



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
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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- Legislative framework insufficient, outdated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