



Regional Meeting on the Intergovernmental Negotiating Body (INB) and Amendments to the International Health Regulations (WGIHR) October 30th, 2023 | Washington, D.C.

FACT SHEET ARTICLE 10: Sustainable production ARTICLE 11: Transfer of technology and know-how

BACKGROUND

COVID-19 pandemic has led to shortages and inequities in access to essential medicines (pharmaceuticals and vaccines) and other health technologies, hampering the response capacity of health systems and limiting or jeopardizing the delivery of quality essential health services. The health emergency has also revealed the dependence of Latin America and the Caribbean on imports of medicines and other health technologies from outside the Region, the vulnerability of global supply chains in emergencies, and the high degree of heterogeneity in the Americas in terms of research, development, and production capacity.

Ensuring access to essential medicines and other health technologies in health systems demands a broad, comprehensive approach that addresses the different dimensions of access, and requires effective public policy coordination and management to guarantee that the actions and incentives are coherent and well-aligned with each other.

Strengthening regional development and technology transfer capacities for the production of health technologies and its raw materials is important to improve their accessibility, and adequately respond to regional health needs, especially during health emergencies, which also contributes to health security and economic and social development.

To provide a common and sustainable framework with prioritized strategic lines of action, in 2021 PAHO Member States adopted the policy document "Increasing production capacity for essential medicines and health technologies" and its corresponding resolution CD59.R3. Following its mandate, PAHO created the Innovation and Regional Production Platform. The objective of the Regional Platform is to increase regional production capacities for medicines and other essential health technologies to contribute to equitable access. The Regional Platform seeks to foster the strengthening of ecosystems conducive to production, promote the development and technology transfer, facilitate the exchange of information, and encourage cooperation and the development of strategic alliances to expand productive capacities in the region.

Latin America and the Caribbean has diverse experiences in the development and production of health technologies (medicines, vaccines, diagnostics, and others), including own developments, co-developments, and technology transfer processes.

Technology transfer can have a different scope depending on starting points and objectives, and requires a technology holder entity and a recipient entity. Convergence between technology holders and potential recipients occurs predominantly in countries that have: a mature scientific and technological community capable of understanding and replicating the transferred technology; access to commercially attractive national and international markets; stable, well-functioning and integrated regulatory systems; multisectoral policy frameworks conducive to the production of health technologies.

Beyond the scientific, engineering, and technical aspects involved in the technology transfer process, technology transfer agreements require the parties to negotiate commercial and legal aspects such as markets or territories of reference (exclusions and/or inclusions), timeframes, intellectual property, pricing, royalties, liability, confidentiality, among others.

RELEVANT GLOBAL AND REGIONAL MANDATES

- <u>CD59.R3</u> (2021). "INCREASING PRODUCTION CAPACITY FOR ESSENTIAL MEDICINES AND HEALTH TECHNOLOGIES" (Resolution)
- <u>CD59/8</u> (2021). "INCREASING PRODUCTION CAPACITY FOR ESSENTIAL MEDICINES AND HEALTH TECHNOLOGIES" (Policy Document)
- WHA 74.6 (2021). Strengthening local production of medicines and other health technologies to improve access

IMPLICATIONS FOR THE REGION

Sustainable Production

Article 10 aims to achieve a more equitable geographical distribution of the production capacities of pandemic-related products in the world, to improve timely, fair, and equitable access to safe, effective, quality and affordable pandemic-related products. To achieve this goal, it is important to:

- Collaborate to identify and estimate the disease burden of relevant pathogens with pandemic potential.
- Identify existing production capacities and estimate gaps to cover pandemic-related health technologies needs, both for final products and for their strategic inputs along value chains.
- Maintain, expand, and create new manufacturing facilities in developing countries, both for the manufacture of pandemic-related final products, as well as for their raw materials and inputs along value chains.
- Encourage and provide incentives for holders of pandemic-related final products, raw materials and inputs, to make investments for the expansion and creation of new manufacturing facilities in developing countries.
- Expand local development capacities and technology transfer partnerships, promote the exchange of information and knowledge, and the non-exclusive royalty-free sharing of intellectual property rights for timely manufacturing of pandemic-related products and their raw materials in developing countries.
- Increase public investment and encourage private investment to expand R&D capacities for pandemic-related products and their raw materials and inputs, particularly in developing countries.
- Strengthen the development and implementation of coherent multisectoral national policies for the development of ecosystems conducive to local production, including but not limited to health regulatory systems, research and development networks, and human resource training institutions.
- Strengthen international coordination, participating and collaborating in relevant programs of global and regional organizations.
- Increase transparency of the agreements for pandemic-related health technologies, throughout the entire life cycle.

Transfer of technology and know-how

Article 11 aims to strengthen national and multilateral capacities for technology transfer and the exchange of knowledge for the production of pandemic-related products. To achieve this goal, it is important to:

- Strengthen and develop multilateral mechanisms to share knowledge, intellectual property rights and relevant information to expand and accelerate the production in developing countries of pandemic-related final products, their raw materials and other intermediatory inputs.
- Promote and incentivize holders of pandemic-related final products, raw materials, and other inputs to transfer their technology to manufacturers in developing countries in order to expand equitable access and improve pandemic response capacity.
- Strengthen capacities of developing countries to create ecosystems conducive to receive technology transfers of final pandemic-related products, their raw materials and other inputs; the strengthening of capacities includes, among others, development of R&D institutions and networks, training of human resources, and strengthening health regulatory systems.
- Increase transparency in technology transfer agreements of pandemic-related health technologies, their raw materials and inputs.