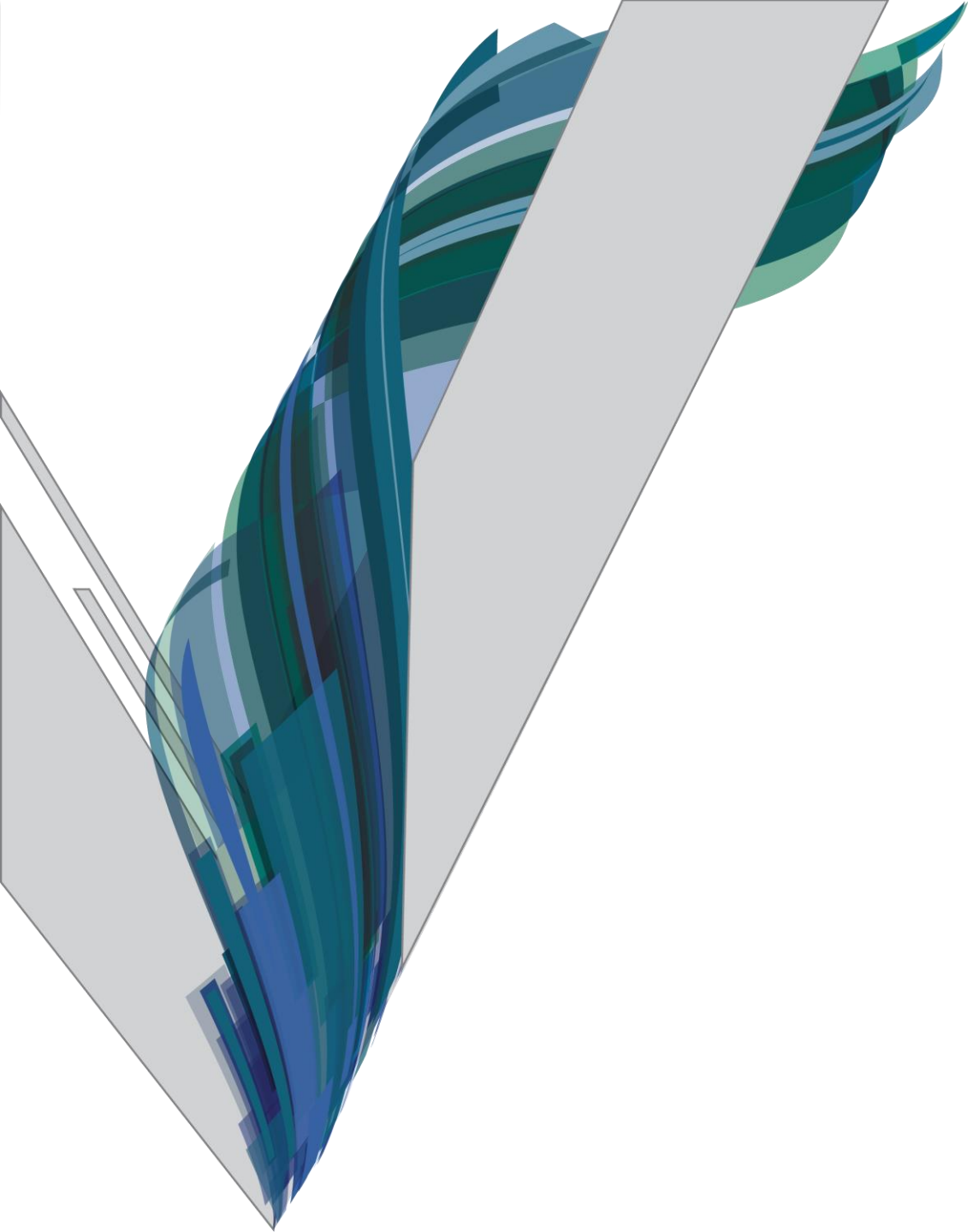

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Regulatory Coherence: Major Elements

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Agenda

- Overview of the AdvaMed Standards Alliance Project
- Overview of Regulatory Coherence
- Central Coordination
  - Benefits
  - Characteristics
  - Functions
- Implementation of Good Regulatory Practices
  - Clarity and Simplicity
  - Transparency and Stakeholder Involvement
  - Valid and Reliable Data and Sound Science
  - Risk-Based Approach
  - Regulatory Impact Assessment
  - Pro-Competitive Analysis
  - International Impact
  - Role of Standards
  - Role of Conformity Assessment
  - Judicial Review
  - Ex-Post Assessment
  - Regulatory Cooperation

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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

Benefits of Central Coordination

- Enhancing regulatory coordination and consistency
- Ensuring political accountability and regulatory credibility
- Raising public awareness on regulation
- Facilitating regulatory cooperation

Central Coordination: Key Variables

- Location
- Formal authority for regulatory oversight
- Independence and staff expertise
- Scope of oversight

Key Functions of Central Coordinating Body

- Enhancing regulatory coordination
- Ensuring forward-looking planning of regulatory activity
- Reviewing draft proposed and final regulations before they are published
- Establishing good regulatory practices
- Coordinating regulatory cooperation

GRP 1: Clarity and Simplicity

- Regulations should be clear, concise, and easy to comprehend for regulated entities and members of the public

- Clarity improves compliance and predictability

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GRP 2: Transparency and Stakeholder Involvement

- Regulatory forecast
- National regulatory register
- Advance notice
- Opportunity for public comment
- Publish proposed text, along with evidence and analysis
- Respond to stakeholder input
- Entry into Force

GRP 3: Valid and Reliable Data and Sound Science

- To ensure valid and reliable data, one must maximize the quality, objectivity, utility, and integrity of the data
- Ensure that such data is placed in the docket, allow stakeholders to challenge it
- Sound science: methods and analysis generally accepted within the scientific community
- Importance of peer review

GRP 4: Risk-Based Approach

- Risk assessment vs. risk management
- Can't eliminate all risk (risk-risk and risk-benefit trade-offs)

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GRP 5: Regulatory Impact Assessment (RIA)

- Identify the need for a regulation and define the problem to be solved
- Set out and analyze different feasible alternative options
- Set out and assess the costs and benefits of each option and identify the alternative that best achieves the policy objective
- Assess that the benefits of the chosen option justify the costs

GRP 6: Pro-Competitive Analysis

- Looking at regulatory design through a competition lens can help the regulator avoid inadvertently picking winners and losers, prevent market entry, favor larger companies over smaller ones, and stifle innovation

GRP 7: International Impact

- Supply chains are increasingly global
- Ensure compliance with international obligations
- Minimize unnecessary differences with global norms and best practices, regulatory approaches in major trading partners

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GRP 8: Role of Standards

- Standards play an important role in regulation: development is fast and cost-effective, high technical quality, based on the latest trends and technology, market relevant
- Governments need to send their technical experts to participate actively in standards development
- This includes standards development by intergovernmental bodies, one country-one vote bodies, engineering and technical societies, and fora and consortia
- Agencies need to comply with WTO rules on standards-related measures (TBT)
- Important to provide regulators with guidance on how to determine whether to use a standard in regulation

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GRP 9: Role of Conformity Assessment

- Use of private sector CA mechanisms is encouraged in lieu of creating government-unique compliance mechanisms
- Different types of conformity assessment available for different situations and levels of risk (e.g., SDoC, testing, inspection, certification)
- Agencies need to comply with WTO rules on standards-related measures (TBT)
- Important to provide regulators with guidance on how to determine the type of CA program to implement

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GRP 10: Judicial Review

- Important to have possibility of independent review: ensures regulator accountability, enhances legitimacy, and predictability
- Ensures that proper procedures were followed, and the final decision was well-reasoned, supported by evidence in the record, and consistent with law
- Review bodies should have the power to set aside actions and send them back to the regulator to be remedied
- At the same time, review bodies should give deference to agencies in areas where the agencies have substantive expertise

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GRP 11: Ex-Post Assessment

- As time passes, regulations can prove to be ineffective, inefficient, and/or become outdated due to technological or other developments
- Important to periodically review regulations on the books to determine whether they need to be streamlined, modified, or repealed
- To enable ex-post assessment, the agency needs to be collecting data on its experience implementing the regulation and industry's experience in complying with it
- Having a strong ex-post system will improve the quality of new regulations as regulators learn which approaches work – this will inform ex-ante impact assessments for other regulations

GRP 12: Regulatory Cooperation

- Regulatory cooperation yields benefits to regulators, consumers, workers, and patients. It enhances economic growth and trade, promotes investment, innovation, and ease of doing business. It helps regulators do their jobs better.
- There are several types of regulatory cooperation, including: harmonization, alignment/convergence, joint regulatory development, mutual recognition/reliance, and information-sharing
- All regulatory cooperation activities must at least maintain existing levels of protection
- Regulatory cooperation is usually easier ex ante than ex post
- The mechanism selected will depend on a variety of factors, including compatibility of legal frameworks, experience/trust
- Regulatory cooperation should avoid areas of active trade irritants
- Regulatory cooperation is facilitated by central coordination and use of GRPs

Questions?

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