Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

Executive Committee Conference Call

May14, 2020

Agenda

Topic	Responsible	Time (min.)
Opening remarks	Steven	5
Introduction of the Executive Committee Members	Sandra	5
Review of the Role of the EC	Sandra	5
Update: ABD & IDB – Health Group	Steven	5
Review and approve Coalition Priorities & Metrics	Sandra	30
Next Steps & Final Comments	Sandra & Steven	10

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Vision

The Vision of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector ("the Coalition") is **one standard, one test, accepted everywhere** for any medical technology scope.

This Vision implies that medical technology regulators across the Western Hemisphere base their national medical device regulations, standards and conformity assessment criteria on the relevant international standards for medical technology.

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Mission

The Coalition's Mission is to lead the coordination of all materially affected stakeholders to achieve this Vision.

This includes promoting regulatory cooperation across the Western Hemisphere to **achieve internationally aligned medical technology regulations, standards and conformity assessment requirements** within a continual process of convergence to maximize patient access to live-saving and life-improving medical technologies.

Executive Committee – Structure

Permanent Members

AdvaMed – **Steven Bipes**

ALADDIV – **Leticia Fonseca**

ALDIMED – **Marisol Sánchez**

Elected Members (2020 – 2022)

Argentina – CADIEM - **Fernando García**

Brazil – Representing ABIIS, ABIMED, ABRAIDI, CBDL, IES - **Sergio Madeira**

Colombia – ANDI - **Damaris Zambrano**

México – AMID - **Yadira Sandoval**

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Executive Committee 2020-2022

Steven Bipes
AdvaMed

Leticia Seixas
ALADDIV

Marisol Sánchez
ALDIMED

Sergio Madeira
AABIIS / ABIMED / ABRAIDI / CBDL

Damaris Zambrano
ANDI

Yadira Sandoval
AMID

Fernando García
CADIEM

Executive Committee Members – Role

- Meet periodically to:
  - Advance the Coalition's Action Plan
  - Prepare for Coalition meetings
  - Prepare for external engagements
- Analyze, provide inputs and approve by full vote by majority, the documents proposed by the Technical Secretariat to then be circulated to the Principal Members
- Undertake remediation for members who do not agree with a vote result

Priority Topics – First Round

Source	Number of Topics
Principal Members	63
Pacific Alliance	11
Total	74

Priority Topics – COVID-19

Source	Number of Topics
Colombia Post-COVID-19	8
Mexico Post-COVID-19	1
ABD Policy Rec. COVID-19	10

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ABD Policy Recommendations - excerpt

1	**… define essential infrastructure, industries, goods, services, and workers,**
2	**… engage in a coordinated, coherent and cooperative international response,**
3	**… cooperate with each other and industry to protect the global medical supply chain, and abstain from implementing export restrictions**
4	**… avoid excessive stockpiling of medicines and medical devices (including equipment, In Vitro Diagnostics and supplies)**
5	**… work to ensure that international trade and investment flows continue uninterrupted and to protect and strengthen global and regional supply chains that are critical for the continued delivery of essential goods and services.**
6	**… work to implement Good Regulatory Practices (GRPs) and strengthen regulatory cooperation to facilitate trade in essential goods.**
7	**… prioritize critical regulatory and supervisory matters related to market conduct…**
8	**… accelerate their digital transformation to ensure that public administration may continue and to enable remote working and business operations…**
9	**… collaborate with the private sector to support testing, scientific research and clinical trials in pursuit of effective vaccination and treatment alternatives.**
11	… **increase health investments as a strategy for economic growth and recovery.**

Priority Topics - Summary

Crisis Management Preparadness - Post COVID19 - Regulatory Framework
GRP Legislation
GRP implementation policy - RIA implementation
WTO - TBT Committee Commitments
Electronic Submissions + eIFU + eSignatures
Prioritized use of international standards - baseline for new regulations - IMDRF, ISO, etc. (21st. Century Cures)
Designation of a standards & conformity assessment: executive/program- Health Regulators
Designation of a standards responsible - MedTech Associations
Medical Device Definition - Pacific Alliance
Risk Classification of MDs - Pacific Alliance
Use of MDSAP / In-country Implementation
Agreement for Reliance - Approvals recognition
Technovigilance
Labeling: Legal Manufacturer, Country of Origin, Physical Manuf., Storage Temp., Exp. Dates, local re-labeling
UDI/GMDN
Counterfeit & Smuggling
Regulation of SaMD (PAHO WG + MX new GMP Norm)
Regulatory Authorities Financial Independence i.e. FDA's MDUFA - User Fee

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Priorities: 2020 – 2025

Top Priorities	Proposal for 2020 - 2021	Proposal 2021 - 2025
Crisis Management Preparadness - Post COVID19 - Regulatory Framework	Initiate	Ensure 100% of Issues are addressed via Good Reguatory Practices (GRP)
GRP Legislation	Training - Diagnostic - Initiate	
GRP implementation policy - RIA implementation	Training - Diagnostic - Initiate	
WTO - TBT Committee Commitments	Training - Diagnostic - Initiate	
Electronic Submissions + eIFU + eSignatures	Initiate	
Prioritized use of international standards - baseline for new regulations - IMDRF, ISO, etc. (21st. Century Cures)	Training - Basic requirement for all initiatives	
Designation of a standards & conformity assessment: executive/program- Health Regulators	Initiate	
Designation of a standards responsible - MedTech Associations	Implement	
Medical Device Definition - Pacific Alliance	Implement	
Risk Classification of MDs - Pacific Alliance	Implement	
Use of MDSAP / In-country Implementation	Training - Initiate / Implement	
Agreement for Reliance - Approvals recognition	Initiate	
Technovigilance	Training - Initiate / Implement	
Labeling: Legal Manufacturer, Country of Origin, Physical Manuf., Storage Temp., Exp. Dates, local re-labeling	Training - Initiate / Implement	
UDI/GMDN	Training - Initiate / Implement	
Counterfeit & Smuggling	Training - Initiate / Implement	
Regulation of SaMD (PAHO WG + MX new GMP Norm)	N/A	Training - Initiate/Implement
Regulatory Authorities Financial Independence i.e. FDA's MDUFA - User Fee	N/A	Training - Initiate/Implement

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Priority Topics Matrix

Top Priorities	ARG.	BR.	COL.	CH.	ECU.	MEX.	PER.	USA Reco.	TOTAL	ABD
Crisis Management Preparadness - Post COVID19 - Regulatory Framework			1			1		1	3	x
GRP Legislation						1		1	2	x
GRP implementation policy - RIA implementation	1	1	1	1	1	1		1	7	x
WTO - TBT Committee Commitments						1	1	1	3	x
Electronic Submissions + eIFU + eSignatures		1	1			1	1		4	x
Prioritized use of international standards - baseline for new regulations - IMDRF, ISO, etc. (21st. Century Cures)	1	1	1	1	1	1	1	1	8	x
Designation of a standards & conformity assessment: executive/program- Health Regulators				1				1	2	x
Designation of a standards responsible - MedTech Associations								1	1	x
Medical Device Definition - Pacific Alliance			1	1		1	1		4	x
Risk Classification of MDs - Pacific Alliance		1	1	1		1	1		5	x
Use of MDSAP / In-country Implementation	1	1	1	1	1	1		1	7	x
Agreement for Reliance - Approvals recognition		1	1	1		1	1	1	6	x
Technovigilance			1	1	1			1	4	x
Labeling: Legal Manufacturer, Country of Origin, Physical Manuf., Storage Temp., Exp. Dates, local re-labeling			1	1		1	1	1	5	x
UDI/GMDN	1	1	1		1	1		1	6	x
Counterfeit & Smuggling			1		1				2	x
Regulation of SaMD (PAHO WG + MX new GMP Norm)	1	1	1	1	1	1	1	1	8	x
Regulatory Authorities Financial Independence i.e. FDA's MDUFA - User Fee								1	1	
TOTAL	5	8	13	10	7	13	8	14	78	

Country Specific Issues & Obligations

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INMETRO Ordinance 54/2016 (under revision draft INMETRO Ordinance 259/2019) Conformity Assessment Requirements for Medical Devices

Brazil's unique requirements:

1) A medical device test report validity of two years for small devices and four years for large devices that requires that medical devices be retested every two or four years respectively;
2) A medical device certification validity of five years that requires that medical devices be recertified every five years;
3) A Brazil-unique label to be affixed to imported medical devices prior to arrival at Brazilian port.

Mexico

USMCA:

- Chapter 12-E: MDSAP Implementation – Alignment of GMP NOM (project);
- Chapter 11: TBT, use of international standards;
- Chapter 28: GRP - Revision of the COFEPRIS NOM process, using international standards as the basis

Development of Guidelines for Registrations Review

Peru

- DIGEMID – high agency staff turnover
- Issuance of sanitary registrations based on both legal and physical manufacturer, therefore costly and inefficient process
- EU - Declaration of Conformity is not recognized as sufficient support to demonstrate compliance with international standards
- Prescription required for purchasing of MDs
- Design validation and verification reports are requested in a "country - unique" format
- Date of issuance of Legal and technical documents should not exceed two years
- Registrations are required per GMDN or ECRI preventing for product families to be included in a single registration

Regional Metrics

Top Priorities	Metrics
Crisis Management Preparadness - Post COVID19 - Regulatory Framework	% Countries
GRP Legislation	% Countries
GRP implementation policy - RIA implementation	% Countries
WTO - TBT Committee Commitments	% Countries
Electronic Submissions + eIFU + eSignatures	% Countries
Prioritized use of international standards - baseline for new regulations - IMDRF, ISO, etc. (21st. Century Cures)	% Countries
Designation of a standards & conformity assessment: executive/program- Health Regulators	% Countries
Designation of a standards responsible - MedTech Associations	% Members
Medical Device Definition - Pacific Alliance	% Countries
Risk Classification of MDs - Pacific Alliance	% Countries
Use of MDSAP / In-country Implementation	% Countries
Agreement for Reliance - Approvals recognition	% Countries
Technovigilance	% Countries
Labeling: Legal Manufacturer, Country of Origin, Physical Manuf., Storage Temp., Exp. Dates, local re-labeling	% Countries
UDI/GMDN	% Countries
Counterfeit & Smuggling	% Countries
Regulation of SaMD (PAHO WG + MX new GMP Norm)	% Issues
Regulatory Authorities Financial Independence i.e. FDA's MDUFA - User Fee	% Increase

*Weighted figures calculated from the LATAM Countries improvement targets

Next Steps

Action	Responsible	Date
Feedback from members on approval of the priorites discussed in the Executive Committee Call	EC Members	21May
Deploy Coalition Priorities & Metrics - Country Specific Action Plan Preparation Playbook (2020-2025)	Sandra	25 May
Coalition's Website Go-live	TecSec	25May
GRP Training and Policy Webinars	TecSec	25May, 02, 08 & 15 June
Follow Up Sessions with Individual Members	Leticia & Sandra	1 – 5 June
Action Plans, Objectives & Metrics from Members to TechSec	Principal Members	22 June
Virtual Meeting: Action Plans, Objectives & Metrics – Presentations	Principal Members + TechSec	1 July
Coalition's Meeting in October	TechSec	TBD