PAHO REGULATORY RESPONSE COVID19 PANDEMIC FIFARMA ANNUAL REGIONAL VIRTUAL MEETING

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PAHO/WHO

Pan American Health Organization
World Health Organization
Regional Office for the Americas

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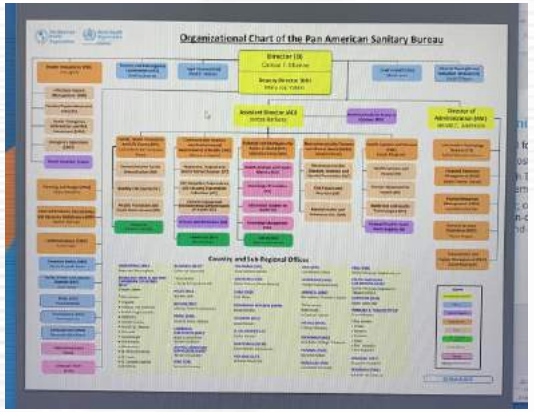
Overview of Presentation

- PAHO Medicines and Health Technologies Unit
- COVID work
- COVID regulatory work
  - Where are there strategic partnerships?
- Any questions

Organizational Context



- PAHO is regional arm of WHO for the Americas
- PAHO has local offices in most of the 35 countries in the Americas
- PAHO Medicines and Health Technologies (MT) Unit is situated in the Department of Health Systems and Services in Washington, DC
- Other departments include: communicable diseases and environmental determinants of health; non-communicable diseases and mental health; family, health promotion and life course; and evidence and intelligence for action in health

Organizational Context

- The MT unit is comprised of advisors and technical experts including:
  - regulatory strengthening,
  - rational use, essential meds, antimicrobial resistance, pharmacovigilance, evidence
  - medical devices and health technology assessment,
  - blood and blood products,
  - supply chain,
  - pharmaceutical policy and access to medicines,
  - radiation and radiological devices,
  - PAHO Strategic and Revolving Fund quality assurance,

PAHO Emergency Response

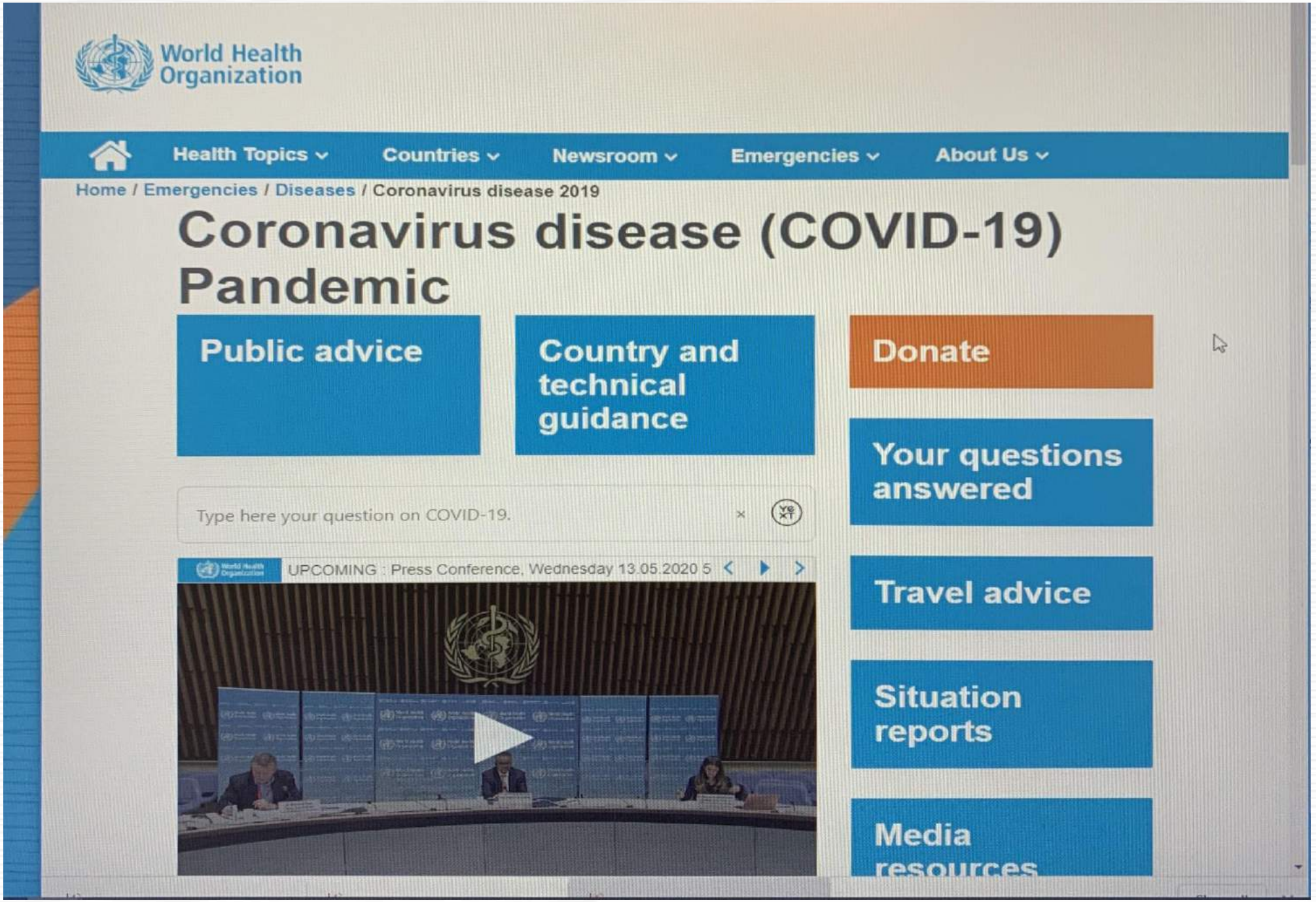
- Incident Management Structure, manager
- Within Emergency Operations Center
- Persons divided into different thematic areas-
  - Medicines and health technology work is within the cluster that includes health systems, workers, medicines, evidence, etc.

Types of Requests Driving PAHO's Response

- Country requests for information
- Country requests for technical cooperation
- Country requests for norms, standards, guidance
- Country requests for help with procurement

Specific Topic Areas to Date

- Quality standards and procurement of personal protective equipment
- Advice on and quality standards of test kits
- Advice on and quality standards of ventilators
- Advice on medicines, convalescent plasma
- Joining SOLIDARITY clinical trial
- Local production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Coronavirus disease (COVID-19) Pandemic
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Country and technical guidance
Donate
Your questions answered
Type here your question on COVID-19.
UPCOMING : Press Conference, Wednesday 13.05.2020 5
Travel advice
Situation reports
Media resources

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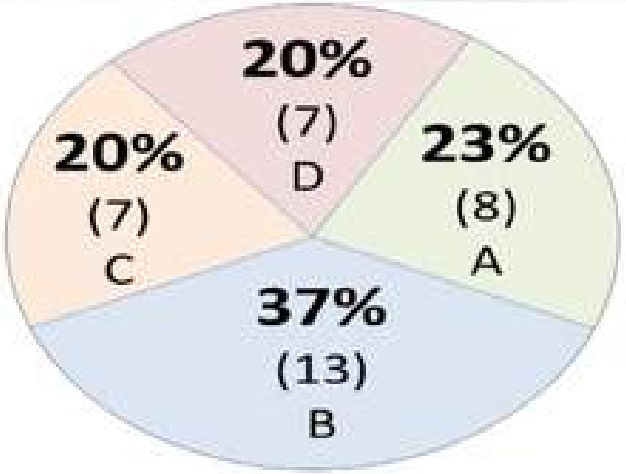
Development of Other Guidance

- Essential Medicines List for Management of Patients admitted to Intensive Care Units with Suspected or Confirmed COVID-19 Diagnosis
- Technical specifications of medical devices for the case management of COVID-19 in healthcare settings
- Requirements and technical specifications of personal protective equipment (PPE) for the novel coronavirus (2019-ncov) in healthcare settings

Regulatory Strengthening in the Americas

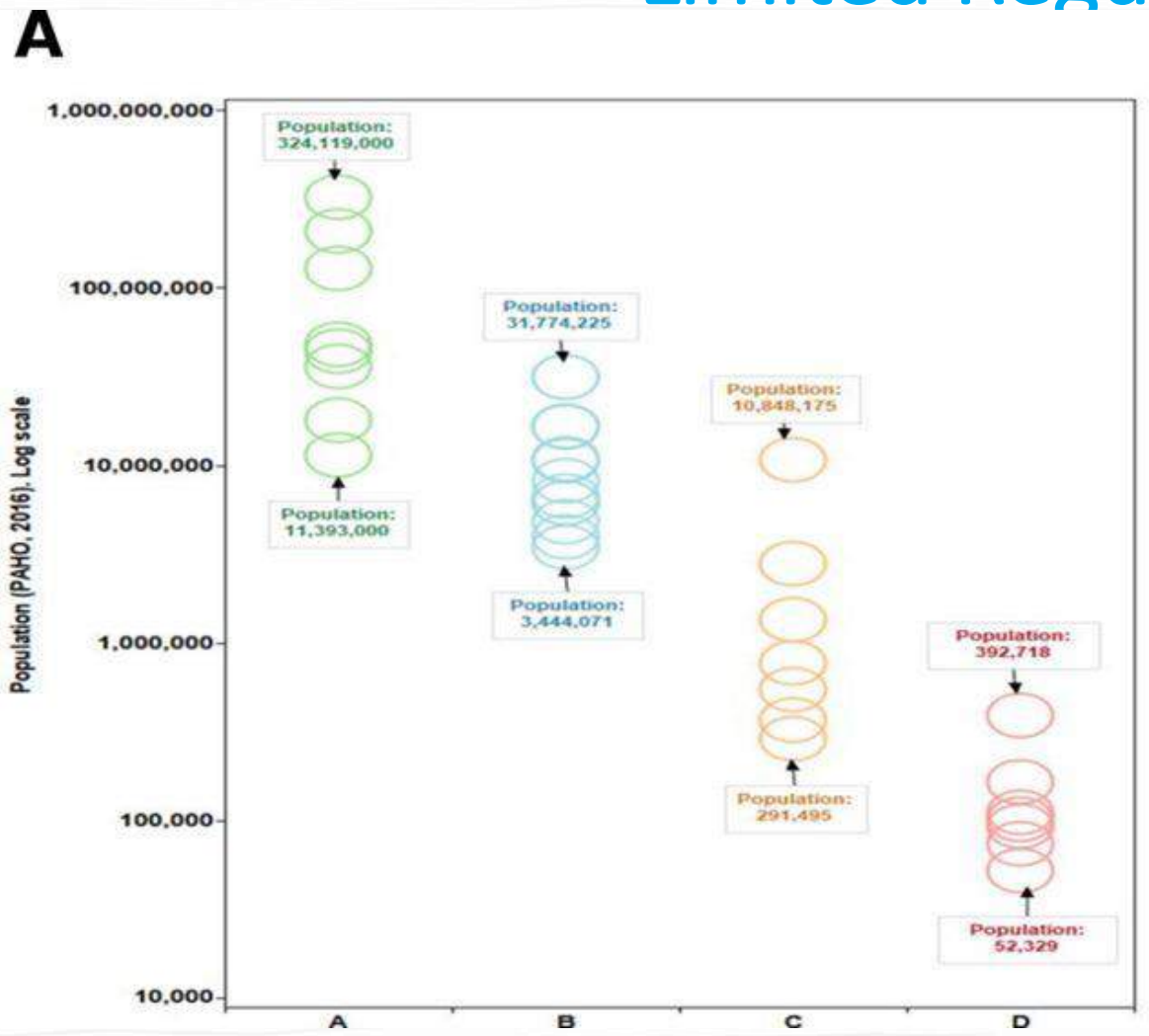
- PAHO has a strong relationship with regulatory authorities in the region
- Pan American Network for Drug Regulatory Harmonization
- National Regulatory Authorities of Regional Reference
- Assessment program
- Sub-regional regulatory mechanisms in Caribbean, Central America

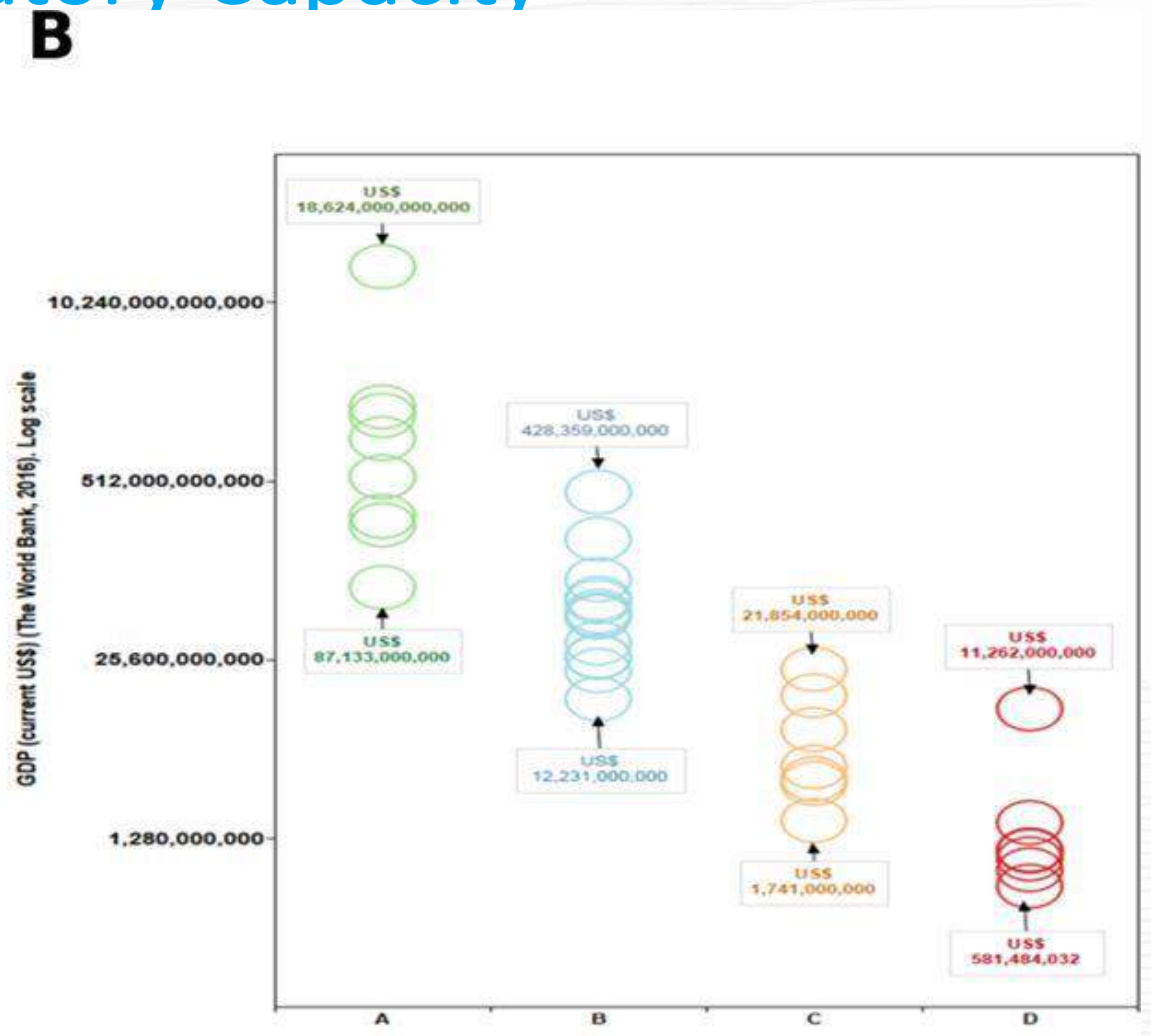
Regulatory Situation in the Americas (N=35)



- A - States with National Regulatory Authority of Regional of Reference according to CD50.R9 (NRAr)
- B - States that have legal bases and organizational structures for a comprehensive regulatory system
- C - States that have some legal bases and organizational structures for a regulatory system
- D - States that do not currently have legal bases and/or organizational structures for a regulatory system

Association of Population and Absolute GDP with Limited Regulatory Capacity





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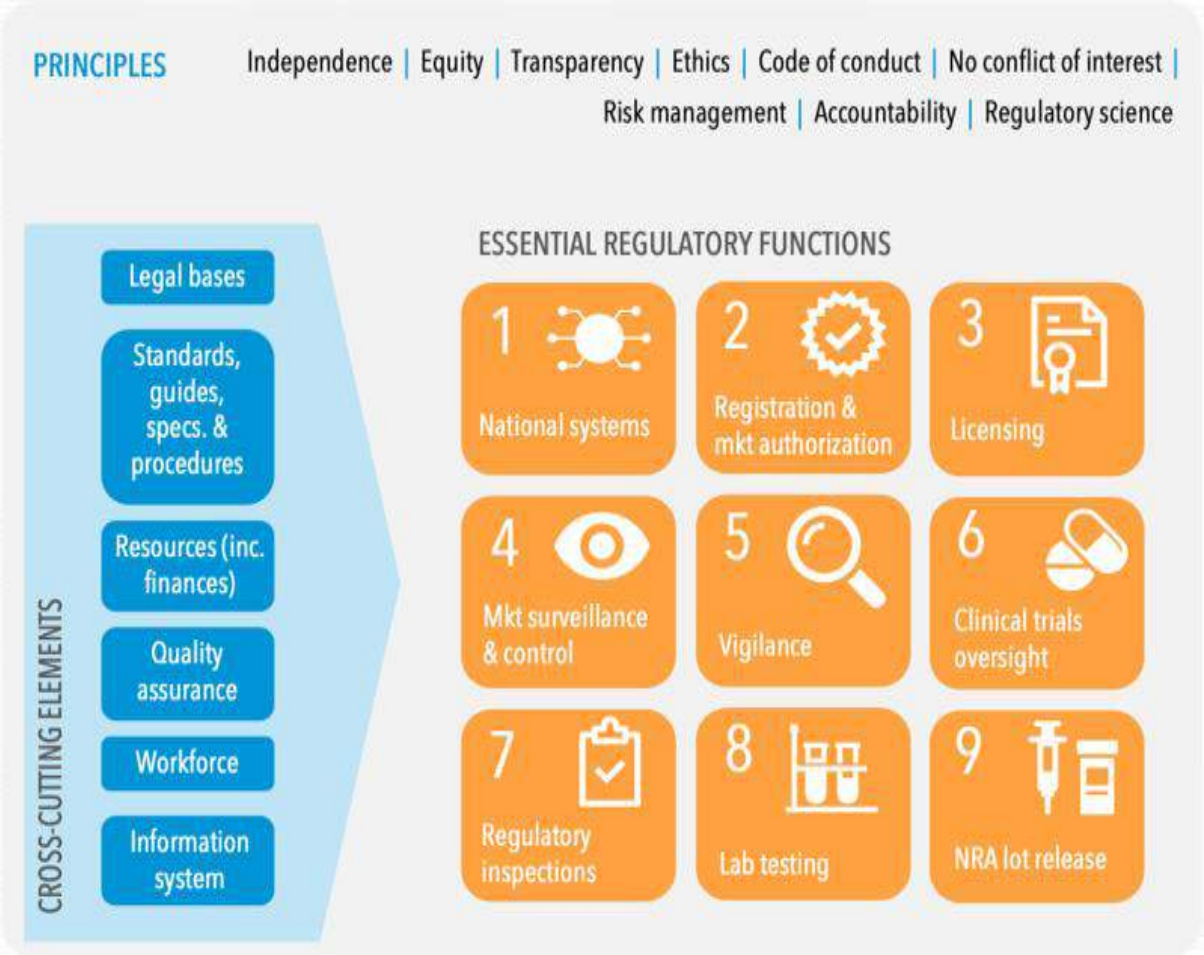
Sub-Regional Mechanisms to be Aware of

- Within CARICOM block of countries, CARPHA/CRS
  - Reliance mechanism, with verification procedure- drugs, biologics, IVDs
  - Recommends products to MS
  - Post market surveillance system

- Within Central American countries, new regional mechanism
  - Joint reviews

Regulatory Support in a Pandemic

- Multiple regulatory functions implicated:
  - **Market authorization**, **post market surveillance**, **clinical trials**, laboratory, inspections, licensing of establishments, **lot release**
- We leverage tools/thinking from WHO Pandemic Influenza Preparedness Framework
- Have experience with other epidemic/pandemic situations



Major Regulatory Initiative in COVID-19

- Support National Regulatory Authorities in the Americas to better respond to COVID-19 pandemic:
  - Establish a network of high-level focal points from NRAs responsible for COVID-19 to enable information sharing and rapid response
  - Update legal and policy frameworks for regulatory response during COVID-19
  - Identify the regulatory challenges around COVID-19, and provide guidance to NRAs on regular basis

PROPOSED ACTIONS FOR MEMBER STATES

- Incorporate recommended regulatory approaches relative to the pandemic with regulatory functions.
- Promote the establishment of a regulatory crisis management committee that can articulate with other National Health Authorities and improve communication with other national government stakeholders, and civil society.
- Evaluate, identify and address regulatory gaps based on WHO/PAHO checklist
- Document regulatory actions taken during the crisis to improve transparency and monitor their impact.

Regulatory Support in a Pandemic

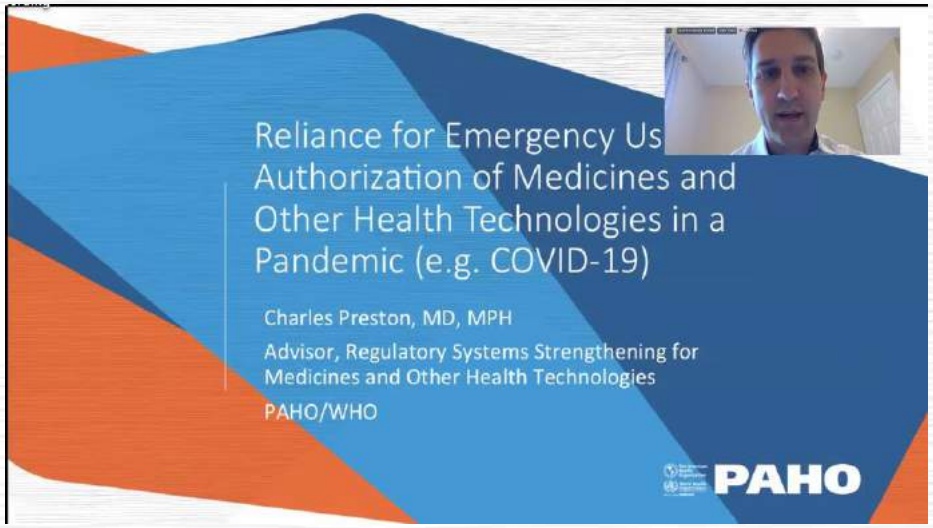
- Hold bi-weekly meetings on key regulatory topics
  - Hosted by PAHO Assistant Director Jarbas Barbosa

Regulatory considerations on authorization of the use of convalescent plasma (PC) to address the COVID-19 emergency, 22 April 2020
https://iris.paho.org/handle/10665.2/52036

Reliance for Emergency Use Authorization of Medicines and Other Health Technologies in a Pandemic (e.g. COVID-19)
https://iris.paho.org/handle/10665.2/52027

Crisis Management during an Epidemic: General guidelines for efficient response coordination by national regulatory authorities, May 2020
https://iris.paho.org/handle/10665.2/52098

REGULATORY ACTIONS DURING PANDEMIC:
Reliance for Emergency Use Authorization in a Pandemic



We are thinking about how we set up systems that will most efficiently get drugs, vaccines, diagnostics to populations in COVID-19- what do we need to do to prepare?

- Scope- drugs, vaccines, IVDs
- Conditions for declaring emergency
- Risk based approach- use reliance on reference authorities

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Suggested Technical Requirements for Pharmaceuticals, Vaccines, and IVDs for EUA

- Assurance of sameness
  - Cover letter, marketing authorization certificate
- Product description
  - Summary of product characteristics or equivalent, package insert
- Manufacturing information
  - List of all sites involved in manufacture (API and FPP)
  - FPP GMP certificate or ISO 13485 certificate if IVD
- Product labeling
  - PDF artworks in national language

Regulatory Support in a Pandemic

- Upcoming topics
  - Clinical trials regulation
  - Post market surveillance
  - Donations
  - TBD- welcome your thoughts

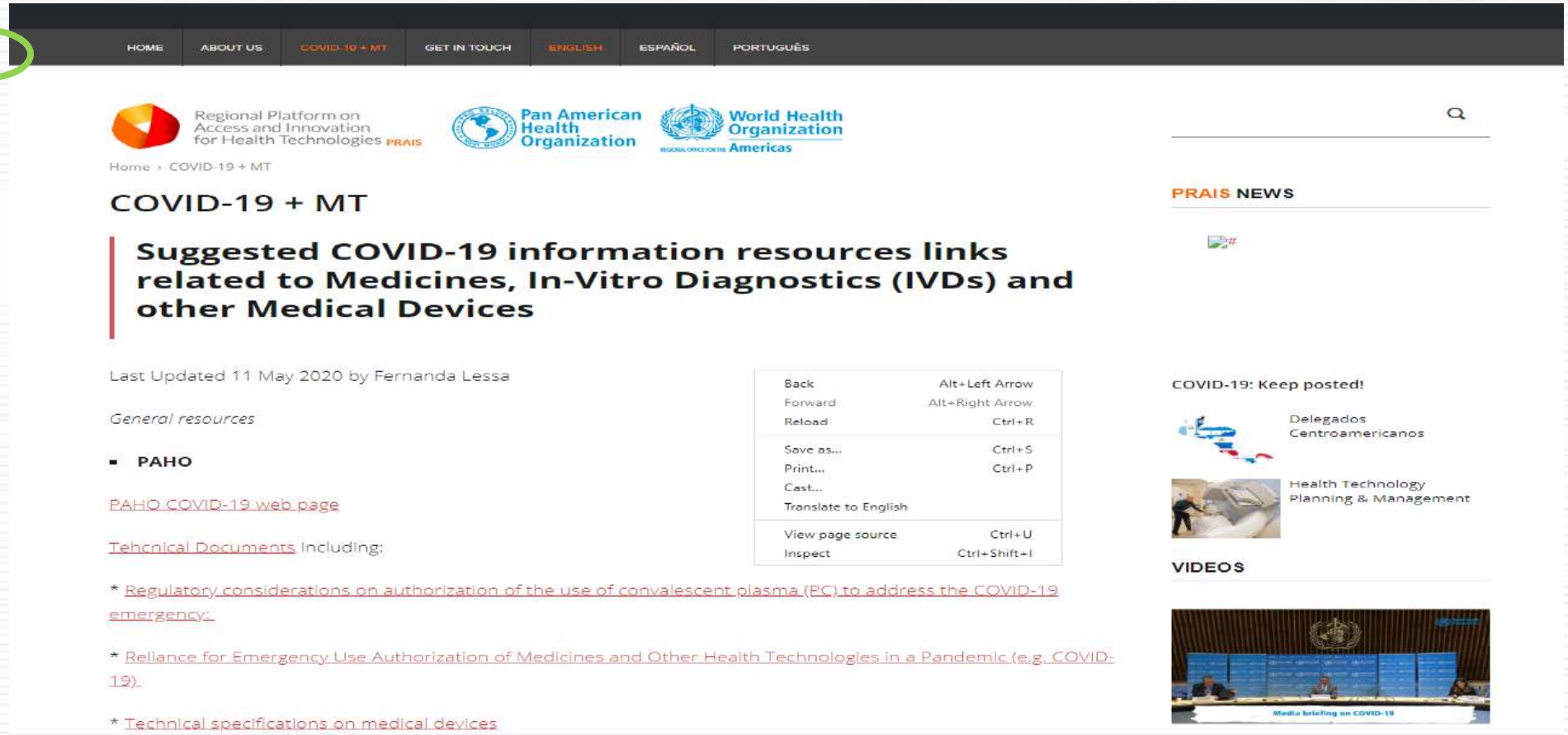
Clinical Trials Regulation Guidance (Upcoming)

- Basic elements of clinical trials regulation
- How to move expeditiously during pandemic situations
- How to leverage efficiencies such as collaborative reviews, reliance on decisions

REGULATORY ACTIONS DURING PANDEMIC:
Topic-Specific Meetings

- Evidence in the Treatment of COVID-19
- Regulation of ventilators in COVID-19
- Training sessions on Quantification Tool of medicines, medical supplies and PPEs
- Regulation and procurement of PPE in the COVID-19 context
- Ethics review and oversight of COVID-19-related research

REGULATORY ACTIONS DURING PANDEMIC



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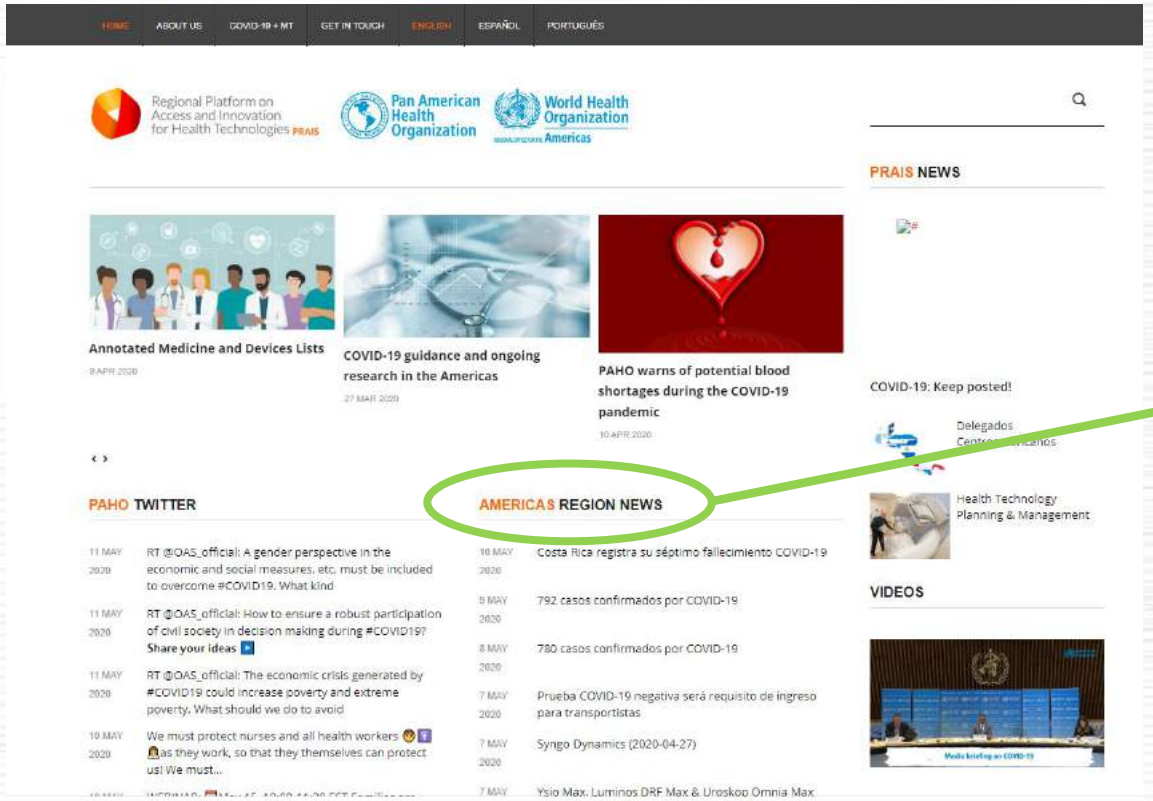
REGULATORY ACTIONS DURING PANDEMIC



- Publication of updated regulatory actions on COVID-19 of the NRA of regional reference:
  - ANMAT, Argentina
  - ANVISA, Brazil
  - Health Canada
  - ISP, Chile
  - INVIMA, Colombia
  - CECMED, Cuba
  - COFEPRIS, Mexico
  - US FDA, USA

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FIFARMA and PAHO

- How can we work more closely in this pandemic?

Thank You

Thoughts?

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Questions?