Cutting-Edge Health Technologies: Opportunities and Challenges

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Topics

- regulation of cutting-edge health technologies, such as biotechnology, medical devices and IT
- access to cutting-edge health technologies in LMICs from a regulator’s perspective
- data required in regulatory procedures
- particularities for cutting-edge health technologies
The Americas

- **North America**: United States, Canada and Mexico
- **Central America + Cuba + Dominican Republic**: Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panamá, Cuba, Dominican Republic;
- **Caribbean**: Antigua and Barbuda, Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, St Kitts and Nevis, Saint Lucia, St Vincent and the Grenadines, Suriname, Trinidad and Tobago
- **Andean Region**: Bolivia (Plurinational State of), Chile, Colombia, Ecuador, Peru, Venezuela (Bolivarian Republic of)
- **Southern Cone**: Argentina, Brazil, Paraguay, Uruguay
Vast differences

Resources & GDP
R&D capacity
Production Capacity
Regulatory Capacity
NEGOTIATING CAPACITY
Territorial size & Population
IP regimes
Trade (FTA’s, legislation)

But also similarities

Disease burden
- NCDs (CV diseases, Cancer etc.)
- Infectious diseases
Some (current) regional developments to increase affordable access to Quality HC products

- Joint Negotiations (UNASUR)
  - Hep C medicines; Darunavir prices lowered
- Publication of Prices of HCM (Hepatitis: SOF/VEL; SOF/DCV) PAHO
  - Access through PAHO revolving fund of strategic public health supplies (Strategic Fund)
- Biosimilar regulation and evaluation (ie. Colombia)
- Legislative changes affecting IP regime (Chile)
- Mechanism for the joint evaluation of dossiers of medicines and other health technologies among the National Regulatory Authorities (just launched)
- CARPHA Caribbean Regulatory System to centralize evaluation and registration of medicines for the CARICOM region
  - Based on prior evaluation of reference authorities
  - Verification mechanism
Challenges of the Caribbean Region

- Human resources
- Regulatory capacity
  - Assure quality
- Negotiating Capacity
- Access & Equity
- (IP regimes)
- Relative high prices for Medicines and other Health Technologies (all imports; no local production capacity)
- Trade concerns (FTA’s)
- Legislative framework insufficient, outdated
Main concerns for the Caribbean

- Access does not only depend on IP and Trade law, but also on Absorbing Capacity for new trends
- This results in higher prices
- Double burden of disease
- Renewed efforts of partner organisations to consider challenges for Small Island States
Thank You
Dank u wel
Tangi