

# DECLARACIÓN DE ACAPULCO



JOINT WORKING PAPER OF THE HEALTH AGENCIES OF  
MEXICO, COLOMBIA AND CUBA

**AMLAC**

Agencia  
de **Medicamentos**  
Latinoamérica y el Caribe

 April 26th of 2023, 12hrs,  Acapulco's Botanic Garden

Non-official translation produced by the Inter-American Coalition for Regulatory Convergence, Medical Technology Sector

**The Latin America and Caribbean Medicines Agency** is an international organization established in accordance with public international law, for the benefit of cooperation among Latin American and Caribbean States, without discrimination, in research, cooperation and advisory activities that contribute to and strengthen human health and access to medicines and medical devices, for the benefit of public health in Latin America and the Caribbean.

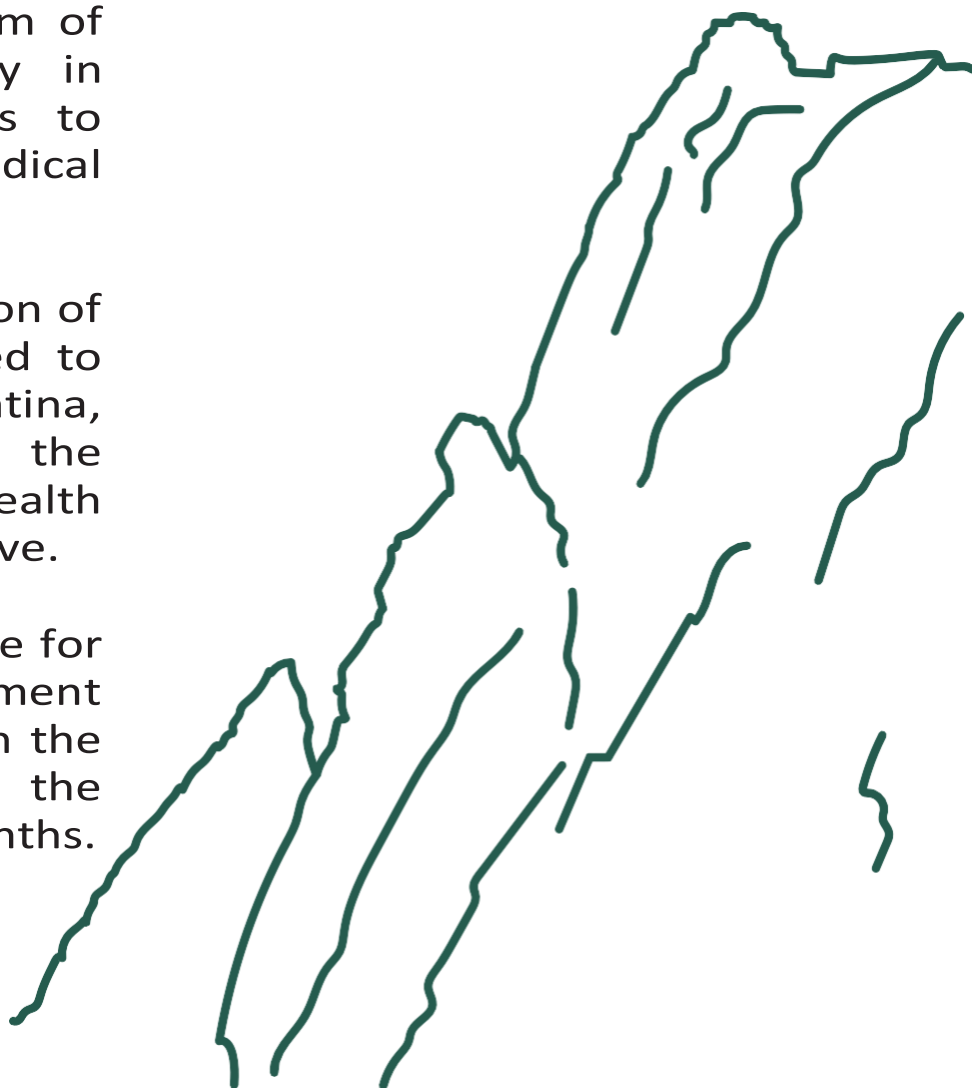
📍 **Acapulco's Botanic Garden**  
**09:00-11:00 hrs**

Signing of a joint declaration between Colombia, Cuba and Mexico to formalize the beginning of negotiations for the creation of AMLAC. The participants present the first draft of the Constitutive Agreement of the new international institution.

Colombia, Cuba and Mexico agree to begin talks to create the AMLAC, with the aim of achieving self-sufficiency in health care and access to medicines and medical devices in the region.

Agree that the constitution of AMLAC will be presented to CELAC, and invite Argentina, Brazil, Chile and the Caribbean Public Health Agency to join the initiative.

Proposes a work schedule for negotiating the agreement establishing AMLAC, with the objective of signing the agreement within six months.



# Context

Despite their political, social and cultural similarities, as well as efforts to create trade alliances such as the Pacific Alliance or Mercosur and regulatory strategies aimed at achieving sanitary self-sufficiency, **the countries of Latin America and the Caribbean remain disjointed.**

This perpetuates the region's **dependence on trade with the major powers**, which mainly seek low-cost manufactures and raw materials and, at the same time, place their products in Latin American and Caribbean countries, imposing prices that guarantee them substantial profits.

**This situation inhibits the development of an integrated regional context that would allow self-sufficiency in strategic inputs**, such as medicines, vaccines and medical devices, aimed at the prosperity and well-being of the population. It also **perpetuates a pattern of conditioned dependence** and, in turn, the lag in building technological and organizational capabilities for the development of new pharmaceutical products **that better respond to the public health needs of our nations.**

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## Objective

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Advance self-sufficiency and sanitary sovereignty in the Latin America and Caribbean region with shared strategies for sanitary regulation among the countries of the region.

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## Strategies

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**Implement the first stages of the Health Self-Sufficiency Plan** designed by ECLAC and presented during the CELAC 2021 Summit through a partnership between INVIMA, CECMED and COFEPRIS.

Undertake actions in the short (2 years), medium (4 years) and long term (6 years) that will contribute to the birth and **consolidation of the Latin American Medicines Agency.**

# Short-term measures to be implemented

## Regulatory Convergence

Promote the establishment of regional working groups to promote regulatory convergence in the following areas:

- i) Authorization of medicines and health supplies, particularly for emergency use.
- ii) Standards for testing the efficacy of high-demand drugs in public health.
- iii) Clinical research for regional pharmaceutical development.
- iv) Quality Management Systems for laboratories.
- v) Inspection of establishments and production lines for Good Manufacturing Practices accreditation.
- vi) Elimination of technical barriers to the safe supply and regional production of Active Pharmaceutical Ingredients (APIs).

