



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

**Los Angeles | 7 June 2022**

*Welcome Members*



## General Information

- **Virtual guests:**
  - Please keep yourself muted throughout the duration of the session.
  - Use the chat box for any questions or comments.
  - *If you have any technical difficulties accessing the meetings during the day of the event, please contact: [hugo@perlitteras.com](mailto:hugo@perlitteras.com); [ablasi@crowell.com](mailto:ablasi@crowell.com)*
- **In-person guests:**
  - Masks are available upon request, please let a team member know.
  - Simultaneous translation is offered for all hybrid Coalition activities. Please connect your device to the meeting Zoom (such as a cell phone or laptop) along with headphones. *Please keep your mic muted once connected.*
  - Restrooms
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# ***Formal Launch and Signing Ceremony of the Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector***



***Ambassador Robert Holleyman***  
***President & CEO, Crowell & Moring International***  
***Former Deputy U.S. Trade Representative***



***Nacho Abia***  
***Chief Executive Officer, Olympus Corporation of the Americas***  
***Chief Operating Officer, Olympus Corporation***  
***Board of Directors, AdvaMed***

# ***Strengthening Democratic Governance in the Americas through Ethical Business Conduct and Launch of the AdvaMed Code of Conduct***



***Ian Saunders***  
***Deputy Assistant Secretary for the  
Western Hemisphere,  
Department of Commerce  
United States***



***Lorena Brito da Justa Croitor***  
***Federal Auditor of Finance and  
Control, Coordinator of Audit in  
the Health Area,  
Comptroller General of the Union  
Brazil***



***Christopher White***  
***General Counsel &  
Chief Policy Officer  
AdvaMed***

# ***High-Level Remarks on the COVID-19 Medical Device Regulatory Convergence Project: MDRC Successes and Goals Through 2024***



***Mileydi Guilarte***  
*Deputy Assistant Administrator,  
Bureau for Latin America and the  
Caribbean, USAID  
United States*



***Joseph Tretler***  
*Vice President, International  
Policy, American National  
Standards Institute (ANSI)  
Virtual*



***Hector Orellana***  
*Vice President for Mexico and  
North Latin America, Medtronic*

# ***Driving Regional Trade and Investment***

## ***The Role of Good Regulatory Practices and Anti-Corruption***



***Daniela Ferreira de Matos***  
***Deputy Secretary of Foreign Trade,***  
***Ministry of Economy***  
***Brazil***



***Hector Orellana***  
***Vice President for Mexico and***  
***North Latin America, Medtronic***

# The role of Good Regulatory Practices and Anti-Corruption on Driving Trade and Investment



MINISTÉRIO DA  
ECONOMIA



[www.economia.gov.br](http://www.economia.gov.br)



✓ **Good Regulatory Practices and Anti-Corruption** are crucial for the business environment

**Transparency**



**Rational Decision Making**

**Predictability**



**Foreign Direct Investment**



**Trade**



## The cost of regulatory inefficiency

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State administrative inefficiency estimated to represent **13%** of the "Brazil-cost"

Around **US\$ 30 - 40 billion** dollars / year



Equivalent to the estimated cost of **tariff protection** in Brazil !

"At the border"  $\neq$  "Within the border"



## Domestic Initiatives

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### **Economic Freedom Law**

(Law n 13.874/2019)

### **Brazil Public Procurement Law**

(Law n 14.133/2021)

4 Regulatory Decrees

### **Regulatory Agencies Law**

(Law n 13.848/2019)

### **Business Environment Law**

(Law n 14.195/2021)



## International level Initiatives



### OECD Recommendations

- Improving the Quality of Government Regulation
- Regulatory Policy Governance

### Trade Agreements

- Brasil - Chile FTA
- Brasil - US Protocol on Trade Rules and Transparency
- Government Procurement Agreement
- WTO
- Services Domestic Regulation WTO

### Cooperation

Commercial Dialogue



Brasil Foreign Trade Secretariat

US Department of Commerce

# Good Regulatory Practices Annex



## Central Coordinating Mechanism

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coordination and review of good regulatory practices within the federal government

## Regulatory Agenda

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publication of a biennial regulatory agenda and annual report on regulations

## Public Consultations

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private sector and civil society participation in regulatory process

## Review of regulations in effect

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verify if the regulation achieved its desired objective, is still relevant, or if the current circumstances present alternatives to the current regulation

## Regulatory Impact Assessment

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mandatory impact assessments for regulations of significant impact

# Anti- Corruption Annex



One of the first trade agreements to contain provisions on Anti-Corruption

Reinforces legislative obligations already assumed by Brazil and the United States in multilateral instruments

Mutual commitment to the fundamental elements necessary for a **fair shake** on trade



# Government Procurement Agreement (GPA/WTO):

"Anti - corruption Agreement "

Transparency and non-discrimination in bidding processes

More **efficiency** and less costs in public purchases



**US\$ 1,7 trillion** market access for brazilian companies



Positive consequences in **combating corruption**

# SECEX initiatives on Good Regulatory Practices

- ✓ Publication of the Foreign Trade Yearbook
- ✓ Impact Assessments for all trade agreements
- ✓ Public consultations for all regulations and impact assessment for high impact regulations
- ✓ Promotion of Good Regulatory Practices with governmental bodies involved in trade



# Concluding Remarks

Good Regulatory Practices and Anti-Corruption are essential for a sound business environment

**Complexity** = Regulations affecting trade involve many different actors

Usually not simple/straightforward solutions



Disciplines in trade agreements and other international commitments **feed back** into domestic process



# Thank you!



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## ***Joint Coalition Closing Lunch***

***Reminder: Reception Tonight with  
U.S. Deputy Secretary of Commerce Don Graves***

**Los Angeles | 7 June 2022**

