

## Towards A Latin American and Caribbean Medicines Agency (AMLAC)<sup>1</sup>

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On 26 April 2023 in Acapulco, Mexico, the Medicines Regulatory Authorities of Colombia (INVIMA), Cuba (CECMED) and Mexico (COFEPRIS) signed the "Declaration of Acapulco" for the creation of the Latin American and Caribbean Medicines and Medical Devices Regulatory Agency (AMLAC).<sup>3</sup>

*AMLAC will be established to contribute to regional integration through harmonisation and convergence in health*

*regulation and to the creation of a regional medicines market in Latin America in pursuit of access to safe, effective and quality medicines and medical devices. This Policy Brief examines the context, criteria for and objectives of the creation of AMLAC.*

The "Declaration of Acapulco" proposed the creation of AMLAC as a mechanism to contribute to regional integration through harmonisation and convergence in health regulation, in pursuit of access to safe, effective and

### Abstract

On 26 April 2023 in Acapulco, Mexico, the Medicines Regulatory Authorities of Colombia (INVIMA), Cuba (CECMED) and Mexico (COFEPRIS) signed the "Declaration of Acapulco" for the creation of the Latin American and Caribbean Medicines and Medical Devices Regulatory Agency (AMLAC). This declaration was confirmed in Bogota, Colombia on 16 June 2023 in a meeting called "Regulatory convergence" by the heads of the medicines regulatory agencies of Argentina, Brazil, Chile, Colombia, Cuba and Mexico who agreed on the progressive creation of a Latin American and Caribbean Medicines Agency (AMLAC).

AMLAC was created to contribute to regional integration through harmonisation and convergence in health regulation, the creation of a regional medicines market in pursuit of access to safe, effective and quality medicines and medical devices.

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*El 26 de abril de 2023 en Acapulco, México, las Autoridades Regulatoras de Medicamentos de Colombia (INVIMA), Cuba (CECMED) y México (COFEPRIS) firmaron la "Declaración de Acapulco" para la creación de la Agencia Latinoamericana y del Caribe de Regulación de Medicamentos y Dispositivos Médicos (AMLAC). Esta declaración fué confirmada en Bogotá, Colombia el 16 de junio de 2023 en una reunión titulada "Convergencia regulatoria" por los responsables de las agencias reguladoras de medicamentos de Argentina, Brasil, Chile, Colombia, Cuba y México que acordaron la creación progresiva de una Agencia Latinoamericana y del Caribe de Medicamentos -AMLAC-.*

*La AMLAC fué creada para contribuir a la integración regional a través de la armonización y convergencia en materia de regulación sanitaria, la creación de un mercado regional de medicamentos en busca del acceso a medicamentos y dispositivos médicos seguros, eficaces y de calidad.*

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*Le 26 avril 2023 à Acapulco, au Mexique, les autorités de réglementation des médicaments de Colombie (INVIMA), de Cuba (CECMED) et du Mexique (COFEPRIS) ont signé la "Déclaration d'Acapulco" pour la création de l'Agence latino-américaine et caribéenne de réglementation des médicaments et des dispositifs médicaux (AMLAC). Cette déclaration a été confirmée à Bogota (Colombie) le 16 juin 2023 lors d'une réunion intitulée "Convergence réglementaire", réunissant les responsables des agences de réglementation des médicaments de l'Argentine, du Brésil, du Chili, de la Colombie, de Cuba et du Mexique qui se sont mis d'accord sur la création progressive d'une Agence des médicaments pour l'Amérique latine et les Caraïbes (AMLAC).*

*L'AMLAC a été créée pour contribuer à l'intégration régionale par l'harmonisation et la convergence des réglementations sanitaires, la création d'un marché régional des médicaments et l'accès à des médicaments et des dispositifs médicaux sûrs, efficaces et de qualité.*

quality medicines and medical devices. In addition, the "Declaration of Acapulco" invited the National Regulatory Authorities of Regional Reference of Argentina, Brazil and Chile to join this initiative, as well as the South Centre, an intergovernmental organization of developing countries to which Colombia, Cuba and other countries of the Region belong, to add their technical and political support in the international arena.

Likewise, it was agreed to keep the Pro-Tempore Presidency of the Community of Latin American and Caribbean States (PPT-CELAC) duly informed about the process of setting up AMLAC, in order to foster a broad exchange of knowledge and receive the contributions of interested member countries.

On 15-17 June 2023 the heads of the medicines regulatory agencies of Argentina, Brazil, Chile, Colombia, Cuba and Mexico met in Bogota, Colombia and agreed on the progressive creation of a Latin American and Caribbean Medicines Agency.

This proposal is mapped out in the framework of the Declaration of Ministers of Health of the Community of Latin American and Caribbean States (CELAC) of 24 November 2022, which states: "To confirm that medicines, vaccines, treatments and other health technologies developed in response to a public health emergency are global public goods and an essential element of the right to health. (...) Sustain a strong commitment to any regional or global initiative aimed at facilitating universal and equitable access to medicines, vaccines, treatments and other health technologies (...)"

## **General Context**

One of the functions of the constitutional mandate of the World Health Organization (WHO) is "to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products",<sup>4</sup> and in this context WHO has been working to develop, establish and promote international standards for food, biological, pharmaceutical and similar products. In this context, WHO has for some 30 years been supporting and recommending to countries the formulation of pharmaceutical policies as an important component of national health policies and formulating standards such as good manufacturing practices and other norms through its expert committees. As far as drug regulation is concerned, the States themselves are responsible for establishing National Drug Regulatory Authorities (NDRAs).

Apart from the regulatory agency of the United States of America, (FDA) created in 1906, the major agencies of the industrialized countries France,<sup>5</sup> England, Germany, Spain, Australia, Japan and Canada, were created only 30 to 40 years ago.

In Latin America, in the last 30 years, medicines regulatory agencies have been created such as CECMED in Cuba - 1989, ANMAT in Argentina - 1992, INVIMA in Colombia - 1994, ANVISA in Brazil - 1999, COFEPRIS

of Mexico - 2001, and ANAMED of Chile in 2016. According to the WHO classification, these are level IV agencies.

The main objective of these agencies is to protect public health through the surveillance and control of the quality, safety and efficacy of medicines and medical devices.

In 1980, WHO created the International Conference of Drug Regulatory Authorities (ICDRA), which meets every two years, and in 1999 PAHO decided to create the Pan-American Conference on Pharmaceutical Regulation (PPRF), which, unlike the WHO ICDRA, the pharmaceutical industry participates and contributes to its funding.

The European Medicines Agency is an agency of the European Union established in 1995. It has been based in Amsterdam since 2019. With the United Kingdom's exit from the European Union, the agency moved from London to the Netherlands.

In February 2019, the African Union States signed a treaty creating the African Medicines Agency.<sup>6</sup>

## **The International Council For Harmonisation (ICH)**

The International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation (ICH) was established in April 1990 by representatives of regulatory agencies and pharmaceutical industry associations from Europe, Japan and the United States.

Since the creation of the ICH in 1990, WHO was reluctant to participate in an international health regulation initiative, launched, promoted and financed by the pharmaceutical industry of the United States, the European Union and Japan. After complicated internal controversies within WHO,<sup>7</sup> it opted for the ambiguous "observer" status that the WHO has been participating in for 30 years.

During the World Health Assembly in May 2015, the United States and the European Union tabled a draft resolution for WHO members to adopt the ICH standards for medicines. Developing countries, led by Argentina and Colombia, succeeded in having this attempt rejected.

Although this adoption of commercial rather than health standards was prevented at the 2015 World Health Assembly, the ICH continues to operate in parallel with the regulatory agencies of industrialized countries, the European agency and WHO itself. The ICH has created a culture in which national drug regulatory agencies have been and continue to be influenced. But beyond the ICH, it is the very structure and philosophy with which drug research and development in industrialized countries developed as a business rather than a service. Business in many cases highly profitable, as demonstrated by the development and commercialization of vaccines for COVID-19 in the last two years.

The need to harmonize norms and standards in pharmaceutical regulation in a globalized world is perfectly obvious. The problem is defining the criteria and objectives of such harmonisation.

The ICH wants to harmonize drug regulation with the main objective of protecting the markets of the companies that finance it. National agencies act under two pressures, which are not easy to reconcile: the commercial interests of industry and the state's function to protect consumers by guaranteeing the quality, safety and efficacy of medicines.

The ICH uses high levels of standards that do not correspond to health requirements but are used to exclude industries in developing countries, i.e., to block competition.

It is a well-known fact that many of the standards promoted by the ICH are aimed at protecting markets and not patients. Under the pretext of harmonizing regulatory requirements for marketing authorization of new drugs, the drug regulatory agencies of the world's wealthiest countries and three pharmaceutical industry trade associations, joined together since 1990 in the ICH, are promoting their own interests by imposing their criteria for evaluating drugs on the whole world. The toxicity standards advocated by ICH sometimes promote faster, cheaper drug development over patient protection. The drug quality standards advocated by ICH sometimes increase manufacturing costs without providing any public health benefit. It would be preferable if the World Health Organization were in charge of setting standards for drug development, focusing on patients' interests.<sup>8</sup>

Health registration in the context of the culture promoted by the ICH has become a marketing authorization, a complex, cumbersome and time-consuming procedure. It is undoubtedly the "gateway" to the market, which makes it commercially valuable. Health registrations are counted as intangible "assets", and this is due to the fact that, in a certain way, whoever holds a registration has "managed" to pass a series of tests, which are not always objective, not always transparent, and which are not defined in terms of the real "stakeholders" of the regulatory agencies, that is society in general, and not the pharmaceutical companies.

One of the consequences of this "culture" is the excessive number of medicines in circulation in most countries. As an example, according to WHO figures, 7,500 medicines are authorized for circulation in Switzerland, 12,000 in South Africa, 13,500 in the Netherlands, 17,000 in Colombia and 56,000 in Argentina. The latest revision of the list of essential medicines in 2021 contains only 479 medicines.

Health surveillance has been practically reduced to the administrative process of registration. Although an important value is placed on GMPs and operating authorizations for producers, it is the registrations that are important. And developing countries do little in the way of on-site surveillance and much more in the way of document review for issuing health registrations.

## **Some Criteria and Objectives of a Latin American Food and Drug Regulatory Agency**

- An independent agency is needed, based mainly on health criteria and responding to the socio-economic, industrial and sanitary level of the region.
- To set norms and standards that guarantee the quality, safety and efficacy of medicines and pharmaceutical products based strictly on health requirements.
- Harmonize the requirements for placing on the market in order to facilitate the development of a regional pharmaceutical industry and a regional market for medicines and medical devices.
- Avoid standards and technological requirements that do not correspond to sanitary requirements and that may represent a barrier to the development of national drug industries in Latin American countries.
- The regional regulatory agency can help to "clean up" health registration. A few years ago, Nordic countries in Northern Europe had a rule that a drug that did not represent an advantage over what was already on the market could not be registered. Today, our regional agencies register products that are useless or inferior to what is already on the market, but which manage to gain a foothold through intense advertising and promotion.
- A regional regulatory agency can also help to avoid duplication of processes. Requirements and procedures can be harmonized based on standards appropriate to our public health needs, adjusted to the needs of an industrial policy and, above all, appropriate for economies that are very different from those of industrialized countries.
- Develop a regional register of medicines more in line with WHO recommendations on drug selection.
- Promote the use of generic medicines.
- Develop standards and criteria for the sanitary registration of biological products and biosimilars (generics of biological products).
- Establish relations with national patent offices in order to harmonize patentability criteria for medicines with a public health perspective.
- Define a form of funding that is not exclusively based on fees paid by industry for the registration of their products. This practice can be an incentive contrary to the health interest, insofar as more registrations can mean more budget.

## **Conclusion**

The research, development and marketing of medicines in the United States of America, the European Union and Japan are highly profitable industries where commerce and economic profit are put before the well-being and health of citizens. The challenge that Colombia, Cuba, Mexico (Declaration of Acapulco) and Argentina, Brazil,

Chile, Colombia, Cuba and Mexico (Bogotá, Regulatory convergence meeting) want to lead today is to create a Latin American medicines agency where health comes first and medicines are not mere commodities but public goods at the service of protecting and restoring the health of citizens. In a market of 500 million people, this public good, that is the medicines, will also be able to make a financial contribution to the region's economy.

### Endnotes:

<sup>1</sup> This policy brief is partially based on an article published in the *Monde Diplomatique* in May 2023. Velasquez G. "Towards a Latin American Medicines Agency", Year XXVII No. 331 of May 2023.

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<sup>3</sup> "Declaración de Acapulco", <https://www.cecmed.cu/noticias/declaracion-acapulco-creacion-agencia-reguladora-medicamentos-dispositivos-medicos>.

<sup>4</sup> WHO Constitution Article 2, letter u). <https://aplicaciones.sre.gob.mx/tratados/ARCHIVOS/OMS-CONST.pdf>, June 1946.

<sup>5</sup> ANSM, France <https://ansm.sante.fr/>.

<sup>6</sup> African Union, [https://au.int/sites/default/files/treaties/36892-treaty-0069-ama\\_treaty\\_f.pdf](https://au.int/sites/default/files/treaties/36892-treaty-0069-ama_treaty_f.pdf).

<sup>7</sup> In 1990 there were two departments in the WHO dealing with pharmaceuticals, with different policies and strategies. One department was very close to the European and Ameri-

can pharmaceutical industry, and the other, where I was, was closer to the developing countries, and defended clearer principles of public health, and standards for medicines clearly based on public health and not on the commercial interests of the pharmaceutical industry.

<sup>8</sup> "ICH: An exclusive club of drug regulatory agencies and drug companies imposing its rules on the rest of the world", *Prescrire International*, August 2010; 19(108):183-6. *Prescrire Int.*

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