

Inter-American Coalitions, COVID-19 Medical Device Regulatory Convergence Project (MDRC) Sessions and the Summit of the Americas, June 6 - 8, Los Angeles, CA, USA

We have compiled a comprehensive readout of the Coalitions Sessions as well as key Summit outcomes, including links to the presentations and recordings of each session.

Photos: Coalition and MDRC meeting photos from 6-8 June may be accessed [here](#) (password: crowell).

Agendas 6 - 7 June are available [here](#).

6 June: Meetings of Inter-American Coalitions for Business Ethics and Regulatory Convergence in the Medical Technology Sector

In the morning of 6 June, the Inter-American Coalition for Business Ethics convened in-person for the first time since the start of the pandemic. Christopher White (AdvaMed) presented the AdvaMed Code of Conduct and facilitated a discussion on its contents and launch. Thereafter, Sujata Dayal (Medline), in her capacity as Chair of AdvaMed's Chief Compliance Officer's Committee, presented on the Global Distributor Compliance Toolkit. Attendees discussed aspects of the Toolkit's operation and next steps for implementation across the Americas in accordance with the Coalition's action plan.

The Brazilian In-Vitro Diagnostics Chamber (CBDL, Carlos Gouvêa) and the Brazilian Health Products Importers and Distributors Association (ABRAIDI, Bruno Boldrin Bezerra) joined Brazil's Ministry of Health (Carolina Palhares) and Brazil's Comptroller General of the Union (Lorena Brito da Justa Croitor) to present on Brazil's Public Procurement Law (law n. 14.133/21). The panelists led a detailed discussion on driving integrity through public procurement, indicating the integrity provisions in the Law represent just a first step. Ms. Palhares provided additional perspective on the Ministry's wider integrity priorities, including on transfer of value disclosure. This discussion was followed by status reports by Coalition members (see attached presentation).

On the afternoon of 6 June, the Inter-American Coalition for Regulatory Convergence convened for its first-ever in-person meeting. A progress report of Coalition activity was provided. Highlights of the report include: 2,000 stakeholders have participated in Coalition Capacity Building initiatives; the Coalition has developed a position to support the Chilean Regulatory Authorities on Utilization of International Standards and References as a base for their upcoming MD Regulatory framework; a position was also developed on the Mexican COFEPRIS Good Manufacturing Practice NOM241; the Coalition has translated multiple international reference documents into Spanish – now available at the [Coalition website](#).

The Office of the U.S. Trade Representative provided remarks on its efforts to advance GRP at bilateral, sub-regional, and regional levels.

Brazil's Secretariat for Competition Advocacy and Competitiveness (GeanLuca Lorenzon), Colombia's Ministry of Commerce, Industry and Tourism (Aurelio Mejia), and Mexico's Secretariat of Economy (Rubisel Velázquez Lugo) provided a high-level report on their GRP trade commitment implementation efforts. The representatives spoke to long-term objectives for those efforts as well as challenges in their implementation. These reports were followed by a presentation by the President of the Brazilian National Institute for

Metrology, Standardization and Industrial Quality (INMETRO, Marcos Heleno Guerson de Oliveira Junior) on Brazil's National Quality Infrastructure.

The U.S. Food and Drug Administration provided remarks on its efforts across the Americas to promote good regulatory practices and regional medical device regulatory convergence in 2022. The Pan American Health Organization also shared their initiatives to promote Good Regulatory Practices including the utilization of International Standards as well as Good Reliance Practices.

Materials

Ethics Coalition Session:

Slides Deck

[English](#) Spanish

Recordings

[English](#) [Portuguese](#) [Spanish](#)

Regulatory Convergence Coalition Session:

Slides deck

[English](#) Spanish

Recordings

[English](#) [Portuguese](#) [Spanish](#)

7 June: Joint Session of the Inter-American Coalitions for Business Ethics and Regulatory Convergence in the Medical Technology Sector

On 7 June, the Inter-American Coalitions for Business Ethics and Regulatory Convergence in the Medical Technology Sector convened their first-ever joint session. The session included the official signing of the Terms of Reference and launch of the Inter-American Coalition for Regulatory Convergence in the MedTech Sector, opened by Nacho Abia (Olympus) and joined by Hector Orellana (Medtronic), Abbott, and Roche. The in-person signatories include:

- José Márcio Cerqueira Gomes, Executive Director, Brazilian Innovative Health Industries Alliance (ABIIS)
- Angélica Marques, Regulatory Affairs Manager, Brazilian High-Technology Health Product Industry Association (ABIMED)
- Bruno Boldrin Bezerra, Executive Director, Brazilian Health Products Importers and Distributors Association (ABRAIDI); Chair – ABIIS
- Carlos Gouvêa, Executive President –CBDL & also IES/ABIIS/ALADDIV
- Marisol Sánchez, Executive President, ANDI Medical Devices Chamber

- Cristina Murgueito, Executive Director, Ecuadorian Medical Product Importers and Distributors Association (ASEDIM)
- Ana Laura Riquelme Francistain, Executive Director, Mexican Association of the Innovative Medical Device Industry (AMID)
- Sandro Stapleton, President, Lima Chamber of Commerce Health Guild
- Christopher White, General Counsel & Chief Policy Officer, Advanced Medical Technology Association (AdvaMed)
- Leticia Fonseca, Executive Director – Latin American Alliance for the Development of In Vitro Diagnostics (ALADDIV)

A signed Terms of Reference including virtual signatories will be shared in the coming days.

Following the launch, AdvaMed (Christopher White) joined the U.S. Department of Commerce (Ian Saunders) and Brazil's Comptroller General of the Union (Lorena Brito da Justa Croitor) to debut AdvaMed's new [Code of Ethics](#) and [Best Practice Guidance on Value-Based Arrangements](#) in [Spanish](#) and [Portuguese](#). Thereafter, AdvaMed, the U.S. Department of Commerce and Brazil's Comptroller General of the Union provided remarks on strengthening democratic governance in the Americas through ethical business conduct.

As the central implementing mechanism for the [MDRC project](#) (see item 4) in the Americas, the Coalition for Regulatory Convergence convened MDRC partner representatives. Medtronic (Héctor Orellana) opened and facilitated discussion with the U.S. Agency for International Development (USAID, Mileydi Guilarte) and the American National Standards Institute (ANSI, Joseph Tretler). These representatives spoke to MDRC's mission, objectives, methodologies, and successes to-date.

The Joint Session concluded with remarks by Brazil's Foreign Trade Secretariat, Ministry of Economy (Daniela Ferreira de Matos). These remarks were opened and closed by Medtronic (Héctor Orellana) and focused on the roles of GRP and anti-corruption on driving regional trade and investment.

Materials:

Slides deck

[English](#) [Spanish](#)

Recordings

[English](#) [Portuguese](#) [Spanish](#)

7 June: Inter-American Development Bank Meeting on Trade and Investment for the Americas

Trade ministers from the Americas convened as part of [the Inter-American Development Bank's Meeting on Trade and Investment for the Americas](#). The U.S. Chamber of Commerce (Myron Brilliant) presented the [Americas Business Dialogue's Policy Recommendations for the 9th Summit of the Americas](#), featuring a prioritized focus on GRP. These recommendations include the most robust provisions to-date in alignment with key Coalition priorities in trade, health, and ethical business conduct. This includes fostering transparency and integrity, intra-regional trade, and resilient health systems.

Nacho Abia, CEO of the Olympus Corporation of the Americas and AdvaMed board member provided the hemispheric health sector perspective. Nacho Abia spoke to the necessity of governments and the private

sector to collaborate towards accelerating GRP, strengthening ethical business conduct, and building resilient health systems in the region.

The ministers spoke to strengthening value chains and attracting investment, sustainable trade and climate change, and the digital economy in the Americas.

8 June: MDRC Workshop: Advancing the Implementation of Cross-Sectoral, Foundational GRP and Regional Cooperation in Latin America

On 8 June, the first in-person workshop of the [Standards Alliance COVID-19 Medical Device Regulatory Convergence \(MDRC\)](#) initiative. The initiative convened high-level representatives for Tier One (GRP) agencies and bodies responsible for cross-sectoral implementation of GRP in Brazil, Colombia, and Mexico.

The morning, external session enabled industry attendees from the Coalition events to learn directly from those MDRC representatives on their country's efforts to implement GRP and what they hope to achieve through partnership with MDRC in the coming years. The session began with presentations by GeanLuca Lorenzon, Secretary for Competition Advocacy and Competitiveness, Secretariat for Competition Advocacy and Competitiveness (SEAE), Brazil, and Lina Valencia, Director of Governance, Human Rights and Peace, Colombia National Planning Department (DNP), Colombia. GeanLuca Lorenzon used the external session as an opportunity to announce Brazil's elimination of certain port-related fees *—resulting in the equivalent of a 10% reduction in tariffs for all sectors.* GeanLuca Lorenzon also spoke to several novel initiatives developed by SEAE that leverage its regulatory analysis/oversight tools to advance GRP. Those included a regulatory rating system and regulatory body mapping exercise (see attached presentation).

This was followed by presentations by National Standards Bodies representing Brazil, Colombia, Mexico, and the United States on the same topics:

- Jessica Roop, Senior Manager, International Development, American National Standards Institute (ANSI), United States
- Jorge Emanuel Reis Cajazeira, Head of International Standardization, Brazil Association of Technical Standards (ABNT), Brazil
- Monica Vivas, Standardization Director, Colombian Institute of Technical Standards and Certification (ICONTEC), Colombia
- Daniel Trillos, Subdirector of Standardization, Colombian Institute of Technical Standards and Certification (ICONTEC), Colombia
- Raul Romero Anaya, Quality Infrastructure Coordinator, General Directorate of Standards (DGN), Mexico

The external session ended with a presentation by Brazil's National Institute of Metrology, Standardization, and Industrial Quality (INMETRO, Marcos Aurélio Lima de Oliveira).

Materials:

[Agenda 8 June](#)

Slides deck

[English](#) Spanish

Recordings

[English](#) [Portuguese](#) [Spanish](#)

The external session was followed by an afternoon, internal roundtable for MDRC representatives to share best practices and offer practical guidance on the advancement of their GRP initiatives.

Summit Outcomes

On 8 June, the United States and partners announced the [Action Plan on Health and Resilience in the Americas](#). The Action Plan reflects a number of ABD Recommendations to strengthen the resilience of health systems, examine finance mechanisms for health, promoting business integrity and ethical conduct in procurement, and leverage digital tools. Critically, the Action Plan contains several key initiatives, including two new and complementary mechanisms to bolster resiliency of the hemisphere's health economies and ecosystems:

- [Americas RISE for Health](#) will “harness the collective strengths of the region’s private sector and civil society [in partnership] with the region’s governments” to, among other things, “build the hemisphere’s supply [chain resilience], enable digital health solutions to reach underserved populations, accelerate regulatory improvements, reduce trade and investment barriers to health financing, create ethical environments so health economies can thrive, and address other areas of need.” This initiative is led by the U.S. Department of Commerce in partnership with the U.S. Department of Health & Human Services. Americas RISE for Health is expected to link governments with private sector and civil society stakeholders on priority issues through an annual Forum, with the inaugural program possibly to occur this September in Washington, DC. Further details forthcoming.
- [The Economy and Health Dialogue of the Americas \(EHA\)](#) will “establish a series of official sector-only convenings to increase political will and commitments across health and economy sectors necessary to strengthen public health systems in the Americas by initiating collaboration among countries in the region through ministries of foreign affairs, health, economy, trade” to, among other things, “coordinate on pandemic prevention, preparedness, and response; identify and leverage best practices in the public sector to include health gap assessments, sustainable health budgeting, and effective service delivery to support economic resilience and recovery; promote anti-corruption practices to increase efficiency; and build more resilient health systems.” In coordination with the Americas Business Dialogue, the EHA “provides a government and member state-only platform to enable governments to assess country-specific concrete actions towards policy reform that would enable greater private sector and civil society participation in the region’s health economies, and investment opportunities.”

On 8 June, the United States also announced the [Americas Partnership for Economic Security](#). U.S. officials shared that this initiative plans to identify a core set of countries that will set a very high ambition followed by an open architecture where countries self-select which “pillars” on which to negotiate and join based on their

interests and ability to meet the partnership's high standards. Over the next several months, countries will engage on the scope and sign on to negotiations. Areas of focus include:

- Areas unique to the Americas effort include: broadening participation in the formal economy and biodiversity.
- Reinvigorating Regional Economic Institutions and Mobilizing Investment
- Making More Resilient Supply Chains
- Updating the Basic Bargain: Investments in tax, anti-corruption, and infrastructure, including in health. This includes broadening participation in the formal economy.
- Clean Energy, Decarbonization, Biodiversity
- Sustainable, Inclusive Trade: This includes customs facilitation, GRP, digital, labor and environment standards, and corporate accountability.

On 7-9 June, The U.S. Chamber of Commerce partnered with the U.S. Department of State to host the [IV CEO Summit of the Americas](#) as the official private sector forum of the Summit. The CEO Summit of the Americas featured a health panel with Secretary Becerra, Department of Health and Human Services, who noted the need for public-private partnership. As part of this panel, Sarah Aiosa, SVP and President for Latin America, MSD, asserted health should be a hemispheric national security priority. President Biden's address to the CEO Summit noted efforts to inject more capital into IDB Invest, including for health.

On 9 June, the [Joint Declaration on Good Regulatory Practices \(GRPs\)](#) among 14 countries was announced by the United States, Argentina, Brazil, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Haiti, Panama, Paraguay, and Uruguay. The press release from the Office of the U.S. Trade Representative may be [accessed here](#). This latest GRP Declaration both expands the number of countries with which the United States is engaging on GRP and the number of GRP elements covered. Signatories plan to promote awareness of GRP with regulatory authorities and assess implementation progress by the end of 2023. These components are critical as GRP are implemented not only "horizontally" across the whole of government but also "vertically" at the sector-specific level.

On 9 June, the heads of state and governments attending the Summit adopted a series of political declarations. These declarations reinforce the Coalition's priorities related to GRP, transparency, procurement reform, and others. Those declarations may be found below:

- [Health and Resilience](#)
- [Digital Transformation](#)
- [Accelerating the Clean, Sustainable, Renewable, and Just Energy Transition](#)
- [Our Sustainable Green Future](#)
- [Democratic Governance](#)