



Inter-American Coalition for Regulatory Convergence  
March 30, 2020

Conference Minutes

Attendees:

Country	Organization	Name
Mexico	IACRCMTS	Sandra Ligia González
Brazil	IACRCMTS	Leticia Seixas Fonseca
USA	IACRCMTS	Andrew Blasi
USA	AdvaMed	Steven Bipes
USA	AdvaMed	Adriana Belza
Argentina	CADIEM	Victoria del Castillo
Brazil	ABIIS	José Márcio Cerqueira Gomes
Brazil	ABIMED	Fernando Silveira
Brazil	ABIMED	Angélica Marques
Brazil	ABRAIDI	Bruno Boldrin
Brazil	ABRAIDI	Sergio Madeira
Brazil	CBDL	Carlos Gouvêa
Brazil	J&J	Sandra Dalberto
Canada	MedTech Canada	Diana Johnson
Canada	MedTech Canada	Greg Leblanc
Colombia	ANDI	Alejandra Caballero
Colombia	ANDI - J&J	Damaris Zambrano
Colombia	ANDI - Medtronic	Natalia Valbuena
Chile	ADIMECH	Gabriela Garnham
Ecuador	ASEDIM	Cristina Murgueitio
Ecuador	ASEDIM	Carolina Arévalo
Mexico	AMID	Ingrid González Torres
Mexico	AMID - J&J	Yadira Sandoval

Minutes:

1. Sandra issued a welcome message wishing for everyone and their families to be safe and healthy under the current pandemic situation. Sandra also acknowledging the individual efforts to participate in the Call as it provides the means to continue advancing the Coalition Agenda in lieu of the postponement of the in-person meeting.
2. Steven shared a brief summary of actions being taken regarding of the COVID-19 situation by international institutions.
3. Voting appointees per Principal Members present at the call were named:

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4. Members were invited to make final comments over the latest version of the “Terms of Reference” prior to its voting.
  - a. ANDI confirmed their approval of the proposal made by the Technical Secretariat to address their comments
  - b. Carlos Gouvea (CBDL) proposed for the approval process of documents, to eliminate the alternative for “unanimous agreement” and allow for “full vote by majority” only. The proposal was unanimously accepted.
  - c. Voting members approved the “Terms of Reference” as per the final version agreed upon during the call (Attached – Terms of Reference Final – 30Mar20).
  
5. Executive Committee Election:
  - a. Members were invited to propose candidates
  - b. Adriana Belza, proposed to postpone the voting process as the Principal Members had not completed their candidates’ selection due to the short notice.
  - c. Members agreed and the following process was proposed and approved:
    - i. Each Principal Member will forward their candidate along with a brief Resume to the TechSec by EOB on April 1<sup>st</sup>.
    - ii. TechSec will forward them along with a survey on April 2<sup>nd</sup>. to conduct the voting process.
    - iii. Voting will be closed by EOB on April 3<sup>rd</sup>.
    - iv. Results will be communicated by TechSec on April 6<sup>th</sup>.
  
6. Coalition priorities
  - a. Consolidated priorities from members will be shared with the Executive Committee in the week of April 6 for approval of the top ones.
  - b. Approved priorities will afterwards will be shared with Principal Members for final approval.
  
7. A space was open for Members to share highlights on the situations occurring related to COVID-19 throughout the region:



Coalición Interamericana  
de Convergencia Regulatoria

SECTOR DE TECNOLOGÍA MÉDICA



Coalizão Interamericana  
de Convergência Regulatória

SETOR DE TECNOLOGIA MÉDICA



Inter-American  
Coalition for  
Regulatory Convergence

MEDICAL TECHNOLOGY SECTOR

- a. Brazil
  - i. Expedite approval process by submitting limited information valid for 1 year. Regular validity grant is possible upon submission of missing documents, i.e. stability studies
- b. Chile
  - i. Price control to be implemented for devices required for treatment of COVID-19 patients – potentially at the level of WHO
- c. Colombia
  - i. New regulation to facilitate, through a special permit, the imports of devices required for treatment of COVID-19 patients. Scope is much broader as it includes i.e sutures and monitors, creating a burden
  - ii. Decree was published to allow electronic submissions during the emergency
- d. Argentina
  - i. Granting special approvals for emergency-related products, under a case by case analysis
  - ii. Expecting for a new regulation to be published to standardize the approval criteria
- e. Ecuador
  - i. Expedite approval for IVDs in place
  - ii. Concerns about COVID-19 related IVDs being smuggled - customs are not applying appropriate controls - working with government to strengthen controls
  - iii. Collaboration with government to issue a public tender to manage the black-market situation
  - iv. Brazil shared that associations are making public statements in regards of the risks associated to the “self-testing”, need for tests to be run by professionals and their approaching to the government for a joint effort.