



7 April 2020

Luis Alberto Moreno
President
Inter-American Development Bank
1300 New York Avenue, NW
Washington, DC 20577

Dear President Moreno:

On behalf of the *Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector* (“the Coalition”) – which includes the medical technology industry associations in the Western Hemisphere representing more than 2,000 companies with operations in every Latin American and Caribbean economy¹ – we would like to extend our sincere appreciation for your leadership amidst the COVID-19 public health crisis. We praise your engagement of the Americas Business Dialogue (“ABD”) and the dedicated efforts of the Bank’s Integration and Trade team. **We also welcome your indication with the ABD on 31 March that more must be done to advance regulatory convergence in the medical technology sector across the hemisphere in response to the crisis.** Our Coalition stands ready to work with the Bank and member governments in the region to achieve this objective.

The ABD team within the Bank’s Integration and Trade Sector has called on ABD members to submit by Tuesday, 7 April specific recommendations to address COVID-19 that will be shared with the governments of the region as well as the Bank’s relevant sector teams. Please consider this letter our Coalition’s formal submission to this request with a copy to be electronically submitted to Fabrizio Operti and the ABD team, James Scriven, Bernardo Guillamon, and Ferdinando Regalia. Our brief and actionable recommendations hereafter are separated into three distinct parts:

- 1) **Recommendations for regional governments;**
- 2) **Recommendation for Inter-American Development Bank action; and**
- 3) **Recommendations for Inter-American Development Bank funded projects.**

We would like to discuss advancing them with your team as soon as possible.

¹ Coalition Principal Members include: CADIEM (Argentina), ABIIS (Brazil), ABIMED (Brazil), ABRAIDI (Brazil), CBDL (Brazil), IES (Brazil), Medtech Canada, ANDI-CDMIS (Colombia), ADIMECH (Chile), APIS (Chile), ASEDIM (Ecuador), AMID (Mexico), COMSALUD-CCL (Peru), AdvaMed (United States), AVEDEM (Venezuela), ALDIMED (Regional), ALADDIV (Regional).

Number One: Recommendations for Regional Governments

The Coalition strongly encourages the ABD to advise the region's governments to align their policy response in accordance with the detailed recommendations already issued by the business community and medical technology sector in a variety of forums around the world. This includes:

- [Global Business Coalition \(“GBC”\) Call to G20 for Measures to Enable Global Supply of Vital Protective Gear, Medicines and Medical Supplies \(26 March 2020\)](#)
- [Global Medical Technology Alliance \(“GMTA”\) Letter to G20 Heads of State and Government on the need to collaborate to open global trade in response to COVID-19 \(25 March 2020\)](#)
- [B20/ICC/WHO Letter to G20 Heads of State and Government on the need for coordinated action by G20 leaders in response to the COVID-19 pandemic](#)
- [APEC Business Advisory Council \(ABAC\) Chair Letter to APEC Trade and Foreign Ministers](#) and [Statement](#)
- Business at OECD Statement on the Trade Policy Response to COVID-19 (*Forthcoming on 7 April 2020*)

ABD recommendations to the region's governments also consider statements made by:

- [World Trade Organization Director General Roberto Azevêdo](#), noting that trade and investment flows have a role in efforts to combat the COVID-19 pandemic, and will be vital for fostering a stronger recovery once the medical emergency subsides. The WTO also issued a [new report](#) on 3 April 2020 concerning worldwide trade in COVID-19 medical products.
- [World Economic Forum - COVID Action Platform](#), urging coordinated action by business, in combination with global and multi-stakeholder cooperation, at exceptional scale and speed to pursue mitigation of the risks and impact of the crisis.
- [Pan American Health Organization \(“PAHO”\) Director Carissa F. Etienne](#), calling for private sector cooperation with governments to address the COVID-19 pandemic.

ABD recommendations to the region's governments should also include:

- The alignment of national medical technology technical regulations and standards with international standards – enabling the private sector to do so in line with the statement by PAHO Director Carissa F. Etienne – and the prioritization of IDB funded projects that support governments in achieving this goal.
- The reduction or elimination of tariffs on medical technology during the pandemic. According to the WTO, many countries in the region still maintain tariff rates on medical technology above the global average.



Number Two: Recommendation for Inter-American Development Bank Action

We recommend the immediate establishment of an IDB COVID-19 Task Force, building on the priority support areas announced by the Bank on 26 March. This approach was proposed by Mr. Ralph Ives of the Advanced Medical Technology Association (AdvaMed) to the ABD on 31 March. The action pillars for the IDB COVID-19 Task Force that are in vital need would include:

- Communication / Liaising / Metrics
- Supply Chain / Trade
- Regulatory / Health
- Production / Allocation
- IDB Funded Projects (Coordination, Development, Deployment)

Structural characteristics for the Task Force might include a:

- 1) Mechanism to coordinate and rationalize coherent, effective and timely IDB COVID-19 communications and action (within the IDB, with governments, and with the private sector);
- 2) Connection to the IDB presidency (i.e. strategic core) with coordination of all relevant IDB vice presidencies for countries and sectors (i.e. Integration and Trade, Social, etc.) and their divisions;
- 3) Connection to member governments and relevant ministries (i.e. Presidencies, Finance, Trade, Health, etc.) and other specialist multilateral organizations (i.e. PAHO); and
- 4) Connection with the private sector, including the designation of full-time IDB contacts to liaise with the private health sector to coordinate COVID-19 communications and activities, including a specific full-time IDB contact designated for interaction with the medical technology sector.

AdvaMed and the broader medical technology sector across the Americas, as active members and supporters of the ABD, can designate and fund a central liaison to the Task Force. This liaison would be the Technical Secretariat of the **Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector**. The Technical Secretariat is composed of five (5) dedicated professionals with whom the IDB can interface on every aspect pertaining to action pillars noted above, and they in turn coordinate with the hemispheric industry associations and companies and their in-kind and direct contributions to the IDB COVID-19 response.

Number Three: Recommendations for Inter-American Development Bank Funded Projects

The Coalition calls attention to the [PAHO Response Strategy and Donor Appeal](#) which it supports with the immediate in-kind contribution of the Coalition Technical Secretariat as well as additional contributions that can be made through coordination and collaboration with the IDB. The Coalition likewise recommends that available IDB COVID-19 funding be prioritized toward the PAHO COVID-19 Priority Line of Action Objectives, both directly with PAHO and also with private sector efforts that can support the PAHO Objectives.

The Coalition offers the following specific projects to operationalize the PAHO Objectives to most effectively and pragmatically combat the COVID-19 pandemic. The IDB is uniquely positioned to realize these projects in conjunction with the medical technology sector and measurably save lives across the hemisphere.

- **Recommended Project #1:** Provide immediate training for COVID-19 testing, including implementation of Quality Program for Diagnostic Kits, and working in conjunction with the Latin American Alliance for the Development of in Vitro Diagnostics (“ALADDiV”) and the London School of Hygiene and Tropical Medicine.
- **Recommended Project #2:** Immediate assessment and deployment of ICT tools (surfaces, smartphones, software) and subsidized bandwidth for medical technology agencies and staff – allowing remote work and enabling medical technology to reach hospitals and patients. The average Latin American medical device regulatory agency staff is 15 FTEs or fewer, many now at home without remote access.
- **Recommended Project #3:** Immediate increase of PAHO medical device staff, ICT and communication tools, bandwidth, and management; there are currently approximately three FTEs in Washington, DC.
- **Recommended Project #4:** Immediate online training for national authorities on WHO, PAHO, International Medical Device Regulators Forum (“IMDRF”), and FDA COVID-19 protocols to enable emergency measures protecting against low quality and counterfeit products, to facilitate expedited review of new medical devices, and to accelerate qualified acceptance of qualified regulatory outcomes of partner agencies.
- **Recommended Project #5:** Immediate web training for national authorities on medical device good manufacturing practices, related auditing mechanisms (MDSAP) and the underlying technical regulations, regulatory processes, and related international standards.

Kind Regards,



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Executive Secretary

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